Medicines Optimisation in Paediatric In-Patients (MOPPEt): A Qualitative Ethnographic Human Factors Study

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in the Faculty of Biology, Medicine and Health

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List of abbreviations

A&E	Accident & Emergency
ADC	Automated Dispensing Cabinet
ADE	Adverse Drug Events
ADR	Adverse Drug Reaction
BNFc	British National Formulary for Children
CIEHF	Chartered Institute of Ergonomics and Human Factors
CYP	Children and Young People
CYPHOF	Children and Young People's Outcome Forum
DCog	Distributed Cognition
DSA	Distributed Situational Awareness
DGH	District General Hospital
DRP	Drug Related Problems
EBCD	Experience-Based Co-Design
ED	Emergency Department
FRAM	Functional Resonance Analysis Method
FY	Foundation Year
GA	General Anaesthetic
GEMS	General Error Modelling System
HF/E	Human Factors and Ergonomics
IEA	International Ergonomics Association
IQR	Inter-Quartile Range
MAE	Medication Administration Errors
ME	Medication Errors
MO	Medicines Optimisation
MPE	Medication Prescribing Errors
MR	Medicines reconciliation
NCCMERP	National Co-ordinating Council for Medication Error Reduction and Prevention
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICU	Neonatal Intensive Care
NRLS	National Reporting and Learning System
NSF	National Service Framework
PCNE	Pharmaceutical Care Network Europe
PICU	Paediatric Intensive Care
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RCPCH	Royal College of Paediatrics and Child Health
RPS	Royal Pharmaceutical Society
SEIPS	Systems Engineering for Improving Patient Safety
SPO	Structure – Process – Outcome
SRK	skills, rules and knowledge
UK	United Kingdom
USA	United States of America

WAD	Work as Done
WAI	Work as Imagined
WDA	Work Domain Analysis

List of publications and presentations from this thesis

2019

- Sutherland A, Phipps DL, Tomlin S, *et al.* Mapping the prevalence and nature of drug related problems among hospitalised children in the United Kingdom: A systematic review. *BMC Pediatr* 2019;**19**:486.

2020

- Sutherland A, Phipps DL. The Rise of Human Factors in Medication Safety Research. *Jt Comm J Qual patient Saf* 2020;**46**:664–6.

2022

- Sutherland A, Phipps DL, Gill A, *et al.* A work domain analysis of medicines management for hospitalised children. In: Balfe N, Golightly D, eds. *Ergonomics & Human Factors 2022*. Birmingham, UK: CIEHF 2022.

2023

- A Sutherland, S Grant, DL Phipps, S Tomlin, J Hughes, DM Ashcroft Insight into the systemic causes of medication problems for hospitalised children; Archives of Disease in Childhood 108 (Suppl 2), A422-A422

- A Sutherland, J Hughes, J Chambers, S Kafka, H Ridgewell, D Ashcroft. Parent perspectives on medicines safety systems for children in hospital; Archives of Disease in Childhood 108 (Suppl 2), A397-A397
  (WINNER: Best Abstract, RCPCH Conference 2023. Glasgow UK)

- Sutherland A, Grant S, Tomlin S, Phipps D, Ashcroft DM. The systemic causes of medication problems for hospitalised children. In: Balfe N, Charles R, Golightly D, eds. *Ergonomics & Human Factors 2023*, Warwick, UK: CIEHF 2023

- Sutherland A, Phipps D, Gill A, Morris S, Ashcroft D. Medication safety gaps in English paediatric in-patient units: an exploration using work domain analysis; Journal of Patient Safety (accepted July 17 2023)

Abstract

Introduction

Medication Related Problems (DRPs) affecting hospitalised children and young people (CYP) are common, and yet the incidence of harm associated with these events appears to be relatively low (1-2% of events). Recent systematic reviews relating to Adverse Drug Events (ADEs) and DRPs in children and young people have synthesised global data from the last 25 years, UK-focussed systematic reviews of the incidence and prevalence of ADEs and DRPs are now almost 20 years old. Concurrently, there is a growing interest in the use of Human Factors and Ergonomics (HF/E) methodology in improving healthcare safety.

HF/E approaches are based in socio-technical theory, whereby the complex interactions of technology and people are acknowledged. They involve the use of multiple methods to explore and understand problems, and empower stakeholders and service users in engineering theoretically sound interventions. This PhD thesis aimed to explore the prevalence and nature of DRPs for hospitalised CYP in the UK, and then use HF/E approaches to explore how healthcare systems in English acute paediatric hospital care maintain medicines safety. The findings of such explorations will enable the identification of potential interventions to improve these processes.

Methods

A systematic review was conducted to estimate the prevalence and nature of DRPs among hospitalised CYP in the UK. Nine electronic databases were searched from January 1999 to March 2023. Studies were included if they were based in the UK, reported on the frequency of adverse drug reactions (ADRs), adverse drug events (ADEs) or medication errors (MEs) affecting hospitalised children. Quality appraisal of the studies was also conducted.

Subsequently, a prospective qualitative study in paediatric wards in three hospitals in the north of England was conducted between October 2020 and May 2022. Ethnographic data were collected from documentary analysis, observations and interviews with staff and patients' families. I analysed the data thematically in collaboration with methodological experts (a HF/E practitioner, a social anthropologist and a practicing pharmacist researcher) and four parents through a "family forum." The analysis consisted of work domain analysis ((WDA, Vicente, 1999) to understand the structure and components of the medicines safety system and orientate later elements of the study. Fieldnotes and interview transcripts were analysed inductively

using thematic analysis to understand how medicines safety work was conducted and maintained. Parents and families were involved in this analysis, as well as experienced researchers.

To conclude this project, experience-based co-design (EBCD) methods were used involving broad stakeholders including medical, nursing and pharmacy staff and parents and families, to propose and prioritise potential new interventions to improve medicines safety in acute paediatric care and identify future research.

Results

26 studies were included in the systematic review of which 13 were considered high quality. DRPs were distributed throughout the medication system and affected 23.1% of CYP admitted to hospital (range 20.1-46%). 45% of children were affected by DRPs in documentation on admission or discharge, 70% (range 50-78%) of which were potentially harmful. Clinically significant prescribing errors are estimated to affect 6.5% of prescriptions (IQR 4.7-13.3).16.3% (IQR 6.4-23) of observed administrations were associated with medication administration errors (MAEs), including dosing errors. 25.6% (IQR 21.8-29.9) of patients were also affected by adverse drug reactions, 79.2% of which were harmful enough to require cessation of therapy. These results suggested that there were considerable risks associated with medicines within paediatric medication management processes, and a deeper theoretical exploration and understanding of these processes, and how safety was maintained were necessary in order to develop future interventions.

The WDA included 72 documents (policies, procedures and reference manuals) and field notes from 60 hours of participant observation. Three potential systemic contributors to DRPs were identified – Resource limitations, cognitive demands and adaptation of processes. The lack of resources (including knowledge and experience) created an environment where distractions and interruptions were frequent. Families provided medicines administration support, but were largely unacknowledged in documents. Different professionals were responsible for different parts of the system. The WDA also provided formative insights into how the system functioned in the real world which facilitated identification of targets for further ethnographic study around environmental design and teamwork.

To explore these constraints identified in the WDA in more detail, a total of 230 hours of observation were undertaken across all three sites, and 404 parents and staff were observed. 19 healthcare staff and parents participated in semi structured interviews. The space in which medicines

safety work was conducted defined how the work was done. Staff groups worked in isolation, even where they were together. Communication was transactional, and prone to omission of detail. There was a lack of a shared mental model, resulting in mismatched priorities and reinforcing poor communication. Distractions and interruptions were unavoidable. However, staff did “reach in” and perform tasks normally reserved for other people, but it was seen to be getting the job done. Most interventions for medicines safety relied on “checks” but these were frequently omitted because of limited resources. Interventions to support adherence to safety policies were also often bypassed because they created more work. Similarly, parents and carers were essential for the safe and timely administration of medicines but were often marginalised by professionals and the organisations. Two of the three study sites displayed characteristics of bureaucratic safety culture, reliant on top-down communication methods and expectations of rote rule following.

Two EBCD workshops were held in March and April 2023, with 19 participants. Both EBCD workshops were planned to run identically, undertaking participant validation, and identification and prioritisation of interventions. However the first workshop organically focussed on the participant validation exercise and confirmed the findings from the ethnographic study. The second workshop was then adapted to focus on intervention identification and prioritisation, and three interventions were identified – the development of a patient-held medication record derived from centralised NHS data sources, the involvement of parents as part of provider training to promote respect for parental skills and attributes and to share their experience and; ensuring that ward teams have an appropriate skill mix including a dedicated pharmacist. Other potential interventions included communication training for healthcare professionals, and parent participation in medication administration and care.

Conclusions

Medication safety is a complex social endeavour with multiple stakeholders and participants. There are structural approaches to improving medicines safety that merit future development and study, including the introduction of full time ward pharmacists to these areas, and the inclusion of parents and carers in day to day work. The inclusion of parents and carers in stakeholder design groups is feasible and received positively and must be part of future development work. This thesis has also demonstrated the importance of theoretically informed exploration of complex systems, and the application of established theoretical frameworks on the study of medication safety which can be adopted in other studies in other settings.

Declaration and Copyright Statement

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Dedication

This thesis is dedicated to those families and parents that dread coming into hospital. That dread having to fight with the system and defend their children. You are heard.

Adam Sutherland

Stockport

June 2023

About the Author

Adam qualified as a pharmacist in 2002 and has worked entirely in hospital pharmacies since his pre-registration year. He moved into paediatric practice in 2004. His primary focus since 2005 has been paediatric critical care and he is one of the most experienced pharmacists in this field in the country. He has had a hand in changing practice in the UK and beyond, from changing the standard-of-care maintenance fluid requirements for hospitalised children from hypotonic solutions to pH-balanced isotonic solutions, to introducing standard concentration infusions first at a local level, and now nationally through his authorship of the National Framework for Infusion Concentrations published jointly by the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacy Group.

He has a burgeoning independent research portfolio, working with diverse partners on topics including Human Factors and Ergonomics to support implementation of fixed concentration infusions in non-specialist hospitals. He has also partnered with industry to evaluate the effectiveness of infusion pump technologies on preventing harmful adverse drug events at scale. This has led to policy influence as the NHS considers how to recommend implementation of these technologies. He is a key opinion leader in the field of smart pump implementation and works closely with commissioners and industry.

He has recently taken up appointment at the University of Bradford as Associate Professor of Healthcare Quality and Safety

About this thesis

This thesis explores the systems and processes for medication safety in English paediatric in-patient units. Chapter one provides a succinct summary of the research in medication safety for children and young people over the last 20-25 years and the interventions that have since been proposed. I highlight that global estimates may not be generalizable to national practice, and that in the UK estimates are currently over 15 years old. I also note that there is a lack of systems-focussed observational studies on medication safety, with many interventions and contributory factors derived from supposition from epidemiological data. Chapter two presents a systematic review of the prevalence and nature of paediatric DRPs in the UK reported empirically, and overlaid into a representation of the medication system using an adaptation of the "Five Major Steps" described in previous research. Chapter three presents the aims and objectives of this thesis.

In Chapter four I critically explore and justify the rationale for a qualitative approach to the study of paediatric medicines safety, with reference to HF/E methodology and sociotechnical theory and outline how using a Safety-II lens may support deeper insights into how DRPs may emerge, and how systems may support resilience in the face of operational ambiguity and error. I then present the methods used for the study.

Chapter five presents a representation of work-as-imagined using Work Domain Analysis which I have used to identify potential contributory factors and resilience factors in medicines systems which then informed targets for further in-depth ethnographic study in Chapters six, seven, eight and nine. Chapter 10 offers theoretical insights and interpretation of the data, using Reason's model of accident causation to explore latent failures in paediatric medication safety systems, and to propose that team-work and skill mix is defective. I have also been able to identify that the environment in which medicines safety work is conducted is also part of the problem, creating barriers to team work. Chapter 11 presents the results from two experience-based co-production workshops held in the spring of 2023 where stakeholders (medical, nursing and pharmacy staff, and parents) worked together to explore and propose potential future research and interventions for further development.

Chapter 12 pulls these diverse data sources together into a coherent discussion and comparison with existing studies and theories to identify new information and theoretical propositions. I propose that the novelty in this thesis is the identification of parents as the key knowledge brokers and resilience factor in paediatric medicines safety, and yet there is considerable epistemic injustice at a professional and organisational level that seeks to marginalise and discredit parent concerns and experience. Further I have also identified that there is little or no theoretical exploration or development in existing medicines safety processes, which may explain why paediatric medicines safety interventions are less effective than expected. Contrary to

historical empirical studies of medicines safety, the medication itself appears not to be a significant problem in medicines safety – it is the design and delivery of the processes to prescribe, dispense and administer them that are the central limiting factor.

In Chapter 13 I outline my conclusions and offer my suggestions for future study, and implications for future policy. Paediatric medicines safety is a largely social phenomenon, with parents an integral part of the system. There is organisational conflict within systems that are designed around adult models of care where adults have agency and autonomy, and competent advocates are part of care decision making only in exceptional circumstances. Supporting information and practice guidance is developed in a normative context, which results in inadequate information or resource to healthcare workers to make the right decision at the right time, and they are subsequently blamed for making decisions in hindsight. There is a need to consider redesign of paediatric services to support the inclusion of parents as advocates, and to support healthcare workers in adaptation and responding to ambiguity and uncertainty.

1 Introduction and Background

1.1 Avoidable Healthcare Related Harm and Public Health

Healthcare related harm is a persistent and serious problem for modern healthcare services. Modern healthcare has been described as a “risky enterprise”, and as early as 1910 Codman identified 123 errors in 337 patients related to misdiagnosis, poor judgement, technical errors, lack of equipment and calamities of surgery.[1,2] However, understanding how to prevent patients being harmed by errors such as these has been a challenge.

The scale of healthcare related harm was acknowledged as a public health problem in the mid-1990s with the publication of the Harvard Medical Practice studies.[3,4] These studies retrospectively reviewed the medical records of 31,000 hospitalisations out of a population of 2.5 million people in the New York state area in 1984. It was identified that patients experienced harm in healthcare services at a rate of 3.7% of hospitalisations, with 27.6% of these events related to “negligence.” In the context of this study, “negligence” was defined as “…care that fell below the standard expected of physicians in their community.” These findings were not isolated to the United States. A large cross-sectional study of adverse events in 28 Australian hospitals identified that across 14,000 admissions, 16.6% of these admissions were associated with a harmful event that resulted in prolonged hospitalisation, half of which were preventable.[5] Five percent of these events resulted in death of the patient.

These studies drove the development of public policy interventions to manage this emerging problem. In 1999 the United States Institute of Medicine published their seminal report “To Err is Human…”[6] The authors estimated that in America between 44000 and 98000 people died every year as a result of preventable medical events and made a call to arms to healthcare providers to reduce medical “errors” using systems level interventions including error reporting systems, and nationally coordinated leadership and research.

In the UK, Vincent et al. estimated that across 1014 acute admissions to two London hospitals 10% of patients were harmed by their treatment, half of these events were avoidable, and a third led to moderate disability or death.[7] The estimated excess care costs ran to £1bn though the authors were clear that this was an imprecise estimate. Consequently, the Chief Medical Officer for England published “An Organisation with a Memory” which extrapolated the data from the American and Australian studies into the UK context, estimating that as many as 61000 Britons experienced serious avoidable healthcare harm or death every year, at a potential cost to the NHS of £2 billion per annum in excess healthcare costs.[8] This white paper made the same interventional recommendations as the US policy recommending mandatory event reporting, reorganisation of research towards improving safety, and creating leadership space for safety.

However, despite this awareness and effort, it is unclear whether or not healthcare today is “safer” than twenty years ago. There have been multiple explorations of healthcare adverse events across different health economies. Secondary analyses of published studies have not shown a change over time. de Vries et al.[9] reviewed eight studies between 1966 and 2007. Within their sample of 74500 patients 9.2% of patients were affected by healthcare adverse events, of which almost half were preventable.

More recently, Panagioti et al. [10] identified that while there was a great deal of data relating to healthcare harm, the global understanding of avoidable harm remained uncertain. They conducted a review and meta-analysis of avoidable healthcare harm over 70 studies and 337000 patients. Their pooled prevalence estimate for all-cause avoidable harm was 6% (95% confidence interval (CI) 5-7%) with 12% (95%CI 9-15%) of these associated with severe harm or death. It was estimated that medication accounted for approximately 25% (95%CI 16-34%) of this avoidable healthcare harm, of which 6% led to life-changing injury or death. However, there is an uneven distribution of harm between different clinical settings, or clinical areas. The Panagioti review suggested that specialist clinical areas (e.g. surgery or intensive care) recorded a higher prevalence of avoidable harm.

Thus it can be concluded that while there have been some improvements in patient safety in the last 30 years, they may not be consistently realised across diverse healthcare systems. Furthermore, it can be argued that this

lack of improvement may be related to definitional differences between the studies – while Bates et al. used a definition that included temporary harm, Landrigan, Baines and Eldridge used a more permanent definition of harm that required it be present at discharge, thus leading to difference in estimates.[11–13] However, while Eldridge does not conclude any improvement of safety associated with their data, there were clear changes associated with focussed efforts on discrete harms such as surgical complications and hospital acquired infection. Notwithstanding these interventions and allocation of resources, targets for reduction of healthcare associated harm have not been met.

1.2 Defining "Patient Safety"

Safety is a complex construction of social, organisational, and scientific influences and is fundamentally a subjective concept.[14–16] The Oxford English Dictionary definition of safety is simply "The state of being protected from, or guarded against, hurt or injury; freedom from danger."[17] However, this definition is clearly inappropriate for healthcare given the inherent risks associated with any healthcare intervention. Vincent describes patient safety as "…the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare."[1] The challenge then is around who determines what an adverse outcome is, and how adverse outcomes arise from healthcare activities.

Nabhan reviewed definitions of “preventable harm” in the literature and identified seven definitional themes including the presence of a modifiable cause, a likely change in process would resolve the problem, and inadherence to process as the primary cause.[18] However, within this review it was identified that there was little data pertaining to the validity of the definitions used, with inter-rater agreement scores being used to support the validity of the terms. There was considerable evidence of “hindsight bias” in the application of definitions, which is understandable given that most healthcare adverse event explorations are based in “root cause analysis.”[19,20] Some authors have described healthcare safety as a cultural phenomenon,[21–23] and a lack of professional and organisational change may be the reason why safety improvements have been so elusive. Furthermore, there is a preponderance towards an assumption that “Zero Harm” can be achieved in healthcare. Given the subjectivity of assessment methods in the literature, and the basis of most research being encapsulated within an error-reduction paradigm, it is unreasonable to expect that all avoidable harm can be prevented. Thus there are calls for a new perspective considering the context and practice of work in complex systems is required.[24–26]

1.3 From Safety-I to Safety-II

The reactive investigation of adverse events to identify risks and propose actions has been defined as Safety-I.[25] Safety-I works on the assumption that systems either function as intended, or do not, and that we can decompose and understand those systems. Because Safety-I is focussed

on failure, much of the effort associated with decomposing and understanding the system is targeted to those rare occasions where the system fails. However these assumptions are being challenged.[27] As systems become more complex and technological change becomes more rapid, it becomes harder for us to learn from experience and new types of hazard emerge.[28] Perrow states that in modern complex systems accidents are inevitable and should be considered “normal” events.[29] Thus the concept of “Safety-II” asserts that systems fail in the same way as they function normally, and the challenge then is to understand the features and context around normal operation.[30,31] A comparison of the two concepts is presented in Table 1.1

	Safety-I	Safety-II
Definition	Learning from when things go wrong	Learning from how things function normally
Principles	Reactive; respond to events or risks	Proactive; anticipating developments and events
Role of the human	Humans are one of the hazards. They can be fixed or removed	Humans provide flexibility and resilience
Investigation approach	Examine failures and malfunctions to identify their antecedents and root causes	Explore how things usually go right with contextual insights to suggest how things may occasionally fail
Risk assessment approach		Understand the sources and nature of performance variability and identify where they become impossible to monitor or control

Table 1.1 – Comparison of Safety-I and Safety-II principles. Adapted from Hollnagel, Wears & Braithwaite (2015)

Safety-II considers how the system can adapt and correct for periods or situations where normal function is impaired. It must be acknowledged that complex systems are seldom static, and none more so than busy healthcare settings. Cook and Rasmussen set experience in nuclear power against complex healthcare systems in order to describe how these two systems consist of multiple delivery systems and processes that are closely linked.[32] Using Rasmussen's "Dynamic Safety Model" they demonstrated that such closely linked systems are hard to control in the event of unexpected failure. This is exacerbated by healthcare systems that are working at the limits of their capacity.[33] However, there is interest in how these complex systems cope with disruption and unexpected events.

1.4 Resilience Engineering and Resilient Healthcare

Thus there is interest in the concept of “resilient healthcare.”(RHC) Paries defines resilience as the robustness of organisations (or systems) against threats to safety.[34] Similarly, Nemeth defines it as “…the ability of a system to adjust its functioning prior to, during, or following changes and disturbances so that it can sustain required operations…”[30] However, this is a narrow definition. Resilience is a multi-level concept that embraces the agency and autonomy of front-line workers and acknowledges and accept the trade-offs and workarounds that they undertake in order to cope with complex systems.[35] RHC places the person at the centre of the system and considers how they interact with the system, and how the system impacts upon them, including organisational and managerial decisions.

RHC is a challenge to study because some authors propose that it is an emergent property of complex systems – the whole is greater than the sum of its parts and in many cases the “resilience” cannot be seen or predicted. Further, events within complex systems are described as “emergent” – they cannot be explained using causal terms or by decomposing the system into its component parts.[31]

1.5 Work as Imagined versus Work as Done

If resilience considers how complex systems adapt to unexpected events or threats in order to maintain their function, and emergence considers how components of the system interact in unexpected ways, there naturally follows a mismatch between work as we imagine it to be (Work as Imagined, WAI) and work as it is actually conducted in real life (Work as Done, WAD).[36] These concepts first emerged in studies of driver behaviour as it was observed that defined tasks were conducted differently and interpreted differently between drivers and analysts.[37] Increasingly however the difference between WAI and WAD is used as a basis on which to study operational safety and resilience.

WAI refers to the fallacious nature of organisational and personal ideas of tasks and activities.[38] WAI is often oversimplified and under-resourced so that in the messy reality of every day work, operators will adjust their delivery of the task to meet the constraints set around them (WAD). In the event of accidents under safety-I conditions, these proximal adjustments will be perceived to represent “violations” of the WAI model and thus these natural actions of autonomous actors will be assigned contributory or causal contributions to the accident. Yet under safety-II conditions, the comparison of WAI with WAD and consideration of how the adjustments and adaptations emerge is fundamental to understanding how safety is created and maintained. Further, compliance with WAI models (as might be desired by managers and supervisors) leads to no work getting done. Dekker describes this as “malicious compliance” and reinforces the importance of WAD

because "…work gets done because of people's effective informal understandings, their interpretations, their innovations and improvisations outside of those rules."[39]

There is considerable interest in how this applies to healthcare. Ellis et al. reviewed the literature pertaining to resilient healthcare (RHC) in peer reviewed journals, books and conference proceedings.[40] They identified that RHC focussed on three concepts – the misalignment of work as imagined and work as done, Safety-II and learning from successful work and, complexity science. Qualitative approaches predominated the empirical literature with 51/81 included studies using interviews and observation, suggesting the importance of deep understanding of everyday work.

In a more focussed review of methods and potential resilience factors in healthcare work, Iflaifel identified 36 studies, with two predominant data sources – interviews and focus groups, and observations.[41] Within this review, two studies were identified studying medication work and one study was focussed in paediatric care. A further study exploring the gaps between WAI and WAD in community pharmacies was published after this review was completed.[42] Thus there is a lack of literature that considers medicines safety through a Safety-II lens.

1.6 Medicines Safety as a Patient Safety Issue

As I have already demonstrated, medicines safety accounts for 25% of avoidable healthcare harm and there have been repeated calls for

interventions to mitigate these risks. Ahsani-esahbanati et al.[43] conducted a systematic review of reviews of interventions to reduce medical error in healthcare systems, and described 66% (49/76) being focussed on medication errors. While the majority of these studies demonstrated a reduction in medication error there was no measure or description of any reduction in patient harm associated with these interventions. An example of this would be the intervention of electronic prescribing, which reduces all-cause medication errors by up to 96% but has no discernible impact on avoidable harmful ADEs.[44,45] While this can in part be associated with the increasing complexity of modern medicine and an aging population,[46] there are still likely issues with the way healthcare views harm and how it emerges.

Medication is the single most prevalent medical intervention in modern healthcare systems.[47] In preparing “An Organisation with a Memory” the Chief Medical Officer used clinical negligence claims to produce estimates of medication related harm in the NHS and it was found that medication accounted for 25% of claims in England. These pressing economic and patient safety burdens have led to policy intervention. In 2004 the Chief Pharmaceutical Officer for England published “Building a Safer NHS for Patients: Improving Medication Safety” [48] which hypothesised that 10-20% of preventable medical harm was related to medicines, costing the NHS between £200 million and £400 million every year. These early estimates have been shown to be quite robust. Elliott et al.[49] estimated that in England there were 237 million medication errors every year of which88 million occurred in hospitals. Medication errors in totality were associated

with 1700 deaths and cost the NHS just under £100 million per year. However these estimates were obtained through systematic data extraction from existing studies and reviews of medication error, with a strong reliance on spontaneous error reporting. The authors were very clear that accurate estimates were difficult to produce, and that the results were likely an underestimate of the prevalence and burden because of the incompleteness of reporting data.

In 2004, “Building a Safer NHS” provided recommendations to support the NHS reducing medication errors by 40% within five years. This paper proposed interventions including introduction of new technologies, incident reporting and data collection, specific interventions targeted at high-risk drugs and behavioural interventions such as improved documentation, education and training. However, the 40% reduction in harmful events target was criticised as unachievable because the data on the prevalence and severity of harmful events was not available at that time.[50] In recognition of this changing data field over the last twenty years, the World Health Organization established their third patient safety challenge in 2017, with the stated goal of reducing avoidable harmful medication errors by 50% in five years.[51] However, at the time of publication, there was considerable uncertainty about the burden of harm associated with ADEs.

In a retrospective review of centrally held incident reporting data in England between 2005 and 2010, medication represented 9.6% (526,186 / 5,437,999)

of all reported incidents to the National Reporting and Learning System (NRLS).[52] 16% of these (86821/526,379 reports) reported actual harm, but 13% were classified as "low harm." 0.9% (822/526,379 reports) of incidents were categorised as "death" or "severe" (defined as "…causing permanent harm and/or a near death experience.") In a more recent analysis of the NRLS database between 2006 and 2017,[53] it was identified that fatal medication administration errors accounted for 0.04% of reported medication errors. 31.4% of these (72/229) were related to failure to administer a medication.

Hodkinson *et al.* conducted a review and meta-analysis of 81 studies including 285,687 patients to compare the prevalence of avoidable medication-related harm.[54] The pooled prevalence was 3% (95%CI 2-4%) with more than a quarter of the harm identified being severe or life-threatening (26%; 95%CI 15-37%). Inpatient elderly care was associated with the highest prevalence (11%; 95%CI 7-15%) and children the lowest (1%; 95%CI 0-2%). The process most susceptible to harmful ADEs was prescribing (58% of studies; 95%CI 42-73%) followed by administration (21%; 95%CI 11-33%).

1.1.1 *Defining the harm associated with medication*

Throughout the literature, there is a focus on "medication errors." "Errors" are events that can be detected, reported, counted and characterised.[55,56] The National Co-Ordinating Council on Medication Error Reporting and

Prevention (NCC-MERP) defines a medication error as "*…any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."* [57] However, it is recognised that this definition is broad [58] and takes no account of outcome and harm.[59] Ergo, a major critique of the medication error "construct" is the likelihood of inflated prevalence and incidence estimates as a result of including administrative errors such as syntax and spelling,[60,61] which leads to the obscuring of truly harmful medication related events that are very rare.[62] Clinician-derived definitions are available, which include an estimation of harm (actual or potential) in order to improve these estimates, but they carry a subjective element in their application.[63]

It is a descriptive term of a complex concept but it has stuck in the psyche of researchers and policymakers. When considering "errors" it is essential to bear in mind that healthcare is complex, and treatment is a balance of risk and benefit. Correspondingly, much healthcare associated harm is unavoidable. However, there are challenges in differentiating between adverse events that are avoidable, and the harm that they may cause. A conceptual model of how adverse events, medication errors and adverse reactions are related is offered in Figure 1.1

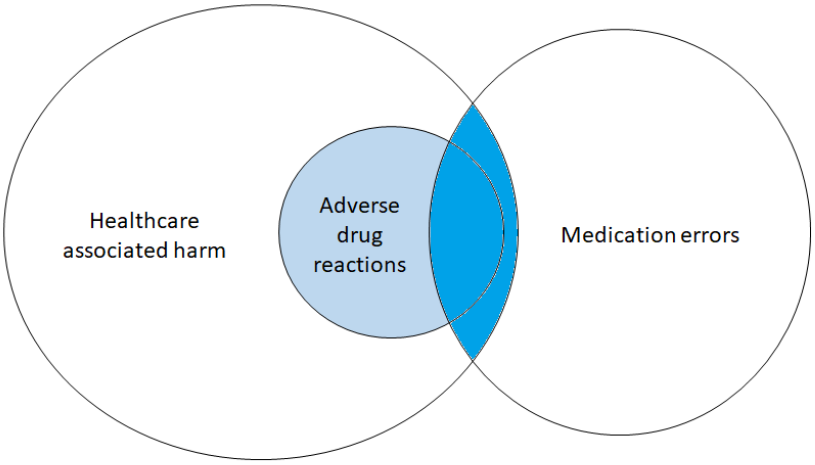

Figure 1.1 – Graphical representation of the association between healthcare harm and medication errors. Darker shaded sections represent avoidable harm related to medicines. Diagram adapted from Bates [64] *and Dean.*[65]

Yet within each of these conceptual spaces, there are multiple definitions. Lisby [61] undertook a systematic review of 203 studies into medication error and adverse drug events (ADE), identifying that only 45 of them carried a definition of a medication error. Within these there was no standardised definition of an "error" or "harm" or ADEs with 26 discrete wordings for error alone identified. Similarly in studies of paediatric medication error, Ghaleb and Barber identified nine discrete definitions across 32 studies.[66]

These definitional discrepancies lead to difficulty in comparing estimates between studies, and have inhibited development of a definitive estimate of adverse drug event prevalence and estimates of harm.[62] Similarly, there is

no agreement on definition of “harm” associated with medication. The NCCMERP advocate the use of a nine-point severity estimation index alongside their definition of medication error. This index ranges from A to I where A is “No error” and I is “death.”[67] This has become a popular framework for categorising errors and has been used in several large scale multicentre studies of medication associated harm.[68] The UK NRLS uses a five-level subjective categorisation ranging from “no harm” to “death” but these allocations are made at the point of reporting, and subsequently validated by clinicians.[52]

This definitional challenge of “harm” and “error” continues into the 2020s. In a narrative review, Falconer et al. argued that the diversity of definitions led to enormous variation in the proposed outcomes of studies into medicines safety, which made it difficult for policy makers and clinicians to communicate the burden of healthcare associated harm, but also contributed to problems in working to mitigate these harms. Thus there is a need to bear these inconsistencies in mind when developing new theories or interventions.

The impact of this definitional inconsistency is best demonstrated with studies considering administration time as an opportunity for error. Delayed and missed doses are of great concern throughout acute healthcare settings because there is a great deal of morbidity and mortality associated with failure to administer medicines when required.[53] However, there is concern that the use of “wrong time of administration” inflates wider

estimates of harm because the definition of a “wrong time” is largely subjective and there is uncertainty about the harm associated with these events. In a 2013 systematic review [60] it was identified that including “wrong time” errors with a +/- 30minute discrepancy from prescribed time increased observed error rates in one study from 27% to 69%. Other studies have counted “wrong time errors” as being +/- 1 hour from time of prescribing.[69]

1.1.2 Medication as a process, and distribution of ADEs and harm

Medication use should be viewed as a process made up of discrete tasks including prescribing, dispensing, preparation, administration and monitoring.[70,71] Walsh has defined the medication process in a conceptual form (Figure 1.2)

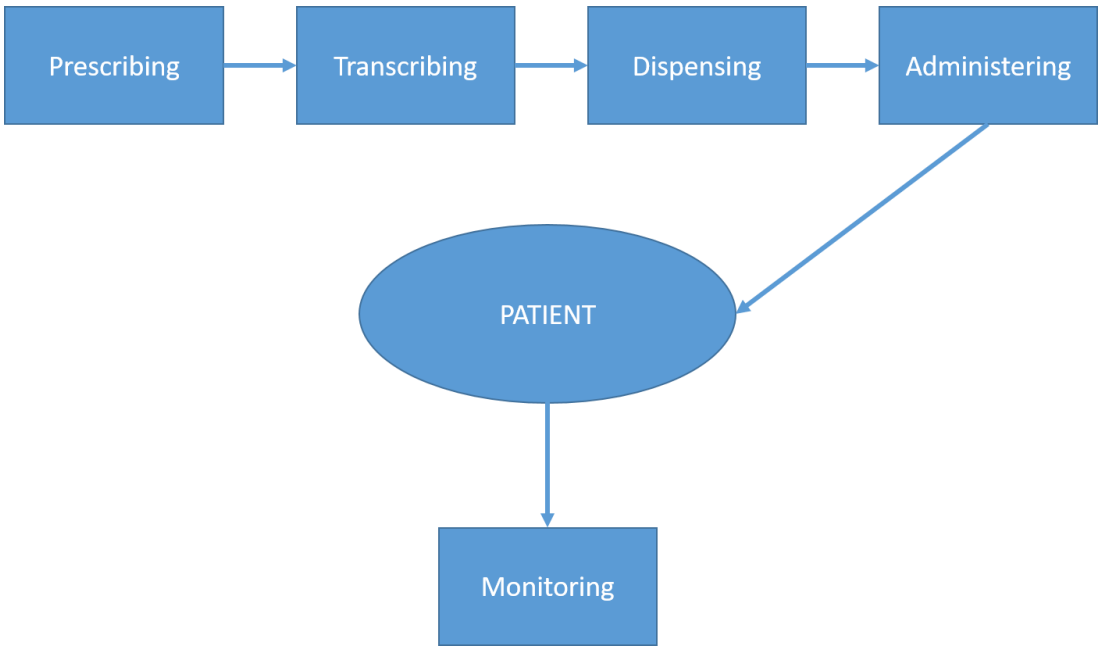

Figure 1.2 – Conceptual model of the medication process adapted from Walsh et al.[72]

In Hodkinson's systematic review, prescribing errors accounted for 58% (95%CI 42-73) of the observed errors in 81 studies.[54] This was followed by administration and monitoring errors. On the other hand, Naseralallah et al. in an umbrella review of systematic reviews identified that 17 of 27 identified reviews did not report medication error incidence by stage of the medication process.[68] Of those studies that did report a process stage, eight studied administration errors but four examined administration errors by patients or carers, and two studied prescribing errors. There were no studies citing data pertaining to dispensing or monitoring of medication.

Prescribing errors are perhaps the easiest of the medication errors to identify and categorise. Lewis et al.[73] synthesized the results of 63 studies on incidence, prevalence and nature of prescribing errors between 1985 and 2007. 47 of these studies were set in either the US or the UK and were mostly (55/65) in single hospital sites. 7% (IQR 2-14%) of prescriptions in these studies were associated with an error using various definitions. The highest rates were obtained using retrospective chart review or direct observation. Lower rates were obtained using spontaneous error reporting. Dosing errors were the most commonly reported event with the remainder made up of incomplete orders, omission of therapy or illegibility.

Interestingly, many prescribing "problems" could be construed as decision making mistakes, which Lewis went on to further study using qualitative methods.[74] Prescribing errors in this study were proposed to emerge from

cognitive limitations (described as knowledge based mistakes). This is supported by the findings of Barber et al. who identified training, standardisation of information and processes and reorientation of perceptions towards prescribing being a complex technical act as the key interventions to improve prescribing safety.[75] There is evidence that these interventions themselves may not be effective. A qualitative exploration of prescribing errors in two paediatric intensive care units identified that prescribing was still viewed as a menial task, and that some important information was cognitively inaccessible to those who required it.[76]

Administration errors represent the second most common medication error, and by definition are likely to be those associated with the most harm.[69,77,78] Keers et al. identified a median medication administration error (MAE) rate of 19.6% (IQR 8.6-28.3) across 91 studies published between 1985 and 2012. Intravenous MAEs occurred at almost three times the rate of all-cause MAEs (53.3%; IQR 26.6-57.9%) suggestive of a more complex process associated with IV medications. This was explored by Lyons et al. in a large scale multi-centre observational study of IV medication errors.[79] In this study of practice over 16 hospitals, 2008 infusions were observed with 240 errors observed. Harmful MAEs were observed in only 1.1% of infusions, with discrepancies (defined as a failure to follow policy or procedure) accounting for 1491/2008 infusions. In a follow-up study comparing this data with a similar US study [80] where more technological intervention was used, it was found that there was no difference between US and UK error rates.[81] Between US technologically supported infusions,

and English traditionally supported infusions, harmful MAE rates were 0.43% and 0.5% respectively. Thus MAEs (and intravenous errors specifically) may be related to more complex interactions between people, devices and the processes that they are following.

1.7 Other approaches to detecting and exploring ADEs

The studies and reviews described above used quantitative observational approaches to identify and describe ADEs. However, other methods have been used to provide greater contextual information on the causative factors of these events. In a systematic review of the causes of medication administration errors, Keers et al. (2013) identified that of 55 included studies, only six specifically studied causative factors as a primary outcome.[82] In the remaining studies, causation was evaluated as a secondary outcome (with prevalence and nature as primary). Within these studies, data collection methods included direct observation, conversation with healthcare practitioners and formal interviews.

There has been an advance in the use of mixed-method studies of healthcare quality and safety in recent years. Dixon-Woods described the utility of ethnographic approaches (using observation and participant enquiry) in exploring healthcare errors, and posited that these approaches could offer explanation for some adverse events "…through interrogating the everyday understandings that staff have of their own practices and… cultural contexts of practice."[83] Ethnographic methods have become commonplace, forming

the backbone of a programme of healthcare safety research in emergency departments, operating theatres and surgical services.[84,85] Blandford et al. used a mixed-methods approach including direct observation and focus groups to explore the aetiology of intravenous medication errors.[79,86] This study included two paediatric hospitals, but did not conduct a separate analysis of the paediatric data.

Manias conducted an integrative review of the impact of interdisciplinary collaboration on ADE incidence over the last ten years,[87] and identified ethnographic methods and exploratory focus group and interview studies as the predominant qualitative methodologies for the evaluation of these interventions. Critically, there have been few qualitative studies of medication systems relating to children and young people in hospital. Borrott et al. studied medical and nursing medication communication practices in a single Australian paediatric hospital.[88] Rosenfeld complemented this study with an exploration of interprofessional collaboration in medication processes involving pharmacists.[89] Both studies used ethnographic methods and concluded professionals undertook their work in good faith, with a commitment to safety but there were systemic issues with communication and exchange of information that may contribute to ADEs.

1.8 ADEs in Children and Young People

There is conflicting data in the literature pertaining to the prevalence of ADEs in children and young people. Kaushal undertook a retrospective chart

review in two academic medical centres and identified 616 medication errors in 10778 orders (prevalence 5.7 per 100 orders).[90] The definition of "error" used was "…an error in drug ordering, transcribing, dispensing, administering or monitoring." 74% (454/616) were related to prescribing errors, and 13% (78/616) to nursing administration errors. Their results showed that potential ADEs were almost three times more likely among hospitalised children and young people compared with a previous adult study in the same centre (1.1% vs. 0.35%) but preventable ADEs were similar (0.5% in each study).[64]

This study is now over twenty years old, and estimates of ADEs among hospitalised children have been refined. Gates et al. used preventable ADEs as a surrogate for harm associated with ADEs and conducted a review of published studies between 2000 and 2017.[91] The incidence of preventable ADEs in general paediatric wards accounted for 1.3% of all ADEs. In Intensive Care settings, this rate was 1.5% of all ADEs. When considering data across the whole spectrum of paediatric hospital care, the rate of preventable ADES was 2.6% of all ADEs. Thus the authors conclude that one in 40 children is potentially harmed by preventable ADEs.

Hodkinson's review (2020) identified that the preventable harm associated with medication in children and young people was lower than in other settings, between 1 and 2% of all episodes of patient harm.[54] The inclusion criteria of this review included primary, secondary and tertiary care

settings, and nine studies were included, accounting for 24531 patients. When examining the included studies in detail only three used a recognised tool to evaluate the preventability of observed events, with the remaining six using methods based in physician assessment. Furthermore, six of the nine studies (65.6%; 16,098/24531) were conducted in the first ten years of the 20th century.

Critically, this study included data related to ADEs and included adverse drug reactions (ADRs) only where preventability was evaluated. And yet, there are important studies pertaining to the prevalence ADRs in this group that present interesting systemic insights into harmful ADEs for children and young people but did not meet the inclusion criteria. A prospective observational cohort study in a large English tertiary paediatric hospital included 5118 patients over 6601 admissions and identified a rate of harmful ADRs of 17.7% of patients.[92] Patients undergoing a general anaesthetic (GA) or receiving opiate analgesics accounted for 50% of ADR cases, and 0.9% of these children required escalation of care or were permanently harmed. The hazard ratio of experiencing an ADR from a general anaesthetic was 6.4 compared to patients who did not receive an anaesthetic. Further, patients on oncological therapy were 1.9 times more likely to experience an ADR compared with other patients.

Further, it is known that children and young people are exposed to unlicensed and off-label medicines more than adults. A multi-centre

international survey of prescribing for children estimated that 46% of medicines (range 30-66%) of medicines prescribed to children and young people were being used outside of their marketing authorisation.[93] In neonatal care, estimates are as much as 80% of medicines prescribed for these patients being unlicensed or off label.[94] Further, in a scoping review of causes of prescribing errors in children and young people, Conn and Tully identified that the increased prevalence of unlicensed and off-label medicines were one of the contributory factors to prescribing errors in children.[95]

There is evidence that this use of unlicensed medicines leads to patient harm. In a single-centre nested case control study of 10699 courses of medication administered to 1388 patients, patients receiving unlicensed medicines were 2.25 times more likely to experience an ADR compared with their peers receiving authorised medicines.[96] In this study, unlicensed medicines accounted for 31.2% of prescribed medication courses, which suggests little or no improvement in prevalence of this practice since Conroy's earlier 2000 study.

While the incidence of preventable medication-related harm this is low in comparison with other patient populations, there are specific problems associated with children's medicines that suggest that generalised interventions derived from the wider literature may not be applicable to hospitalised children and young people.

Kozer et al.[97] reviewed all medication error reports in a Canadian children's' hospital and identified 10-fold dosing errors at a rate of one per 22500 doses, and potentially causing six deaths and nine life-threatening events. It was without question that medication related harm in children was a problem, but there was insufficient data to estimate the burden of the problem. The Chief Pharmaceutical Officers report referred to this study and other small scale single-centre studies in order to support its recommendations relating to dose calculation and availability of drug and patient information to support these calculations.[98]

An insight into the UK experience is provided by Ghaleb and Wong's first prospective empirical study of the prevalence and nature of medication errors in paediatric inpatients.[99] Studying five hospital sites in the Greater London area, they found a prescribing error rate of 13.2% (391/2955 orders) and an administration error rate of 19.1% (429/2249 opportunities for error). Of prescribing errors, dosing errors were the third most common (11.3%), with incomplete prescriptions (41.2%) and abbreviations (24.0%) being the most common. The remainder pertained to dose frequency, prescribed rate (for intravenous medicines) or incorrect route. Of administration errors incorrect preparation and incorrect rate of administration occurred with almost the same frequency (20.7% and 19.8% respectively.) No data pertaining to the severity of the ADEs observed in this study were offered.

Wong, Wong and Cranswick presented a narrative review of ADEs in children and young people and how to mitigate them in 2009.[100] Many of their recommendations pertained to the management of dosing-related errors, but also began to allude to other systemic contributors to paediatric ADEs including the training and experience of the clinicians working in the paediatric field, and the impact of communication between healthcare services.

In 2014 Sutcliffe et al. reviewed the UK literature on the nature of paediatric medication errors for the Nuffield Foundation and found 11 studies across acute and primary care.[101] Dosing errors were the single most common error identified, accounting for around 20% of ADEs. There was also a suggestion the MAEs were associated with higher risk environments and medicines (anaesthesia and vaccines.) However this review while being wide ranging and informative lacks supporting data on the harms associated with the observed medication error rates. Furthermore, while there was evidence to support the impact of electronic prescribing to manage ADEs, the authors concluded that the way these systems were conceived and implemented was likely to be crucial in their success.

Yet children are confronted with unique medication related issues that may have implication for assessment of preventability of ADEs and have implications for healthcare professionals and caregivers in ensuring appropriate and safe medicines use. Children and young people are

physiologically immature and handle medicines differently to adults which results in a bespoke approach to medication dosing and administration.[102] This bespoke approach to medication dosing has been hypothesised as a disincentive to medication research,[103] as up to 90% of medicines used in paediatric and neonatal care are unlicensed or off label [93,104] and despite regulatory intervention to improve access to appropriately studied and licensed medicines this has not moved much.[105]

1.8.1 Policy Recommendations for Improving Paediatric Medicines Safety

These systemic challenges to medication access and use have led to the development of specific paediatric interventions to improve safety. As part of the wider quality improvement efforts of the early 20th century, the NHS in England published the National Service Framework for Children (NSF) in 2004 which incorporated specific standards for medicines.[106] This framework identified the contributory factors to ADEs described above, but also included the increased risk from adverse drug reactions (ADRs) as a result of developmental immaturity and the high prevalence of unlicensed and off-label medicines. While the British National Formulary has been available since the late 1970s, the NSF laid the groundwork for a version with suitable information for CYP.[107] Prior to this, the Royal College of Paediatrics and Child Health (RCPCH) produced their own manual for prescribing, administering and monitoring of medicines from 1994 onwards. The National Children and Young People's Outcome Forum (CYPHOF) (2011) identified that the lack of suitable medicines and formulations for

children and young people was of importance to health outcomes for this population. The lack of information around these medicines was also cited as a continuing problem into 2016 and continues to be a problem into the recent past, with lack of clear information for paediatric medicines being a proposed contributory factor to prescribing errors.[95,108]

There is a historic lack of robust, evidence based medicines support for CYP, and qualitative explorations of medicines related problems for CYP have identified this lack of information as a contributory factor to ADEs.[76,109] Further, ten-fold dosing errors continued to be observed and reported into the 2020s however it though these events were more common among children, they were not unique to that area.[110] Thus there is a likelihood that paediatric medicines safety is not just a matter of “errors” but also other rich contextual issues relating to access to information and medicines, which may not be detected in observational ADE studies.

1.9 The Concept of Medication Related Problems

Ergo when considering children’s medicines and their safety and effectiveness, a focus on “medication error” may not be that helpful. The term “Error” carries strong moral associations that appeal to funders and consumers of research.[111] However “error” is a heavily laden term, implying failure or incompetence and may not be a fair label. Hollnagel has described error as being a fallacious construct, based in hindsight bias.[112] Most studies of medication error use either trained human assessors to

determine *post hoc* whether or not an error has been committed, or use data from spontaneous incident reports. In many studies, the language around error belies an organisational presumption towards failure and the necessity to improve and resolve problems. However a focus on "error" has led healthcare industries and researchers to lose sight of the wider field of healthcare-associated harm and has created an environment where policy makers mistakenly believe that "error" and avoidable harm in healthcare can be eradicated.[24,113]

In developed healthcare systems there is a clear exhortation to move towards a more open approach to managing "error".[25,114,115] Healthcare associated harm can be associated with other process issues, rather than error. There are considerable "system" related contributions to healthcare associated harm, which may not be associated with an error. "Drug" or "Medication" related problems (DRP or DRP) encompass errors, but also include ADRs and patient non-adherence.

They have been defined as "…an event or circumstance involving drug therapy that actually, or potentially, interferes with desired health outcomes."[116] and have been useful in identifying wider systemic issues with medication processes than just errors alone. Globally, the incidence and prevalence of DRPs in children and young people is estimated at up to 87.7%.[117] Over 50% of DRPs are related to safety or drug optimisation issues. In a 2012 study of DRPs between the UK and Saudi Arabia, rates

were higher in Saudi Arabia (51.1% 95%CI 45.8-65.3) than in the UK (39.4% 95%CI 34.4-44.6).[118] Similarly, Ibrahim noted that among renal patients in a single English healthcare service, the incidence of DRPs was higher in hospitalised patients than in ambulatory patients (51.2% vs 32%; p=0.04).[119] Thus there are wider problems associated with medicines for children in hospital and focussing on “errors” may overlook sub-optimal medicines use that may also lead to patient harm.

1.10 Changing Views of Medication Safety

Previous research has focussed on the phenomenon of error – events relating to the prescribing and administration of medicines that are unintended, and may or may not lead to harm. The intention of this focus is admirable – errors may be observable and describable, and may lead to physical, psychological and financial loss. Increasingly, healthcare safety is being combined with a new focus on healthcare *quality* because of these connections, and the view of healthcare as a public good.[120] The World Health Organization (WHO) defines quality health services as:[121]

- Effective – people can access services and treatments that are evidence-based
- Safe – services avoid causing harm to their service users
- People-centred – services and treatment are tailored to individual needs and preferences.

In the UK these have been operationalised by the Royal Pharmaceutical Society (RPS) and National Institute for Health and Care Excellence (NICE) into guidance on “Medicines Optimisation.” (MO)[122,123] There are four principles of MO:

- Incorporate patient lived experience in practice
- Offer medicines with an evidence base where possible
- Endeavour to use medicines as safely as possible
- Make MO part of routine practice.

As well as summarising the evidence for indicators of medicines safety that has been explored in earlier parts of this thesis, these guidance documents identified that variation in practice and lack of patient involvement in medicines selection led to enormous financial waste and poor patient outcomes. As well as medication errors, it is estimated that among patients with chronic disease, or in those over 75 years of age, 38% of patients do not take their medicines as intended (either intentionally or unintentionally).[124] Some of the factors for this non-adherence identified in this study included practical elements around medicine presentation or previous medication experiences.

These aspects of paediatric MO have not been studied robustly. Benn conducted a narrative review of the literature and identified formulation problems and physiological differences with adults as being the common contributory factors to paediatric MO issues.[103] Within the wider literature

however, there are few studies of paediatric MO. However, there are some insights into paediatric MO experience that have emerged in the last five years.

Aston et al. used qualitative methods (telephone interviews) with parents of patients with chronic diseases to explore their experiences of medicines at home.[125] Issues that arose for families were around adaptation of family schedules to accommodate new medicines, negotiating medicines around school, packaging of medicines at school and the co-ordination and provision of medicines information. Further, it has been estimated that up to 50% of parents adjust or change their child's prescribed medicines without reference to a physician or pharmacist, and a third of these changes are to meet the needs of family routines or a lack of suitable equipment.[126] However, many of these parental adjustments for home routine are reported as "parental medication errors."

Walsh conducted two empirical studies using home visits and direct observation of parental medication skills for children with chronic diseases (epilepsy and sickle cell disease) and cancer, and found rates of medication error in home of 18.8% of medication administrations to children with cancer, and 22% of medication administration to children with chronic diseases. Subsequent expert review of each error assigned a causative factor and these were communication problems relating to dose changes, and

inadvertent over or under-dosing related to dose changes or inability or inappropriate equipment.[127,128]

These findings were supported by a later systematic review by Lopez-Pineda. In 19 studies specifically focussed on medication errors for children in the home.[129] Rates were between 30 and 80% of administered doses, though there was considerable heterogeneity in the way data on this phenomenon was collected. That being said, important insights around parental abilities were identified particularly around technical skills regarding measurement and administration of medicines, and the management of medicines within the home.

Thus there are many paediatric “medication errors” that may pertain to wider systemic issues around communication between complex systemic issues pertaining to how we as healthcare professionals work with and engage with families in the medication needs of children and young people. Current UK centric research is largely in the perspective of medication errors, and present error rates of between 20 and 30 per cent.

1.11 Chapter Summary

While avoidable healthcare harm associated with medicines for children and young people appears low compared with other populations, there has been little or no consideration of the context in which medicines safety is created.

Safe medicines practice for children and young people is a complex multifactorial system comprised of multiple actors and processes.

Healthcare is taking an increasingly systems-focussed view on the aetiology and manifestation of adverse healthcare events, which requires a new perspective on the study and representation of these events. While the current processes in place may be derived from historical literature, there is a concern that they are rooted in supposition of cause and effect based on the type of events that have been observed or reported. While there has been merit in such interventions in that overall event rates have decreased, there are complex systemic issues at play that may not be fully understood which may contribute to the relative absence of improvement in the rates of harm associated with medicines use.

The physiological immaturity of children and young people, the lack of authorised medicines for them, and the preference for oral liquid medicines creates issues around prescribing and administration. Furthermore, the services in which children and young people are cared for are provided by healthcare professionals who may not work within these constraints regularly, and that may not be well integrated with wider services in which the care of children and young people is undertaken

Thus there are two problems that emerge from this literature review:

1) The data pertaining to ADEs and their prevalence and nature is somewhat out-of-date with few robust estimates published in the last fifteen years. A more up to date understanding the epidemiology of DRPs is important to inform efforts by healthcare professionals, researchers, patients and carers to mitigate these problems through improvement interventions. Also, it has been suggested that because of methodological inconsistency, comparison and extrapolation of event rates across geographical and regulatory boundaries may not be appropriate. Thus there is a need to review the prevalence and nature of DRPs for hospitalised children in the UK, with a focus on processes and systems, in order to identify gaps in the literature and propose directions of onward study.

2) There is also a clear need for research that moves away from the traditional epidemiological study of prevalence and incidence of DRPs for children in hospital, and starts to study the context in which medicines in hospital are used. The historical focus on “errors” as an antecedent of ADEs may lead us to overlook systemic problems with medicines optimisation and hinder the development of robust theory-based interventions to support system-wide improvement.

2 Mapping the Prevalence and Nature of Drug Related Problems in Among Hospitalised Children and Young People in the UK – A Systematic Literature Review

2.1 Introduction

As outlined in the previous chapter, current estimates of paediatric ADEs are limited in scope to “errors” or to specific aspects of the medication process (prescribing and administration). There are no studies that have taken a systems approach to the estimation of the prevalence of ADEs, nor is there an understanding of where ADEs may be distributed within the whole medication system. While there are several global literature reviews offering mixed estimates of the prevalence of ADEs in children and young people,[130,131] there is a need to evaluate a UK estimate to facilitate localised, generalised estimates against which UK practice can be benchmarked and evaluated. Pooled estimates specific to the UK-context are now almost 20 years old, and are in need of updating.

To resolve this question a systematic review of the UK literature pertaining to the prevalence and nature of ADEs using a systems focus was conducted. This was published in BMC Pediatrics in December 2019.[132]

2.2 Review methods

The review was conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [133] and the

review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO; 118535). DRPs were defined using terms related to medication safety – ADEs, ADRs and Medication Errors (MEs). In order to generate a systems view of the prevalence, a conceptual map of the medication system in hospitals was adapted from the model used by Walsh (Figure 2.1) which in turn is based on the Food and Drug Administration's (FDA) "Five Key Steps" for medication safety.[72,134] The adaptations inserted were used to reflect the construction of British medication systems, including large use of stock medication in ward spaces and the use of a single prescribing and administration record (be that in paper or electronic format.)

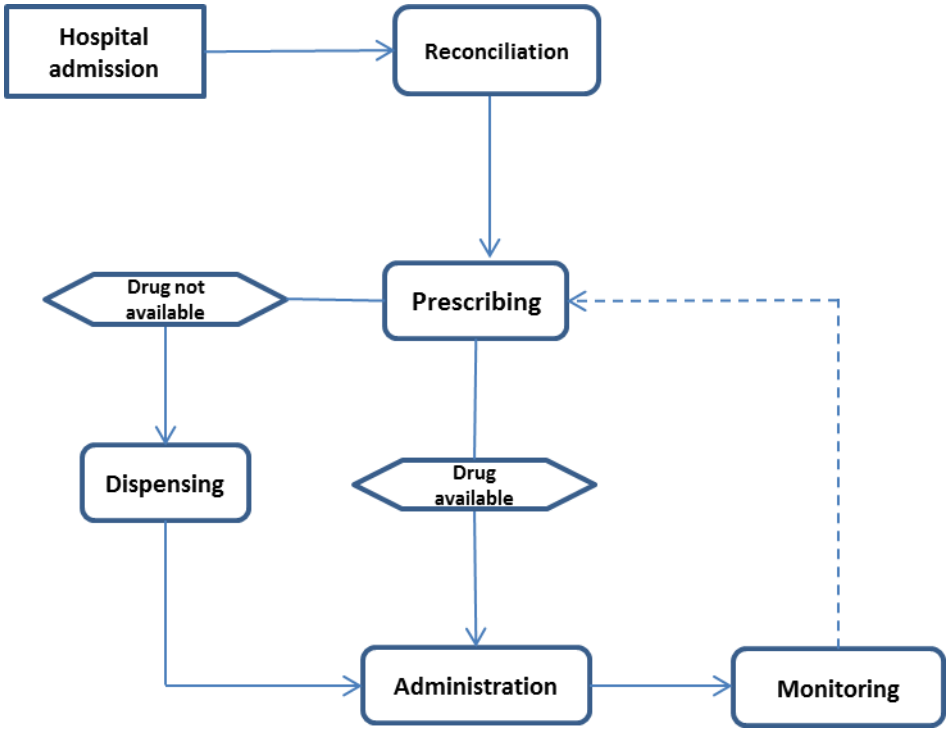

Figure 2.1 – Conceptual map of the in-patient medication process in a British hospital.

Search terms were developed with reference to existing systematic reviews, and supported by a university librarian. Search strings are available in Appendix 3. Nine electronic databases (Medline, Embase, CINAHL, PsychInfo, International Pharmaceutical Abstracts, Scopus, Health Management Information Consortium, the British Nursing Index, The Cochrane library and International clinical trial databases) were searched from January 1st 1999 to April 30th 2019. Searches were updated and re-run in March 2023, with no new studies being identified for inclusion. The grey literature including publicly available government reports, were also searched through the OpenGrey portal (www.opengrey.eu) for studies that met the inclusion criteria. The citation lists of all included studies were hand searched to identify additional potential studies. The search strategy was constructed with reference to previously published systematic reviews [66,135,136], and with the support of a university librarian.

2.2.1 Inclusion and Exclusion Criteria

Studies published in English, presenting data relating to the prevalence of ADRs, ADEs and MEs in hospitalised CYP in the United Kingdom were included. Children were defined as anyone under the age of 18 years of age.[137] Eligible study designs included observational epidemiological studies (including cross-sectional and cohort studies) and interventional studies (randomised controlled trials, non-randomised controlled trials, before-and-after studies and interrupted time series) where pre-intervention data was reported. Conference abstracts were included where they provided sufficient data to enable the calculation of an event rate and expressed a clear denominator. Where studies collected paediatric data but did not

present these separately authors were contacted for access to data sets to permit extraction and analysis by the review team.

Systematic and narrative reviews were excluded, but their reference lists searched for eligible studies. Studies based on spontaneous incident reporting data were also excluded as denominators in these studies are often imprecise and the prevalence not determined. Furthermore, studies on adherence to medication were excluded as hospital in-patient medication is administered by nursing staff and adherence could reasonably be assumed to be captured as "omitted doses."

2.2.2 Data Extraction and Synthesis

Studies were screened against the inclusion criteria by title and abstract. Full text articles were further screened against inclusion criteria by a single researcher. Included articles were then reviewed independently by members of the review team and data extracted using a proforma that collected descriptive details of each study – year of publication, country (England, Wales, Scotland or Northern Ireland), the clinical setting, study design and the duration. Other information extracted included the definitions used and method of data collection, their outcome of interest (ADEs, MEs, or ADRs) including the denominator, and the stage of the medication process at which these events occurred – admission and discharge (intended to include issues arising at transition of care), prescribing, dispensing, administration and monitoring.

The primary outcome of interest was the prevalence rate of MEs, ADRs and ADEs identified at each stage of the medication process. Data on the severity and preventability of events were also extracted where available. Data were summarised descriptively in tables, and prevalence rates were summarised at each stage of the medication process. Heterogeneity of definitions of events amongst the studies made meta-analysis inappropriate; however, within studies of similar design and denominator, results were summarised at each stage as median rates (with interquartile range) to provide an estimate of the prevalence overall.

2.2.3 Assessment of Study Quality

Study quality was assessed using Allan and Barker's method for medication error studies, adapted by Ghaleb and Wong.[66,138] 12 criteria were reviewed for each study using a "Yes/No" qualification.(Figure 2.2) Each Yes scored one point, and higher scores represented higher quality studies. Scores >10 were considered "High Quality."

- Clearly stated aims and objectives
- Clearly stated phenomenon of study – ME/ADE/ADR
- Categories of ME/ADE/ADR specified and defined
- Clearly stated definition of phenomenon of study
- Clearly described method of detection
- Clearly stated setting
- Clearly stated denominator (or ability to calculate one from the data)
- Clearly described sample size and sampling method
- Description of reliability measures
- Description of validity measures
- Listing of limitations
- Description of assumptions made

Figure 2.2 – Allen & Barkers Quality Assessment Framework for medication safety research, adapted by Ghaleb & Wong.

2.3 Results

A PRISMA chart of the literature search is provided in Figure 2.3. 26 studies were identified that met the inclusion criteria.

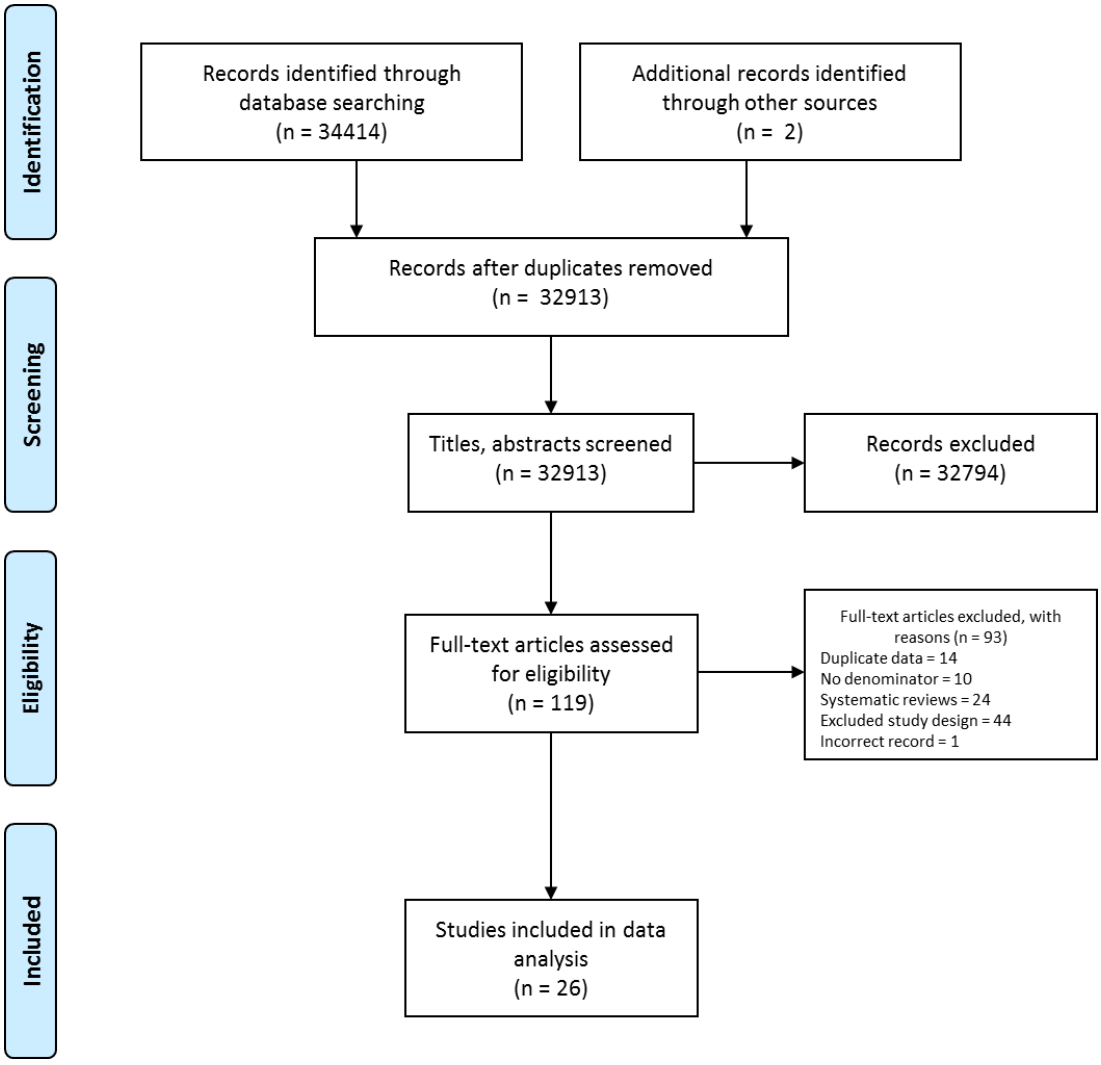

Figure 2.3 – PRISMA flowchart for the review and inclusion of papers into this systematic review

23 studies were set in England (two multi-centre, six in the North of England, three in the Midlands and 12 in London) with two in Scotland and one in Northern Ireland. One study examined both prescribing and

administration.[99] Seven studies were included critical care data – six in Paediatric Intensive Care (PICU) [99,139–143] and one in Neonatal Intensive Care (NICU).[144]

There were three studies examining medicines reconciliation (one on discharge and two on admission to hospital),[145–147]. 16 studies explored Medication Prescribing Errors (MPEs) [99,139–144,148–156]; six studies examined medication administration - four studying Medication Administration Errors (MAEs) [79,99,157,158] and two studying the incidence of adverse drug reactions (ADRs). [159,160]

Two studies examined the incidence of DRPs as a specific concept using the Pharmaceutical Care Network Europe (PCNE) classifications.[161,162] There were no studies relating specifically to ADEs, or to DRPs associated with dispensing of medication or monitoring of therapy.

Three studies used a retrospective approach [149,150,154] and 23 used prospective designs. Retrospective studies all used longitudinal cohort study designs ranging from one month to one year, while prospective studies lasted between one day and ten months. Prospective studies used cross-sectional observational designs, with two studies using an interrupted time series design.[148,153]

There were a range of definitions used. Studies of medicines reconciliation at admission and discharge used a consistent definition and methodology based on construction of a best-possible medication history and comparison of in-patient medication orders. These were treated separately to MPEs. Of the 16 MPE studies, three used Ghaleb's clinical definition of error.[63,151,152,163] Seven defined MPEs as deviation from local and national policy.[141,144,148,153,155,156] Two studies reported data on technical MPEs as a failure to complete prescriptions in line with local policy.[148,151] Five studies provided no definition. [139,140,143,149,150,154]

Two studies of MAEs used a definition based on independent assessment of the likelihood of errors to cause harm to the patient.[99,157] A third study of used an outcomes-based definition to separate "errors" (drug-related problems that may lead to actual harm to the patient) from "discrepancies" (deviations from policy or procedure that would not lead to harm to the patient).[79] One study used quantitative accuracy of measurement of doses as a surrogate of MAEs but made no link to patient outcomes.[158]

Studies of ADRs used two different (but similar) definitions. Bellis and Thiesen [160,164] used the definition of ADR from Edwards and Aronson [165], and Rashed used the World Health Organisation definition.[166] Both definitions purport to exclude MEs.

1.1.3 Study Quality

A summary of the study quality is presented in Table 2.1. 13 studies were considered to be high quality with clear reporting of definitions, validity and reliability methods. However six of these studies were single centre therefore cannot be generalised beyond the study context. All observational studies used site-based data collectors, however only five studies described how these data collectors were trained.[79,99,157,161,167] Ten studies used subject matter experts or independent review of classification to enhance the reliability of the events recorded. [79,146–148,151,152,159,160,167,168]

Paper	Quality indicators												
	Aims and objectives	**Phenomenon of study**	**Categories defined**	**Clear definition**	**Clear detection method**	**Clear setting**	**Clear denominator**	**Clear sample size and method**	**Reliability**	**Validity**	**Limitations**	**Assumptions**	**Quality Score**
Alsulami (2014) [157]	Y	Y	Y	Y	Y	Y	Y	N	Y	N	Y	N	9
Bolt (2014) [169]	Y	Y	Y	N	N	Y	N	N	N	Y	N	N	5
Booth (2012) [142]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Davey (2007) [170]	Y	Y	Y	Y	Y	Y	Y	N	N	N	Y	N	8
Donnelly (2015) [156]	N	Y	N	N	N	Y	N	N	N	N	Y	N	3
Fordham (2015) [144]	Y	Y	Y	N	N	Y	Y	N	N	N	N	N	5
Ghaleb (2010) [99]	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	10
Gordon (2012) [171]	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	10
Huynh (2016) [146]	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	10
Huynh (2016) [172]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10
Ibrahim (2015) [173]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Isaac (2014) [141]	Y	Y	N	Y	Y	Y	Y	N	N	Y	N	N	7
Lane (2013) [149]	N	N	Y	N	N	N	N	N	N	N	N	N	1
Leach (2014) [150]	N	Y	N	N	N	N	Y	N	N	N	N	N	2
Lepee (2012) [151]	Y	Y	Y	Y	Y	Y	Y	N	N	Y	Y	Y	10
Lyons (2018) [79]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Morecroft (2012) [158]	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	7
Morris (2016) [140]	N	Y	N	N	N	N	Y	N	N	N	N	N	1
O'Meara (2013) [152]	Y	Y	N	N	Y	Y	N	N	N	N	N	N	4
Rashed (2012) [162]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12

Paper	Quality indicators												
	Aims and objectives	**Phenomenon of study**	**Categories defined**	**Clear definition**	**Clear detection method**	**Clear setting**	**Clear denominator**	**Clear sample size and method**	**Reliability**	**Validity**	**Limitations**	**Assumptions**	**Quality Score**
Rashed (2012) [174]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Sutherland (2011) [139]	Y	Y	N	N	N	Y	Y	N	N	N	N	N	4
Terry (2010) [147]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	11
Thiesen (2013) [160]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Warrick (2011) [143]	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	10

Table 2.1 – Results of quality assessment of included studies

1.1.4 Patient Outcomes

Seven studies evaluated the potential harm associated with DRPs; two were related to ADRs [159,160] and three to discrepancies detected during medicines reconciliation.[146,147,167] One study examined the potential harm associated with prescribing errors[152] and one reported potential harm of administration errors.[79]

The ADR studies used two differing methods for evaluating potential harm. Rashed (2012) used the Dormann method for evaluating the severity of ADRs [175] and identified that 136 (61%) ADRs were rated as “mild,” 85 (38.1%) “moderate” and two (0.9%) “severe.” Conversely, Thiesen (2013) used the Hartwig scale [176] and identified that 322 (22.1%) ADRs were level one (no harm), 1112 (76.9%) were level two or three (drug held but no lasting harm) and 13 (1%) associated with harm (12 level four and 1 level five.) No fatal or otherwise prolonged harm events were identified.

All three medicines reconciliation (MR) studies used the consensus method described by Cornish to evaluate potential severity of medication discrepancies.[177] For the MR on admission studies, 50-78% of discrepancies were rated to be moderate or severely harmful, while on discharge 22% were rated moderately harmful with no severely harmful discrepancies.

One prescribing error study [152] utilised the consensus method described by Dean et al. to evaluate potential harm.[178] More than half of these errors (63.5%) were considered to be moderate or severely harmful. A prospective observational study on intravenous (IV) medication administration errors used an outcome-related harm categorisation (NCC-MERP) to differentiate errors from discrepancies[79] None of the MAEs noted in this study were associated with any harm.

1.1.5 Incidence and Prevalence of DRPs Distributed through the System

At admission to hospital the median rate of medication discrepancies was 23.1% of documented orders (range: 20.1-46). 70.3% of discrepancies on admission (range 50-78) were deemed clinically significant; that is, rated as moderate or severe. Only 22% of discrepancies on discharge met this threshold.

Of the 16 studies with data on MPEs, seven studies [99,148,151,152,155,156,179] used Ghaleb's intensive chart review method, using a clinician, pharmacist or pharmacy staff member as primary data collector.[99] However, only three of these studies [99,151,152] collected data on clinically significant errors based on similar definitions [63] and were able to support comparison (Table 2.2).

	Orders	Errors	%
Ghaleb [99]	2955	391	13.2
O'Meara [152]	1911	125	6.5
Lepee [151]	657	31	4.7

Table 2.2 – Prevalence of clinically significant MPEs

Ghaleb's 2010 study also included PICU and NICU data which was extracted and presented separately. Across the three studies, the median prevalence of MPEs was 6.5% (IQR 4.7-13.3).

It was possible to extract data on error rates for dosing errors from five studies. [99,151,152,154,155] The median rate of dosing errors was 11.2% of medication orders (IQR 2.9-13)

Seven studies in critical care settings utilized prospective chart review methods to explore the prevalence of MPEs. The duration of studies was variable, and ranged from 96hrs [143] to 36 weeks [142] with two studies not stating a duration.[139,141] Six studies used the number of prescriptions observed as their denominator, and were compared. The median prevalence of MPEs in critical care was 11.1% of medication orders (IQR 8.8-12.5)

Some MPEs were described as “technical” and related to incomplete or improperly formatted prescriptions. Two studies used opportunities for error to explore technical MPEs which allowed comparison.[148,151] The median prevalence was 9.8% (IQR 9.3-10.2). One study [155] used the number of prescriptions as the denominator (76/249; 30.5%) and one study [156] expressed a rate per-ten-drug charts as the denominator (32/12 averaged to 27/10). Woodley [153] used a retrospective study design and identified a prevalence of MPEs of 90.9% of drug prescriptions, compared against in-house standards. None of these studies explored the potential severity of the errors.

Three studies did not state standards or definitions for MPEs.[149,150,154] Bolt and Lane used retrospective chart reviews to assess MPEs in paediatric dental services and cleft services respectively. MPE rates were observed between 13 and 100% of prescriptions with dosing errors being most common, however only Bolt provided a standard against which dosing was compared.

The median rate of MAEs was 16.3% of opportunities for error (IQR 6.4-23). Three studies used direct observation to identify MAEs in clinical areas.[79,99,157]. Two studies were multicentre – one studying MAEs in paediatrics and the other studying intravenous MAEs in adult and paediatric practice.[79,99] The authors of the large multicentre IV MAE study were contacted for paediatric data. One single-centre study observed nurse

double checking of medication.[157] As described earlier, there were differences in the definitions of “error” used across the studies. Alsulami included “parental administration of medication without nursing observation” as a unique error type which has been suggested to inflate error estimates;[60] therefore these errors (64/191) were excluded from our analysis.

Additionally, Morecroft [158] used a surrogate measure of MAE by evaluating “measurability” of medication doses. This multicentre study retrospectively studied 1599 prescribed doses of intravenous and oral medication for 431 patients in three paediatric wards over five weeks and observed 196 unmeasurable doses (12.3%). “Measurability” was defined based on the availability of syringes and assumptions about the strength of liquid medications that were available on the wards. Doses of less than 5ml accounted for 75.5% of these unmeasurable doses.

The median rate of ADRs across two studies [160,174] was 25.9%. 79.2% of reactions were severe enough to warrant discontinuation of therapy. However, there is uncertainty in both estimates due to methodological differences in case identification – Rashed enrolled at 24hrs while Thiesen only considered patients hospitalised for more than 48hours.

Finally, in order to bring a systems view to the data it is possible to populate our system representation with the prevalence and nature of DRPs (Figure 2.4)

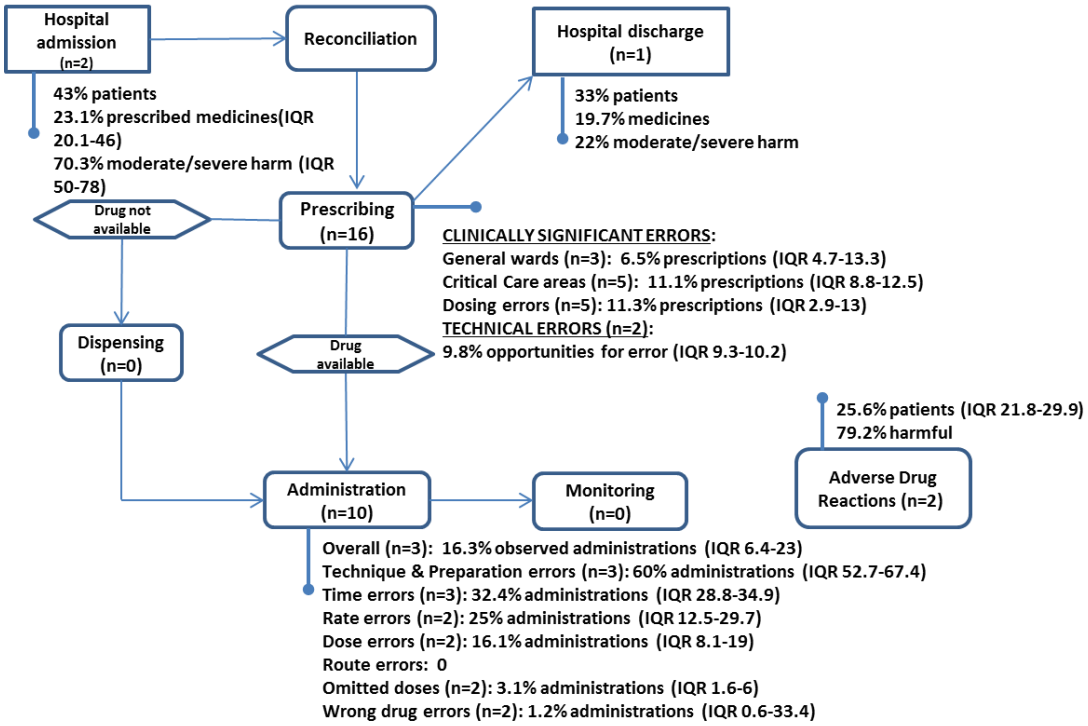

Figure 2.4 – Distribution of DRPs throughout the system

2.4 Discussion

DRPs in children are common throughout the in-patient medication process from admission to discharge. Adverse drug reactions affect more than one in four hospitalised children. Documentation errors on admission affect 43% of patients, with 70% of these errors likely to cause harm. One in fifteen children is affected by a clinically significant prescribing error, and this prevalence increases to one in 10 children in PICU. This estimate is around half the estimated rate of ADEs prospectively identified in British PICUs which found a rate of 20.2 per 100 patients.[131] However, this study looked

at ADEs with no consideration of potential causative factors or associations. The estimated rate of MPEs in American PICUs stands at 11.1%.[180]

The results of this review offer some interesting contrasts with a similar recent review. Gates et al.[130] attempted to meta-analyse ME estimates across the global literature and encountered the same definitional and methodological challenges encountered in this review. MPEs were more prevalent in critical care areas (25.9%; 95%CI 17.3–36.7) compared to general ward areas (14.7% (95%CI 6.1–31.6). However, technical and clinically significant errors were grouped together in a number of studies, which may explain our lower estimates as we have endeavoured to separate these where possible. Conversely, the MAE estimates in Gates's review are far lower than ours (3.1% of observed administrations (0.4–19.5) in multiple wards). While this may reflect differences in inclusion criteria (a large scale multi-centre study of IV medication errors that was included in our review was excluded as children did not account for > 90% of the sample)[79] this cannot solely explain our estimate.

Gates argues that lower-quality studies resulted in higher estimates, and thus the MAE estimate is taken from "high" quality studies. However the range of MAEs in Gates's study using similar denominators to included MAE studies in our review is 0.2–89.9 MAEs per 100 administrations. Thus we can offer a more granular, regional estimate of the prevalence of paediatric MAEs in the UK. To offer further support to my estimate of MPEs, Alenezi et al.

undertook a prospective multicentre observational study over one day a month for six months in 13 paediatric units, and estimated MPE prevalence at 8.9 per 100 orders, affecting 20.7% of patients. Thus my estimates of ADE and DRP prevalence are valid for the UK context, and represent a potential baseline for future interventional studies to base their effect size estimates.

1.1.6 Potential contributory factors to DRPs

In this review, half of all MPEs were a result of incorrect dose selection. This has been a common contributory factor identified in both empirical research and retrospective reviews.[58,74,95,100] Technical prescribing errors occurred almost twice as often as clinical errors. MAEs are the most frequent DRP in UK children in hospital, with rate, dose and preparation errors being most prevalent among them. These findings complement a recent global systematic review of MAEs that found that wrong time errors were most common in paediatrics, followed by preparation and dosage errors, with administration technique and rate the third most prevalent error subtype.[82] This potentially reflects the lack of standardised methods for preparation and administration of medicines especially in children, where adaptation of adult formulations is often necessary for administration.[181]

There are also significant problems around documentation of medication information, particularly with regards to medication histories and documentation of prescriptions. As discussed earlier, the UK continues to

have a largely paper-based prescribing system, which presents issues around accuracy and completeness of prescriptions.

Dosing errors are the most common MPE in hospitalised children and young people. This has been known for some time but appears to remain a problem.[101,182,183] There is a strong human component in the aetiology of these errors. Jani et al. studied the impact of electronic prescribing in a British children's hospital, and reported an overall reduction in dosing error rates from 2.2 to 1.2% (95%CI -1.6 – − 0.5).[179] However in this study, the inpatient rate of dosing errors did not change (1.42 to 1.39%, p = 0.95). Further study of this system identified a high rate of rejection of duplicate-dosing alerts that was later found to be caused by the design of the electronic prescribing system whereby legitimate and appropriate prescriptions were triggering alerts.[184] This also supports the earlier work of Potts et al. who found that while technical prescribing errors (properly formatted and completed prescriptions) were reduced using CPOE by 99.4%, potential ADEs were reduced by 40.9% with dosing errors unaffected.[185] In CPOE it has been found that poor design and implementation can lead to worsening of safety, and even increased mortality.[186] Thus there is a suggestion of a cognitive component in the choice and calculation of doses that has not yet been explored or identified.

Most of the DRPs in this review are of low severity or no harm. This suggests that there are systems in place that ultimately mitigate the harm of errors at

the bedside. Recent literature has highlighted the importance of technological interventions (barcoding medication, “Smart” pumps, electronic prescribing and automated drug dispensing) and unit-based pharmacists to improve paediatric medication safety.[187] However, there is little or no understanding about how effective these interventions are in the UK context.

There was little or no theoretical exploration of how these DRPs emerged. This is common through the literature. Almost 20 years ago, Miller identified that of the 26 strategies to mitigate medication error extracted from 31 empirical studies of paediatric ADEs, none were based on published evidence for effectiveness, or theoretically sound.[188] In a systematic review of interventions to reduce ADEs in paediatric in-patients,[189] five interventions were included:

- Inclusion of a pharmacist in the clinical team
- CPOE
- Barcode medication administration systems
- Structured prescribing proformas
- “Check and Control” checklists with feedback

GRADE assessment of the included studies identified that the evidence for these interventions was of low quality, and none of the included studies demonstrated reductions in patient harm with the interventions studied.

2.5 Conclusions

This systematic review has identified that the majority of studies into medicines and safety in paediatrics still rely on the counting and characterisation of events, using the assessment of independent operators to evaluate potential for preventability and harm. These studies have then proposed potential mechanisms for causation and harm, which have then been translated into interventions (the “find-and-fix” approach). There have been few studies that have used theoretical perspectives to explore the contributory factors of these DRPs in practice. Linear assumptions based on observed “cause and effect” are speculative. Furthermore, despite the potential for harm identified in many of the studies in this review, that has not translated into widespread patient morbidity and mortality related to inappropriate medication use. There are thus potentially hidden resilience mechanisms within these systems that protect patients and staff from ADEs, or mitigate their actual harm. These would not be visible using the approaches identified in this review, nor are there many studies using a resilience-based approach to provide insights on paediatric medication safety.

Medication systems in hospital have been described as complex socio-technical systems where humans are expected to interact with increasingly complex systems in order to deliver care.[190,191] With the drive to improve safety in the NHS by introducing more technology, there is a need to understand these systems and how people and technology work together to ensure patient safety. In considering future research priorities, there is a

need for a systems-based understanding of how medication systems function in NHS hospitals in order to theoretically inform the design of interventions to improve patient safety.

Medicines safety interventions are often “complex” interventions. The Medical Research Council (MRC) describes complex interventions as “… interventions that contain several interacting components.”[192] Because of the complexity of these interacting components, there is a need to consider carefully how interventions are developed. The MRC framework recommends four stages of intervention development that include exploring and building understanding of the context and theoretical nature of the problem (Figure 2.5).[193]

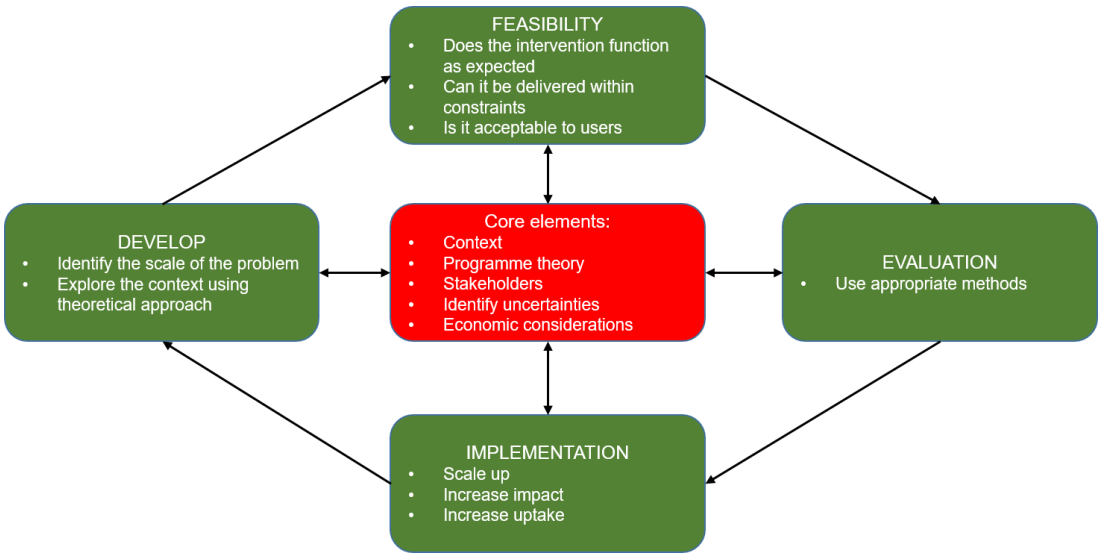

Figure 2.5 – MRC Framework for Developing complex interventions, adapted from Skivington et al.[193]

A package of work is proposed to undertake the core elements and development aspects of this framework in order to provide contextual information to support future intervention development and to understand organisational resilience and improve medicines safety for children and young people in hospital.

3 Aims & Objectives.

3.1 Thesis Aims

There is a paucity of robust qualitative studies exploring the nature of medicines safety work using a systems approach. Furthermore, it is apparent that few interventions to improve medicines safety have been developed with reference to any theoretical framework. Therefore a programme of study was proposed to explore the organisation of medication safety work in paediatric in-patient units, and to generate theoretical insights into the context of paediatric inpatient care which can inform intervention development. Of key importance was the perspective of service users therefore the voice of parents and carers were included in the research to provide their perceptions and experiences. To conclude the study, co-production methods involving healthcare professionals, service users and researchers were used to propose potential interventions for further development and future study.

3.2 Study Objectives

- Developing an understanding of “Work as Imagined” of the medication safety systems used in paediatric in-patient units in several and separate NHS organisations and the constraints interactions within it using the Work Domain Analysis method [194,195] including documentary analysis, observation and participant validation.

- Exploring the “Work as Done” of medication safety in practice using sustained ethnographic observation and in-depth interviews with medical, nursing and pharmacy staff and parents and carers.
- Using experience-based co-design (EBCD) principles to explore the findings from the WDA and ethnographic studies above and consider targets and priorities for intervention development and testing with healthcare workers and parents.

4 A Human Factors Methodology for Exploring Medication Safety in Paediatric Care

4.1 Chapter introduction

There is an emerging paradigm shift in healthcare safety research away from the characterisation of events based on their occurrence and retrospectively identified causal and contributory factors towards more qualitative methods to provide contextual information around how adverse events may occur, and how they are managed in practice. Further, these approaches can also provide important data on the "messy reality" of clinical work which can further inform how good outcomes emerge in the face of seemingly insurmountable difficulties. There is a drive to use Human Factors/Ergonomics (HF/E) approaches in the NHS to support this move away from reactive, linear investigations that produce limited conclusions to holistic, systems-focussed investigations that acknowledge the complexity of healthcare work.[196,197]

This chapter will explore what HF/E is in comparison with traditional paradigms of safety research, and will explore important concepts in healthcare safety including emergence and resilience. It will also consider the theoretical considerations around healthcare safety, moving from the linear cause-and-effect theories of accident causation posited by Reason and Vincent [198,199] to normative theories including the normal accident theory, complexity theory and socio-technical theory.[26,200,201] I will succinctly explore the epistemological and methodological issues arising

within HF/E approaches and then consider the potential methods available using this perspective. It will argue that using ethnographic methods will provide the data required to address the research question.

4.2 A Systems View of Medicines Safety

HF/E is a research discipline that draws from various research traditions including positivist and realist to address a broad range of issues in the workplace. It has been described as a bridging discipline between psychology, physical ergonomics and anthropometrics, and organisational science.[202,203] HF/E is defined by the International Ergonomics Association (IEA) as "…the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimize well-being and overall performance." [204]

There are numerous ways of representing this human-work system. Sharples et al. proposed an onion model (2015) which represents tasks, goals, personal and wider environmental spaces and the organisational context as concentric circles (Figure 4.1).[205] The IEA uses a simple Venn diagram to illustrate how issues relating to people, environment, management and tasks converge into a HF/E perspective on work (Figure 4.2). However, in healthcare terms, these single-system representations may be simplistic or misleading.

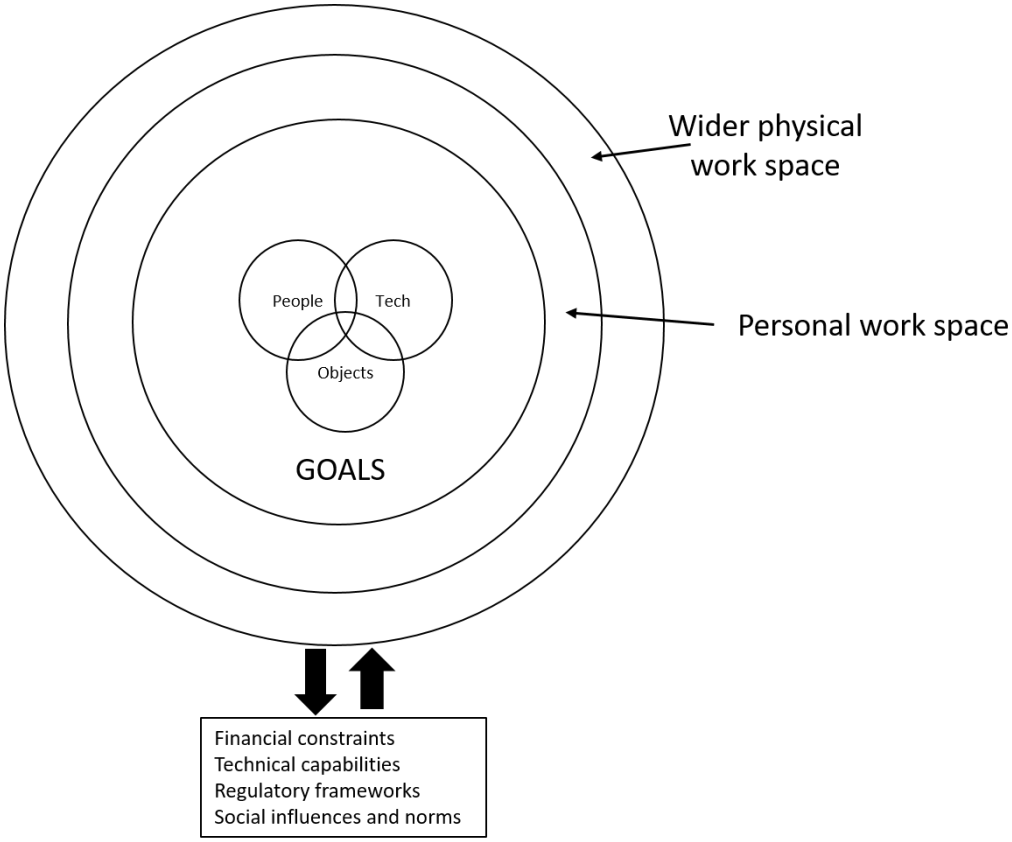

Figure 4.1 – Model of HF/E principles and components (adapted from Wilson and Sharples [205]*)*

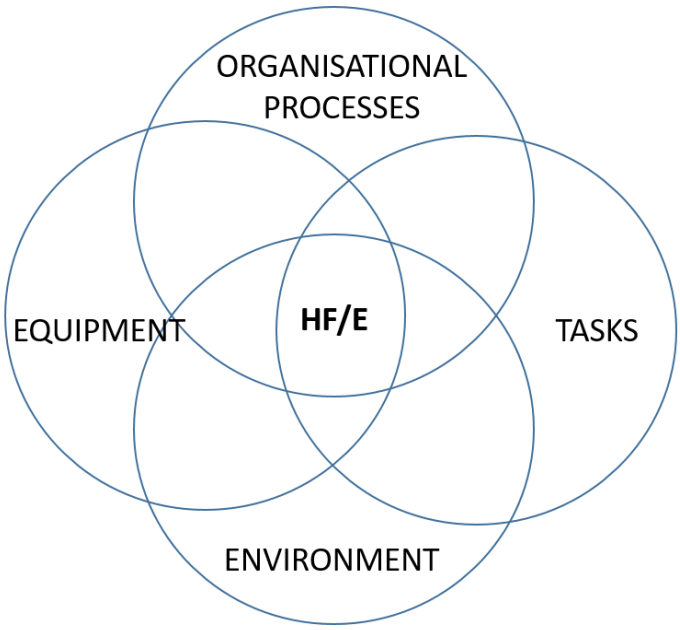

Figure 4.2 – IEA model of components of HF/E

HF/E is a discipline born out of sociotechnical theory (STT).[206,207] STT considers the interactions between humans and the technology and environment around them.[208] STT was first developed through the study of coal miners and their reactions to new mining equipment and techniques. Trist and Bamforth subsequently identified that if new technology is introduced into a complex social work system, there is an inevitable reorganisation of human work, which brings unexpected productivity impacts.[209] Within STT lie further theoretical constructs. Theories of agency (the freedom of action of individuals within a social system and the incentives that support action) and structuration (the interaction of individuals with the structures and technologies of their immediate environment.) have been studied within complex systems in an effort to explain how these systems function.[210–212]

Carayon et al. has attempted to relate the structures and interactions of complex sociotechnical systems to Donabedian's "Structure – Process – Outcome" (SPO) model of healthcare quality evaluation.[213] This model considers the relationships between structure of services and systems, the processes which flow from them and their impact on outcomes. The assertion is that in order to improve healthcare outcomes, one should be able to measure all components, however Donabedian concluded his seminal paper with a question. "More often, one needs to ask "What goes on here?" rather than "What is wrong, and how can it be made better."" (p.721)

In this sentiment, Carayon proposed the Systems Engineering for Improving Patient Safety (SEIPS) model of healthcare which places the complex systems features of HF/E through an STT lens within Donebedian's SPO framework (Figure 4.3).[214]

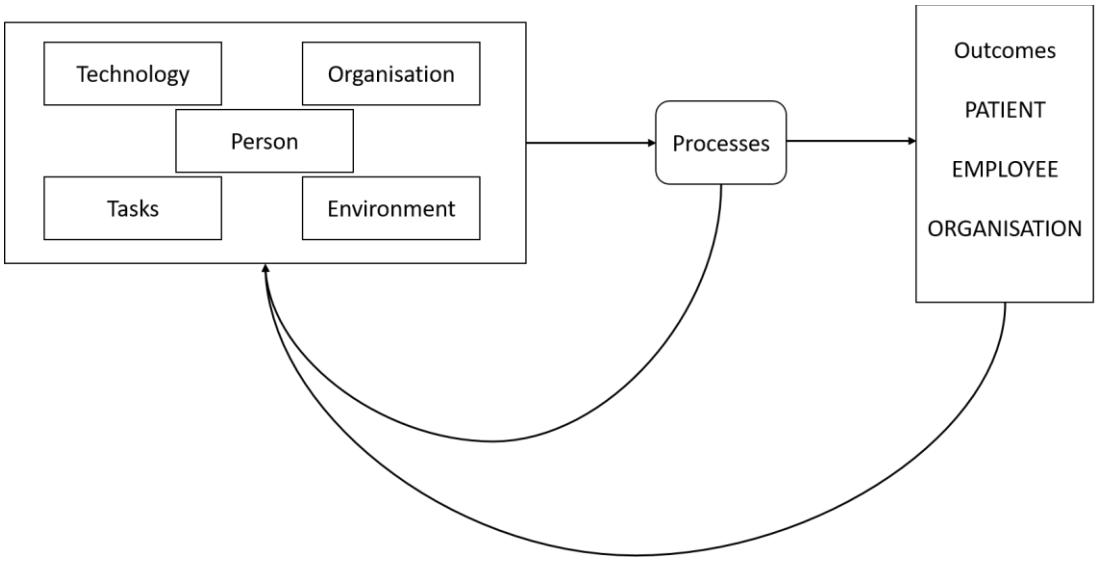

Figure 4.3 – Representation of the SEIPS model of patient safety, adapted from Carayon et al. (2006)

HF/E (and correspondingly STT) has been advanced as the "new" paradigm for studying patient safety in healthcare with comparisons drawn to the improvements in safety found in high risk industries including nuclear power, rail and maritime transportation, and aviation.[215,216] Yet HF/E in healthcare isn't that new, with Chapanis and Safren using the Critical Incident Technique (a structured, contextualised interview method to explore the background to critical events) to study the incidence and nature of medication errors in a US tertiary hospital over sixty years ago.[217] As well as observing and classifying medication errors by type, they also sought contextual information as to the antecedents of those errors and identified just five types of error. These were calculation error, placing prescriptions in

the wrong place, misinterpreting medication information, transcribing medication instructions from the notes incorrectly and failure to follow checking procedures.

While this study was ground breaking at the time, it established the “find and fix” approach to medication events as the default method for studying medicines safety.[218] Briefly, this approach involves the investigation of an adverse event (or events) to identify their antecedents and contributory factors. It has created a culture of doing the same thing but with more intensity – policies and procedures, increased vigilance. However, it is apparent that this is not the right approach because it does not account for the limitations of human capabilities.

HF/E studies seek to improve human performance and well-being through collaborative design approaches. They view systems as a whole, focussing on how they influence human activity, rather than considering human action in isolation. A major strength of HF/E studies is that they draw on multiple data sources to identify the different perspectives on the problem being studied, in order to provide a robust three-dimensional understanding of the problem. They are multi-disciplinary in nature to accommodate those views, with stakeholders invited to provide practical, real-world interpretation of the findings. Consequently, they often incorporate strong co-production elements which lead to stronger, credible conclusions and interventions.[219,220]

4.3 Theoretical concepts of human performance

Rasmussen built a taxonomy of human performance based on three levels – skills, rules and knowledge.[221] He argued that humans are inherently goal-orientated who seek information and feedback relating to their goals. He described skills-based activities as being largely automatic and instinctive with little or no thought required. Rules-based behaviours involve the recollection and reference to a stored rule or process to guide action. These rules can be shared around the operators in the system, or based on previous experience and understanding. Finally, knowledge-based behaviours involve the acquisition of a new skill or knowledge. These situations are slow to complete, and require the active consideration of differing plans and options, and potential outcomes before a course of action is decided on and delivered.[222]

Reason adapted Rasmussen's SRK model into the General Error Modelling System (GEMS), (Reason, 1990) defining errors as "…the failure of a planned action to achieve the desired goal" and generated three distinctive characteristics of errors that have been used empirically to describe and categorise errors:

1) The nature of the failure. Reason posits that errors can either be execution failures or planning failures. Errors of execution are termed "slips and lapses" The planned action is good, but the activity does not go as intended. Slips are related to failures of attention and lapses to memory failures. Planning failures are described as "mistakes." They

can either be knowledge based occurring in new situations where a problem has to be worked out, or rules-based where the person does not have the requisite experience or guidance available to undertake the action.

2) Reason added a third behaviour that is rooted in intention. These "violations" are where an operator intentionally deviates from safe procedures. These can be routine (cutting corners), optimising (action taken for personal gain) or necessary (the established safe procedures appear inadequate for the situation.)[223]

3) Finally, Reason made the distinction between active failures – where the consequences of deviation are almost immediately apparent and are invariably enacted by participants at the "sharp" end of an organisation (the pilot of an aircraft, the engineer in a nuclear power plant, the prescriber in a children's ward) – and latent failures which take some time to emerge and become apparent. These are often related to organisational features including management decisions and culture.

This model has historically, been the dominant paradigm in medication safety research. Vincent's "London Protocol" was designed around active and latent failures, and identifying institutional, organisational, workplace, team, individual and task-related factors of adverse events.[199] This protocol has

been used in many empirical studies of ADEs using qualitative methods to explore critical incidents in clinical practice.[74,224]

However, these approaches can create a human-centric understanding of the causes of adverse events, which can lead to human-centric interventions without considering the impact or contribution of the surrounding context. Hollnagel posited that “human error” is both atheoretical and alogical because the term can be used to describe the cause of an accident, and to describe events themselves.[225] In this paper, he estimated that “human error” contributed to almost 80% of workplace adverse events, but this was primarily related to the final interaction with the system immediately before an observed failure being a human. I have already presented the definition of human error as an observable and measurable event, however the concept of “error” carries considerable theoretical challenges.[112]

Error is characterised as misplaced or unintentional acts that result in unexpected outcomes. Woods described human error as often being the final unsafe act within what is always a complex chain of failures.[226] Consequently errors are a common, almost “normal” pathology within a complex system such as healthcare.[227] However, the prevailing approach in healthcare has been to view errors as exceptional and a problem to be managed. In an effort to cope with these relationships, organisations implement “barriers” – layers of defences within the system to guard against erroneous events and acts. Reason also considers defences within a

system as part of his “Swiss Cheese Model.” Within the system, barriers are represented as slices of cheese. These barriers are imperfect (represented as holes in the slices of cheese) and occasionally these imperfections will line up simultaneously and an adverse event will occur.[228] Yet when, how and why these imperfections will coincide is impossible to predict.[30,229]

Dekker describes there being two views – “old” and “new” - on human error.[230] The “old” view sees human error as a cause of adverse events, that humans are unreliable and threaten the safety of systems, and that the best way to protect systems from human unreliability is through direct intervention on the person through training, procedures, discipline or through removing the human element. The persistence of empirical study that seeks to capture and categorise “errors” continues to take a mechanistic or individualistic perspective on the phenomenon which may lie in a naïve realism that presents simplistic explanations for situations that are complex.[231,232]

The “old” view of error management has focussed on the promotion of safety through elimination of risk. These risks being identified through reactive exploration of critical events to identify causative and contributory factors, and the subsequent development of some kind of barrier to control for that risk in the future. The Chartered Institute of Ergonomics and Human Factors (CIEHF) describe barriers in terms of their utility in risk control (as in they mitigate recognised risks) and resilience (as in they support recovery in the

event of an adverse event.)[233] These barriers can be passive – something that acts as a barrier to an outcome purely by its existence; for example, a railing or wall in front of a precipitous drop. Or they can be active, requiring some kind of interaction with a human in the system. These humans need some form of signal mechanism and the requisite knowledge to make decisions and act on the signals.[233] In healthcare, particularly around prescribing errors, there are multiple barriers that have been studied and the majority (46 interventions of 51 identified) rely on administrative controls based on education and training of individuals.[234] However there are limits to these human-centric interventions, and there is a need to learn from more than just when things go wrong. Hollnagel posits that we need a paradigm where we learn from when things go *right* as well.[235]

4.4 Moving towards a new perspective on paediatric medication safety

Much paediatric medicines safety research is based in a Safety I paradigm, with a focus on counting and categorisation of ADEs and subsequent supposition as to the contributory and causative factors associated with them.[66,95,101,135,188,236] Some argue that safety research in medicines has been rooted in a positivist paradigm (that is, there is a singular truth and can be described, defined and measured) to meet the demands of evidence-based medicine for clear data regarding the prevalence and nature of phenomena in order to define “one best way” of managing a problem.[237,238]

However, this “one best way” may not exist. Many of the interventional studies cited in Chapters 1 and 2 use a descriptive approach to understanding how ADEs occur – that is they view the system as it is supposed to work, and posit interventions based on observed deviations from this model. However, this does not account for adaptation or unexpected events, therefore with reference to Rasmussen’s cognitive systems engineering framework, Vicente proposed a formative approach to cognitive work analysis.[239] Formative approaches provide insight into how the system influences behaviour. In essence, descriptive approaches give the user directions to a given goal, while formative approaches provide a map and a choice of routes and allows the user some discretion in how they reach it.

The drive towards a single “best way” of working, and a descriptive understanding of medication systems goes some way to explain the increasing standardisation of processes and systems, and the reliance on behavioural interventions such as training and guidelines to support “safe practice.” However, the drive to standardisation has been challenged because it does not consider important social contexts that surround much healthcare work.[240] Further, it is suggested that “contingency” – the need for humans to recontextualise data within large complex systems – becomes more important as systems become larger to the point that standardisation and the ability for systems to respond to changing contexts can never be

reconciled, and reinforces the need for formative approaches to medicines safety.[241]

The deficiencies in these operational interventions have been explored in Koeck's review of 45 studies mitigating prescribing errors. They identified and categorised 71 interventions using the National Institute of Occupational Safety and Health (NIOSH) hierarchy of controls.[242] 41 of these interventions were categorised as administrative controls including education, guidelines and expert consultations. Only 63% of these studies reported significant reductions in MPEs compared to 90% of hard controls. Interventions based on "expert consultation" were more likely to produce reductions (75% compared with 63% for guidelines.) This review therefore suggests that there are components of control within healthcare that rely on the expertise and knowledge of wider team members, which cannot be standardised.

These "expert consultations" are best exemplified using two Australian ethnographic studies – one of pharmacist interactions with clinical teams, and the other of medical/nursing interactions around medication.[89,243] Pharmacists in this field were reported as providing critical expertise in the management of complex medication decision making while there were important gaps identified in communication that could lead to medication-related problems and errors. The importance of these studies is that they demonstrate a depth of exploration and understanding as to how

communication issues emerge in complex systems that could not be studied without qualitative exploration.

Qualitative research can be viewed through a post-positivist or constructivist lens. Post-positivism acknowledges the boundaries of positivism and acknowledges that there may a single reality, but there are different perspectives of viewing that reality.[244] An alternative view, held by followers of the constructivist paradigm is that there is no objective reality, and truth is constructed through the words, actions and meaning of the people within the frame.[245] Somewhere in between these two opposing views lies “realism” – a recognition that while there is a single reality or truth, that may be seen differently by different people, it is also affected by events around the phenomenon thus reality may change, and there is a need to understand how those events effect that change.[238]

There is a movement towards realist research in medicines safety, acknowledging the importance of context within the events detected. There are several studies of incident reporting data and qualitative analyses where contributory factors and causal mechanisms can be potentially identified,[109,246] but this could be argued to be naïve realism – that these data represent an objective truth.[247] Bhaskar defines a flexible form of realism – that of critical realism.[248] Knowledge is created by people who are inherently fallible. Presentations of truth therefore are subjective, and can be changed. Facts and our perceptions of them are rooted in our beliefs

and social structures. Further, and of relevance to medicines safety research, is that complex healthcare systems are considered “open” – they are vulnerable to outside influences and do not function in isolation.[249] Pawson and Tilley argue that in order to evaluate whether or not interventions work it is necessary to understand how they work in the context in which they are intended to function,[238] and these are questions that can only be resolved with direct observation and questioning of work.

4.5 Qualitative methods for exploring medicines safety

This chapter has established that there is a need for a qualitative approach to studying medicines safety for children in hospital. Healthcare services are complex sociotechnical systems that are vulnerable to outside influences, consequently they are not static. Positivist studies do not provide the depth of understanding as to the context of the problem being studied, nor the theoretically valid explanatory detail required for future interventional development. While there are many qualitative methodological approaches available to researchers,[250] within a critical realist framework, the options for study are critical realist evaluation, action research and ethnography.

Realist evaluation considers the evaluation of complex social interventions *in situ*, arguing that in order to truly evaluate complex interventions there is a need to understand what happens, to whom, when and under what circumstances.[238] It is a holistic form of evaluation permitting understanding of the context, mechanism and outcome (CMO) and how

different components of a programme interact.[251] However, for the purposes of medicines safety in a context where harm is rare, this may not be a suitable approach to explore and understand the functioning of a complex system.

Action research is where the researcher and client collaborate in the diagnosis of a problem and in the development of a solution to that problem.[252] Action research has been described as synonymous with participant research, whereby research participants contribute to the identification of the research question and evaluation of the response. Within HF/E there is a strong tradition of participation with all stakeholders being part of the process of exploration and evaluation.[253,254] However, action research is limited in its nature to *in situ* study of a specific problem and as such may not develop generalizable insights required in order to address the stated research question.[255]

Vincent and Amalberti suggest that the next step for research into patient safety is ethnographic because there is a need to observe, identify and describe safety relevant activity and interventions that are already in place.[256] There is a rich history of ethnographic studies in the space of organisational management and healthcare going back to the 1960s.[257,258] However, many of the healthcare ethnographies up to the turn of the century were focussed on medical social interactions through a social constructionist lens.[259] This led to a focus on medical work through

professional conduct, which potentially overlooked the cognitive and environmental aspects of work. However, there has been a shift in ethnographic studies specifically of healthcare safety in the last twenty years, as the advantages of ethnography as a flexible and robust methodology have been realised.[260] Wirtz, Taxis and Barber used an ethnographic approach to study the aetiology of IV medication errors in German and British hospitals, using direct observation to identify and characterize medication errors.[261] In a similar study, Carayon et al. used observation techniques to study nursing adherence to IV medication technology.[262] However, both these studies were designed to quantitatively evaluate a technical process, and compare against established policy and procedure – in effect, a comparison of WAD with WAI. Both these studies follow a recommendation for ethnography (and other social science approaches) to be incorporated into HF/E.[207]

Ethnography is described as both method and methodology – it incorporates both epistemological and ontological perspectives and presents a flexible range of methods that can be used to explore the problem.[263] This has led to a lack of definitional clarity.[264] Hammersley compiled multiple definitions, and broadly identified the following common traits of the method:[265]

- Long term data collection
- Occurs in natural settings
- Relies on observation and engagement in the field

- Takes advantage of multiple data sources
- Takes a naturalistic view of the data, and details of activity and social interactions
- Views the situation in the round, taking account of the perceptions and interpretations of the actors within the field.

There have been several large-scale ethnographic studies of medication safety in the last ten to fifteen years. Jennings et al. studied the turbulence of nursing work and one aspect of the their study was to explore medication-related work as it comprised a substantial portion of nursing time.[266] Through this study, they identified that much of the technology deployed to support nursing work contributed to the turbulence they experienced by creating process bottlenecks, being out of service, or requiring the development of work-arounds to navigate day to day operation. Renewed interest in this study emerged in the aftermath of the Radonda Vaught case where a nurse used an automated dispensing cabinet to select midazolam (a short acting sedative) and accidentally picked vecuronium (a long acting muscle relaxant) out of the open tray. This was administered to her patient who subsequently died, and the nurse was subsequently found guilty of manslaughter.[267] Yet patient deaths related to the mix-up of these two drugs is not new with multiple examples in the literature.[268] Thus there are potentially complex systems-related reasons why these problems emerge and defeat the barriers put in place.

There has been an explosion of methodological innovations in the field of ethnography and the study of organisations in the last fifteen years.[269] Iedema et al. developed video-reflexive ethnography in 2009 as a naturalistic method of exploring everyday work and encouraging participants to reflect on their work.[270] It has been advocated as an approach to study improvement in healthcare settings, but carries pragmatic limitations around the ethical implications for collecting in-situ video footage and facilitation of reflexive feedback in the field.[271,272]

In an increasingly constrained healthcare research environment, there has been considerable interest in the use of rapid qualitative methods to make best use of resources and provide findings that can be actioned swiftly. Rapid ethnography (data collection of less than 90 days in duration) is potentially more robust to the progressive changes over time associated with complex open systems.[273] Rapid ethnography covers many data collection methods including video recording, fieldwork, “grand tour” walkthroughs and field surveys, however it is criticised for lacking the requisite time and space to permit the researchers suitable reflexivity and thus there is a strong risk of observation bias because of the short, intensive data collection and reporting periods.[274]

Many of these “efficient” ethnographic methods could be wrapped up in Higginbottom’s “Focussed Ethnography” definition.[275] Whereas historical

ethnographies have been grand scale, lasted years and targeted towards social exploration, focussed ethnographies have been described as:[276]

- Using a single researcher
- Focus on a discrete organisation and/or phenomenon
- Involve limited, well defined participants
- Clearly defined problem and context for study
- Participants are experts in their field and experience
- Observation is episodic.

Knoblauch and Muecke describe focussed ethnography as being the closest to Glaser and Strauss's original proposition based on deductive reasoning and enabling theoretical data analysis and interpretation.[277,278]

There are several pertinent focused ethnographies relating to medicines safety that we can learn from. Hawkins et al. studied the impacts of these automated dispensing cabinets alongside other technological interventions on nursing workflow and complexity.[279] Using direct observation and semi-structured interviews they identified that there were three overarching safety interventions that underpinned medicines safety – the work of pharmacists, the decentralised medicines dispensing systems, and barcode scanning to ensure the right patient gets the right drug at the right time. However, they also identified that nursing staff were the only staff group with responsibility for medication from the point of ordering to the point of administration, such that they proposed a "safety paradox" – stated attitudes to medication safety were undermined by organisational, physical, personal

and team-related factors that implied that cognitive limitations and ambiguity in the system were potential contributors to medication errors.

In a subsequent re-analysis of the same data, the authors posited that nursing work was cyclical and chaotic – the same tasks repeated frequently but often unpredictably.[280] Further they suggest that safety work is inextricably linked to regular work, and in such chaotic contexts nursing staff constantly “lost control” of their work and subsequently found themselves chasing unrealistic standards of care (including “zero harm.”) The study concluded that many safety interventions were impossible for nurses to adhere to and deliver in a dynamic and complex system, and that expectations on nurses were unrealistic in the face of the rigour of daily working life.

This series of studies derived from the same large-scale single centre medication safety and nursing workload study is important because it is among the only studies of its type that specifically studies medicines safety as a form of work. It’s single centre, nursing-focus limits generalisability into other spaces or contexts, but offers some insights into how medicines safety sits within clinical work. There are no ethnographic studies of medicines safety involving children. Thus, focused ethnography would appear to sit well within a HF/E study to explore medicines safety for hospitalised children and young people.

4.6 Study Design

The design and reporting of this study was made with reference to Standards for Reporting of Qualitative Research (SRQR), a 21 item checklist for qualitative studies that is broad, and can be applied to multi-method qualitative studies, and is flexible for methodological orientation (Appendix 10).[281] The study was designed as a multi-centre qualitative study set in acute paediatric wards in English hospitals to support generalisation. Mixed qualitative methods including documentary analysis, non-participant observation and in-depth semi structured interviews were selected to provide breadth and depth of data to support subsequent deep analytical abstraction. Analysis was aligned with a critical realist posture using a sociotechnical theoretical approach, which informed the selection of methods and how the results were presented. Multiple data sources also supported methodological triangulation which will support credibility and validity of the findings, and will offer different perspectives on the phenomena identified.[282]

The programme of research was large, therefore was conducted in two concurrent phases. Multiple data sources were employed and the data collection methods are summarised in Table 4.1.

Method	Phase	Purpose	Reported
Documentary Analysis	1	To identify the components of the WDA	Chapter 5.
Ethnographic Observation	1 and 2	To provide insight into the means-ends links of the WDA, and to explore in more depth the WAD of medicines safety, using the results of the WDA to target observations at specific activities.	Chapter 5 and Chapter 7, 8 and 9.
Semi-structured interviews	2	To provide depth of insight and understanding to the observed WAD and explore worker perceptions of medicines safety work.	Chapter 7, 8 and 9.

Table 4.1 - Data collection methods, the relationship with phases of study, and chapters in which their data are reported.

Phase 1 was the exploration of WAI using an established HF/E methodology (Work Domain Analysis) to create a formative understanding of the work system in its static state, and was conducted in the first six months of the study using early observations and documents. Phase 2 extended the observation of work in the clinical area for a further 18 months and included semi-structured interviews with all stakeholders in the medication safety system – medical, nursing and pharmacy staff and parents and carers of children.

4.6.1 Study Setting

Hospital paediatrics is a speciality made up of sub-specialities, with highly centralised service provision in England. Specialist children's hospitals are found in large cities around the United Kingdom and provide tertiary or quaternary level care across large geographical areas. These services are often commissioned directly according to centralised National Health Service

standards with considerable colocation of staff and expertise, and collaborative links with other institutions. Further, tertiary services will provide advice and guidance for tertiary patients who may be cared for in general (secondary) paediatric services. These centres are also expected to provide general paediatric care (or secondary care) to their local populations. Smaller towns will usually have a secondary care hospital, without specialised tertiary services on site, and these will also provide secondary paediatric care. These services are often commissioned through local health providers to a more decentralised model. Within this model, providers are less integrated with higher level care providers and therefore their systems and approaches to medicines safety may be different.[283]

Three secondary paediatric services were selected to capture as broad a picture of in-patient medication systems as possible, and to identify the constraints inherent in a complex interconnected system like the NHS. Sites were all in the North of England. Two sites were recruited because of their status as tertiary children's hospitals - one a standalone organisation, and the other a tertiary children's service as part of a larger NHS organisation. The differentiation between stand-alone children's hospitals and those integrated into general hospitals was considered important as the cultural and organisational factors affecting practice may have been different. The third and final site selected was a secondary acute care provider in a small suburban town in the North West of England. This site was chosen because of its referral patterns into one of the tertiary hospitals recruited into the study, and into another children's hospital that was not directly related to the

study. The details of each site including location and bed numbers are presented in Table 4.2.

	Location	**Hospital**	**Unit size**
GH1	A small town in the north west of England; pop 55000.	District General (245 beds) Neonatal unit closed prior to initiation.	12 beds, and a six-bed assessment area.
CH1	A post-industrial city on the north-west coast of England; pop. 500,000	Standalone tertiary children's (270 beds). Neonatal care provided offsite.	28 beds
CH2	Medium sized city in northern England; pop. 800,000	The children's hospital (286 beds) on a city centre hospital site (1100 beds); part of a multi-hospital trust (2500 beds)	12 beds. Other secondary care admissions were distributed elsewhere in specialist areas based on bed availability

Table 4.2 – Characteristics, location and size of study sites

The North of England was chosen for two reasons. The first was to exploit a network of closely collaborating research institutions within separate medical education areas (Merseyside and Yorkshire and the Humber.) As demonstrated in the systematic review, the majority of UK research in this field had been undertaken in London or the Midlands. Therefore there was an opportunity to include other areas of England with populations and needs that may be more representative of those localised studies. Furthermore, by having a separation between the institutions there was little risk of cross-contamination between sites and participants. Secondly, there was a convenience element. The lead researcher lived in Greater Manchester with no access to a car and the original funding application for this study was

crafted with reliance on public transport in mind, therefore sites were selected for proximity to mainline railway stations.

4.6.2 The Observer

I am a man employed by an NHS trust separate from the participating sites. During the study I was undertaking doctoral study at the University of Manchester while also working 2 days per week as a clinical pharmacist. I have been a qualified pharmacist for almost 20 years, working in the field of paediatrics, specifically paediatric critical care.

4.6.3 Access to Field Sites

Access and entry to ethnographic research sites is one of the most important aspects of good ethnographic research, and also one of the most challenging.[284] Drawing on my own personal networks and professional connections,[285] access to sites was negotiated through pharmacy and nursing hierarchies initially using informal approaches and then more formal approaches as part of protocol development, study design and health research governance processes. After agreement to participate was secured, suitable sites for observation were identified, and entrée to the wards themselves negotiated further with nursing and medical managers. Formal meetings were held with ward managers and lead clinicians as part of the site orientation visit, with a more in-depth informal interview about service design and training models between the researcher and the lead clinician. Prior to any data collection it was considered critical that staff be

appraised of the study and its objectives, but within constraints set by national regulations as a result of the SARS-nCoV-2 pandemic this was only possible using remote means. Therefore a “podcast” of the nature and conduct of the study was prepared and distributed to staff. Traditional information sheets were made available for staff and parents during observation periods. Access to sites was reviewed and renegotiated continuously through sharing of interim data analysis and findings with ward managers and medical teams, often as part of programmed educational programmes. These interim presentations also created an opportunity for recruitment to interviews or identification of key processes for later observation.

To support onward access and promote good field relations, I chose to wear clinical attire (medical scrub tops, comfortable trousers and shoes) and an identification badge was worn at all times. This presented my photograph and name, and “Researcher” as a job title. I maintained a passive posture, not participating in any decisions or work processes. To support this, I held back my identity as a healthcare professional and experience as a pharmacist. However, in the interest transparency to participants in the field, if I was asked what my job was I would tell them.

This created some interesting dynamics for me with occasional requests for advice and information, which were declined politely and assertively. However, my role as a pharmacist may also have stimulated some honesty

among the wider staff group out of a sense of camaraderie and safety because I was not part of the internal governance hierarchy of the organisation. This supported both the capture of unsolicited oral accounts, and provided a place of safety for short-duration ethnographic interviews.

4.6.4 Document Identification

Documents were identified collaboratively with gatekeepers at each site. Prior to initiation of observations on each site, the site Principal Investigator (PI) was approached with a list of universal documents that all hospitals would have and maintain. Also, in recognition of the diversity and variation in documentary support available in each hospital, it was impossible to predict which documents would be used in which participating site so a priori inclusion criteria were provided to support site PIs to provide other documents that they felt would be of use. These are presented in Table 4.3.

Universal Documents	Inclusion Criteria for others
Medicines policy	• Pertains to medicines prescribing, dispensing, preparation, administration, monitoring
Controlled Drugs Policy	• Routinely referred to
Patient/Parent Self Medication Policy	• Operationally important
Medication error policy	
Clinical Pharmacy standard operating procedures (SOP)	
Nursing medicines management SOP	
Medicine administration monographs (examples of…)	
Prescribing guidelines and protocols (examples of…)	
In-patient medication prescribing forms	
Discharge prescription forms	
Outpatient prescription forms	

Table 4.3 – Document identification criteria

Prior to inclusion in analysis, documents were assessed for validity using the criteria described by Prior:[286]

- Evidence of organisational approval
- Evidence of document control
- A publishing date and an expiry date which had not lapsed.

However, it was also necessary to include documents that did not meet these criteria. Most documents were within their expiry dates, but those that were not were core policies, or were procedures that were referred to frequently, therefore they had to be included. Other documents were also added to library over the first observation sessions where they were identified as being commonly used and referred to. The inclusion of informal

documents and unratified documents was also an important aspect of understanding the processes and functions within the systems.

4.6.5 Ethnographic Observations

Observation sessions were designed to maximise observation opportunity, to promote a healthy work-life balance for myself, and to minimise disruption and burden for clinical teams. Observations were organised into “weeks” which consisted of five observation sessions, no more than four hours in length per session. It was agreed with each site that there would be a maximum of six observation periods, thus a maximum duration of observation of 100 hours per site. There was an additional observation week that was not an active data collection period, but was used as an orientation visit to allow me to get used to the study environment, and to permit some engagement and embedding with the wider clinical teams. There was a rest period between observation weeks of eight weeks in each site to minimise disruption on sites, and to provide time for reflexivity and writing up of field notes.

I assumed the total observer posture to minimise the risks from the “Hawthorne effect”,[287] and to maintain some distance between participants and the observer. Day to day activity was observed, with a focus on all processes that involved medication. In the orientation weeks this became clear as the medical ward round, pharmacy rounds involving pharmacy professionals (pharmacists or pharmacy technicians), nursing work and

medication rounds, and handovers. Open observations were undertaken for the first two weeks, with no targeting or specific activity planned. Field notes were collected in short-hand as typed notes using a handheld tablet computer and were recorded alongside date, time and location. Information relating to the ward acuity (both objective – patient numbers, nursing ratios, other staffing situations – and subjective – how did the ward feel, how did people look and talk) were captured. These draft field notes were then typed up into a formal narrative within a few days of observation. These detailed narrative notes then formed the research data. As data was analysed, targets for observation emerged and were planned into subsequent observation periods. For example, in one participating site it became apparent that pharmacy technicians undertook most of the medication reconciliation away from the clinical area, so it was decided to shadow one of those technicians for an hour to observe them undertake their work.

During observations I would take up an unobtrusive position at a nurses' station or at the reception desk and would passively observe activity. In order to obtain different views or observe specific activity I would move around the ward. I would listen to conversations and on occasion get involved with participants in conversation about their work, and perceptions and their beliefs, using Spradley's techniques for ethnographic interviewing.[288] Occasionally, I would also ask for clarification or additional information about something I had observed. These conversations were documented verbatim as part of the field notes. I participated in ward rounds and medication processes as they occurred. The use of specific wards

allowed me to develop and maintain relationships with the staff participants. The use of multiple sites had the potential to offer comparative insights into the observations but this was not part of the study. However, the dataset was created in order to facilitate a comparative study as a post-hoc analysis.

4.6.6 Semi-structured Interviews

Becker and Geer advocate for a holistic approach to ethnographic data collection that includes both observation and conversation through interviews.[289] Interviews have been described as a “directed conversation” and the method offers the researcher some element of control over the direction of data collection whereas in observation the researcher is largely controlled by the context they observe.[290,291] They also facilitate the development of trust and rapport between interviewer and participant, and it has been said that a richer understanding of perspective and experience can be derived from open interviews.[292]

A purposeful theoretical sample of participants for interviews were identified (Table 4.4). A broad range of experience and perspective was sought, therefore medical, nursing and pharmacy staff were sought from each site. Furthermore, the voice of parents and carers was identified as of importance because their perspective on and contribution to patient safety is an emergent aspect in the literature.[293,294] Therefore it was decided to recruit parents from each site who had had recent experience of ADEs. A maximum of thirty participants distributed in were planned.

	CH1	CH2	GH1
Medical staff (at least one consultant)	2	2	2
Nursing staff	2	2	2
Pharmacy staff	1	1	1
Parents/Carers	2	2	1

Table 4.4 – Purposive sample of interview participants

The following inclusion criteria were applied. For staff, they had to be employed by the organisation in the area of study and been in post for at least six months. This would ensure recent and relevant experience of the field. For parents and carers, their child had to have been an inpatient in one of the study sites within the last twelve months, be on at least one regular medicine and had to have experienced some form of ADE at any point in their child's care. Again, this was to ensure recent and relevant experience of the field. Potential participants were approached to participate in semi-structured interviews in person by the researcher. They were provided with an information sheet and an explanation of the aims and objectives of the interview. Because of the COVID-19 pandemic, restrictions were placed the conduct of interviews. For staff they were permitted to choose whether they participated virtually via a video conferencing platform, or participated in traditional face to face interviews, as the risk of COVID-19 infection for them and the interviewer was no greater because they effectively worked together. However, parents and carers could only be interviewed virtually. This was to mitigate the risks of infection between interviewer and participant.

The validity of virtual interviews compared with traditional face to face is interesting. Some commentators describe distanced or remote interviews as sub-optimal because they do not promote a close physical relationship between the interviewee and interviewer, and potentially reduce the contextual prompts such as body habitus and expressions leading to a less informative interview.[292] Much of the literature pertaining to virtual research methods focuses on the utility of the various tools (e.g. Skype® or Zoom®) and considerations of ethics and equity in on line research, or the utility of on-line data gathering in chat rooms, or in message forums.[295,296]

Given the limitations of the COVID-19 pandemic, there was no option other than to undertake virtual interviews. Keen et al. have described virtual interviews as liberating and allowing access to marginalised communities such as those with mobility impairments.[297] Further, Lobe has argued that ethical considerations for virtual interviews are no different to those for face to face interviews.[298] As part of the consideration of the use of virtual interviews, a parent member of the wider research team was consulted for their perspectives and advised that in their experience the use of virtual methods for accessing research spaces served only to enhance the experience. Therefore the design and conduct of both virtual and face to face interviews were the same and were analysed together with no differentiation.

The interview guide was constructed with reference to Rubin and Rubin's "responsive interview" model – main questions, follow-up questions and probes.[292] This also aligns with Charmaz's question typology (initial, open-ended; intermediate probing and ending).[290] Though this was developed for grounded theory studies, it is viewed as an applicable method for interviews in qualitative research as a whole.[252] The content of the topic guide was adapted from a CWA study examining the management of acute kidney injury patients.[299] The interview guide was also piloted in a single interview with a pharmacist in a site unrelated to the study, and was evaluated using qualitative feedback from the pilot interviewee concerning face and content validity of the questions and probes. These interview guides are presented in Appendix 6 and Appendix 7.

Interviews were recorded and the interviewer made contemporaneous field notes during the interview to guide future analysis. Interview recordings were stored and transferred securely and transcribed by a third-party transcribing service (1st Class Secretarial, Edinburgh, UK). Transcriptions were validated against the original voice recording, with the interviewer correcting errors and omissions, clarifying inaudible sections against their contemporaneous notes, and carefully anonymising the data by removing references to names and places. Voice recordings were destroyed after transcription and anonymization of the data.

The data from field notes and interviews was then used to support the inferences made through the research in the form of verbatim quotes and extracts from the field notes. Field notes while being written contemporaneously and in detail following observation were based on recall of the observed events, while quotes from interviews were taken directly from the transcription. These have been clearly identified throughout the thesis with reference to “Interview” and then the designation of the participant and their location, or “Fieldnote” and then the nature of the field note extract (observation or discussion), the participant and the location.

4.6.7 Analysis

4.6.7.1 Work Domain Analysis (WDA)

WDA is the first stage of a larger HF/E work analysis approach called Cognitive Work Analysis (CWA).[194] CWA sets out to understand why things are done, what tasks are required, how they are delivered, by whom and with what (Table 4.5). It creates a theoretically sound cognitive model of complex systems and work and has had considerable application in command-and-control systems (naval flight decks and air force radar monitoring.)

I used WDA in this setting to explore Work as Imagined (WAI). It was constructed from analysis of documents to identify the stated function and purpose of the system, and in the first three levels of the WDA these were easily identifiable. However, I also used this WDA as a formative illustration

of the Work as Done (WAD) in the system through the relationships of objects and processes within the system, by identifying the multiple ways in which the components of the system may interact and teasing out some of the potential resilience factors that may exist within the system. Additionally, the WDA offered an orientation of the medicines safety system within the field of study. WDA has been used to offer insights and targets for further, more in-depth ethnographic study particularly around the resilience mechanisms therein.[300,301]

The primary use of CWA is as a design tool for complex systems however that is not the question for this study. The objective is to understand how the system functions in its native state, and to explore potential reasons as to why things function because they do. Therefore only the first stage of CWA, WDA, was undertaken.

WDA defines the constraints of the system as the relationship between and the purposes and functions they are intended to deliver.[302] Vicente describes the constraints within WDA as important because they acknowledge that while workers are independent and have agency there are rules and expectations that they must follow within the system.[194] Naikar describes these constraints as physical (the environment and the equipment) and purposive (the behaviours and expectations).[303] Leveson has referred to them as the “rules of behaviour.”[302]

Question	Phase of analysis	Constraints	Tools
Why?	Work Domain Analysis	Purposes, processes, priorities	Decomposition from whole to part using Abstraction Hierarchy (AH); Abstraction-decomposition space (ADS)
What?	Control Task Analysis	Activities	Decision ladder Chained decision ladder
How?	Strategies Analysis	Strategies	Information flow map
By whom?	Organizational Analysis	Function allocation, communication	Responsibility mapping
With what?	Competence Analysis	Cognitive capabilities	Skill-Rule-Knowledge taxonomy

Table 4.5 – Phases of CWA adapted from Jiancaro et al. (2014)

These constraints establish the boundaries of the system and WDA is a method that presents this system in its static state, without the influence of events or actors. It is thus possible to use WDA to create a view of WAI and understand how the components of the system interact. The representation of connections of objects through processes to functional purposes of a system is the abstraction hierarchy (AH) – a hierarchical relationship of constraints in the system from functional purposes to physical objects. The definitions of these constraints were adapted from Read et al.'s Cognitive Work Analysis Design Toolkit which has been applied to studies an Australian urgent care system and British renal care.[299,304,305]

Furthermore, CWA has a clear history of application in healthcare HF/E based studies, with WDA the most common aspect of the analysis undertaken.[306] They are presented in Table 4.6 below.

Functional purposes	What does the system aim to do? • Aims and objectives of the system • Laws, regulations, constraints on action
Values and priority measures	How is the achievement of the functions monitored or identified? • Criteria and targets • Policies • Principles
Process-related functions	What are the people in the system supposed to do? • Roles, tasks and duties • Activites and operations
Object-related processes	What and how do we use the objects to support the processes? • Applications • Characteristics • Utilities
Physical objects	What are the objects required for the processes • Equipment • Devices • People (Staff, service users) • Buildings • Supplies

Table 4.6 – Definitions of the constraints in the AH and ADS

The model of the constraints is the abstraction-decomposition space (ADS) which models the purposive and physical constraints within the system, and the detail that they can use to resolve problems (Table 4.7).

	Whole system	Subsytems	Components
Functional purposes			
Values and priority measures			
Purpose related functions			
Object related processes			
Physical objects			

Table 4.7 – Example of an abstraction-decomposition space

WDA has been criticised as not having an overarching methodology, thus Naikar proposed an eight-step methodological approach which was adapted for this study.[195] Steps one and two define the research question and the project constraints (staffing, time etc.) These were established earlier in the thesis and informed the sampling strategy. Step three establishes the boundaries for the WDA. Specifically in this study we were only interested in the medicine safety work undertaken in acute paediatric admission units in the participating hospitals. No consideration was made of emergency departments or more specialist areas such as intensive care.

In step four the causal-intentional nature of the constraints in the system were identified. Causal constraints are those governed by immutable laws while intentional constraints pertain more to socially structured organisations. For the purposes of this study, constraints were intentional as healthcare is a socio-technical system rooted in personal interactions and shared working.

Sources of information (step 5) were identified through both analysis of the documents obtained above and data from the first week of observation in each site. Additionally a panel of subject matter experts (SMEs) was formed in each site to provide insight into WAI and to support further development of the ADS and AH. These panels consisted of a medical practitioner, a pharmacist, a nurse and a parent. At least one member of each panel was also a member of an organisational governance group with an overview of medication errors.

Data in observations and documents were managed and coded using NVivo version 12 (QSR International) by a single researcher using the five definitions of constraint provided in Table 4.6. Interpretation and analysis of coding was an iterative process following Naikar's method. The researcher alone produced a first iteration of the AH which was then reviewed by SMEs during a table top exercise at each site to produce a second AH. Data was recoded with feedback and comments from SMEs to produce a third and final iteration of the AH with means-ends connections.

4.6.7.2 Qualitative Ethnographic Analysis

Ethnographic field notes and interview transcripts were collated and managed using NVivo version 12. Field notes were composed of typed narrative and reflexive notes and commentary. Commentary and reflexive notes were appended to the data using the "notes" and "memo" function in

NVivo. Data was initially coded thematically using the WDA framework in Table 4.5 as *a priori* codes.

Coding was undertaken in duplicate by an expert analytical panel consisting of the researcher, a HF/E expert (Dr. Denham Phipps, a chartered ergonomist), a social anthropologist (Dr. Suzanne Grant, who has worked using ethnographic approaches to the study of medicines and patient safety in a variety of health settings), an experienced senior hospital pharmacist (Mr. Steve Tomlin, a chief pharmacist at a large children's hospital and director of an academic health research unit) and a parent representative (a mother affected by avoidable medicines related harm, and a patient safety advocate.) To support the parent's involvement in this aspect of the study, their attendance at formal training in qualitative data analysis through the Social Research Association was funded by the University of Manchester.

Coding was reviewed regularly using "data sessions" that were held after every three data collection periods (approximately every two to three months) where analysts would meet and discuss emerging themes and potential analytical insights. It was decided after the first data session that the WDA framework for analysis of the wider ethnographic data was not providing the depth of insights or the level of abstraction required to explore the system, therefore an open coding approach using thematic analysis was adopted.[307]

Thematic analysis offers rich and diverse interpretations of the data and fits well within a realist paradigm. The analysis was conducted with reference to Braun and Clark's six-stage approach which conforms to the cognitive approach to data analysis that Morse believes underpins all qualitative data analysis.[308]

Familiarisation with the data was supported through the process of converting field notes into rich narrative observation records, while interview transcripts were read and re-read against recordings for accuracy and completeness. Members of the analytical team were provided with data and encouraged to read and re-read them as part of their coding. Questions and reflective thoughts were captured through a reflexive diary for the observer and through conversation among the analytical group. Through this familiarisation with the data all coders developed a list of initial themes with which they could begin to identify and discuss segments of data.[309,310] These codes were then organised into overall themes that helped make sense of the emerging insights.[311] A theoretical analytical approach was taken to collation of themes, using sociotechnical terms to guide the insights – environment, tasks, people and teams, tools and equipment and organisational factors. These then guided thematic abstraction and the identification of the overall insights into medicines safety practices.[312] These themes were then labelled among the group.

The voice of parents was an explicit design element of this study, and this was supported in two ways. The parent representative in the analysis group above was an experienced lay researcher with lived experience of medication related harm involving their child. So as to foster a broad experience base, a family forum was convened at the end of the data collection period (Spring 2022) consisting of volunteer parents identified through their participation in the study or through expression of interest after approach by members of the research team.

Four parents joined the forum and their characteristics are outlined in Table 4.8 below. Family Forum sessions were held virtually using Zoom in June and September 2022 and were facilitated by myself. Excerpts from the data that related to parent experience and activity in the ward environments were provided in advance of these sessions and forum members were asked to read them and consider their understanding of the circumstances and the potential meaning of the events from the parent perspective. They were provided with a copy of the codebook and asked to apply these codes to the data provided, and where codes were inadequate, propose their own. These were then discussed and debated during the forum and codes and themes adjusted in line with the Family Forum's perspective.

Parent	Occupation	Location	Relevance to the study
Mother of a fit and well child;	Healthcare professional	Scotland	Historical experience of cardiac surgery in CH1
Mother of a child with medical complexity	Charity case worker	Yorkshire & Humber	Previous in-patient spells in CH2
Mother of a child with medical complexity	Full time carer	Yorkshire & Humber	On-going in-patient spells in CH2
Mother of three fit and well children with one child passed away related to a DRP	Patient safety advocate	East of England	Lived experience and lay researcher

Table 4.8 – Family Forum Composition

These analytical insights were then reviewed and discussed among the expert analytical team, and where there was disagreement or further questions these were passed back informally to members of the Family Forum to consider and agree, thus creating an iterative approach to assimilation of parent and carer views into the wider analytical frame.

4.6.8 Participant Validation

As a final stage of this research participant validation between parents and families, medical, nursing and pharmacy staff was sought through two workshops that were conducted as the conclusion of a programme of Experience Based Co Design (EBCD.) Towards the end of the data analysis period in February 2023, a draft pictorial representation of the system was created which was presented to the expert analytical panel who agreed that it provided a representation of the data. This was then presented to a wider

group of study participants during two co-production workshops where they were asked to provide their opinion and suggestions for improvement of the diagram.

4.6.9 Ethical Considerations

The study was registered with the Health Research Authority (HRA) with the study number 266243. The study was approved by the Leeds West Research Ethics Committee (Appendix 1).

4.6.10 Consent

The need for consent was not disputed, however there are arguments against reliance on written consent in ethnographic studies.[313] The process of obtaining formal written consent, with the associated burden of documentation and waiting periods has been argued to be detrimental to studies where the focus is not on individuals.[314] Consent procedures may be burdensome to participants who have only a brief involvement with the research or in circumstances where the observations are not invasive, or not collecting personal or sensitive data.[315]

In previous studies of patient safety, consent has been an acknowledged barrier to gathering data.[85] In British ethnographies of patient safety in operating theatres, explicit written consent was sought from participants prior to observation, because their unit of observation was a series of single procedures involving a fixed cohort of participants.[316,317] In this study we anticipate observed events being fluid with an ever-changing participant

group. As such a continuous verbal consent procedure was used, justified on three bases:

- The unit of analysis of the observations is the system and how participants interact within it, rather than the participants themselves
- No personal or sensitive data about participants was collected during the observations.
- Previous studies of systems safety in emergency departments and maternity units have also used verbal consent models.[85,318]

To mitigate the risk of coercion a number of measures were implemented to support free participation. Observations were open, and the researcher provided information about the study and its objectives on demand. Written information about the study was also provided to all participants (including families and children) on first approach. Consent provided was re-verified prior to any interaction or procedure. Where potential participants decline to be observed, the researcher removed themselves from that space and undertook observation elsewhere and away from that person's sphere of work.

Consent to interview was obtained by either verbal agreement with statements on an approved consent script that was read to the participant at the commencement of virtual interviews. For face-to-face interviews, participants were asked to complete a traditional paper consent form

(Appendix 4 and Appendix 5). All participants were given time to consider their participation and were invited to ask questions prior to consent.

4.6.11 Confidentiality

Participants for observations and interviews were identified by the participating site and their role only. For the purposes of data withdrawal and further contact, participants were asked to consent to hold contact information (e.g. e-mail addresses) and pseudonymisation of their data. The pseudonymnisation key was held by the researcher with no other person given access to this, and it was stored in a secure University server separately from research data. Hard copy consent forms were locked in a desk drawer, in a secure office on University premises. Consent recordings were also stored separately and securely from research data and the pseudonymisation key.

All research data was anonymised on transcription. As part of the review of transcripts against recordings, names and references to locations were deleted or redacted. No names or locations were recorded in observation data, and where possible they were written in gender-neutral language to further mask potential identities of participants.

4.6.12 Potential Adverse Events

The welfare of all participants in an important concern. There were three potential risks to participant welfare that were identified and required consideration.

- Safeguarding of children and young people.

The lead researcher undertook Level III safeguarding training prior to the initiation of the study, and held an enhanced Disclosure and Barring Service background check. They acquainted themselves with the local safeguarding policies and procedures in each participating site. Where an observation of inappropriate behaviour towards a child, or disclosure was made by a child or young person that constituted a safeguarding concern the observer would follow established safeguarding practice – take the disclosure and document the event in the young person's words. These disclosures or observations would then be escalated to the ward manager and lead clinician and appropriate statements provided. Observation field notes containing details of disclosures would also be handed over after discussion with University data managers.

- Observation of ADEs

There was a strong likelihood that during observation ADEs would be observed. The purpose of the research was the study how the system functions, and ADEs are an inevitable part of that. Therefore it would not have been appropriate or feasible for me to intervene or report every ADE observed as this would erode field relations and undermine the

study. Further, there was value in observing how ADEs emerged and how they were dealt with in the field. Many of these observed ADEs would happen whether I was present or not, and would likely contribute no or very low harm to the affected patients. Where a duty of care did exist was in the emergence of those ADEs that had the potential to cause significant harm to the patient. In these situations, I would use my experience and knowledge as a pharmacist with almost 20 years' experience in the paediatric field to determine if a situation warranted intervention. Interventions would be made politely and assertively and the observer would also flag the intervention to the clinical lead and ward manager on duty for the day and advise the supervisory team.

- Potential recall of upsetting events

There was a possibility of participants becoming distressed when recalling specific events during conversations or formal interviews. A procedure was adopted to support both participant and researcher in these events. Strategies were offered including breathing space, abandonment of research intervention or in more severe distress, the signposting to appropriate support services.

4.7 Study Amendments

During the first year of the study 10 families were approached during their in-patient stay with an invitation to participate in a formal interview about their experience. None had followed up the invitation. Discussion among parent

representatives on the research team identified that during an acute hospital admission parents were more focussed on their child's wellbeing and dealing with disrupted home routines. Thus it was felt that the direct approach in hospital was insensitive to parents concerns at that time. It was decided to engage with local parent support groups, clinical networks and individual clinician-patient relationships to identify potential participants for direct approach and recruitment. This amendment was approved in June 2021 and approaches were made to parents and carers through the Medicines for Children network, Ryedale Special Families in North Yorkshire and the Local Offerings pages of Merseyside, East Cheshire and Leeds City Councils.

5 Exploring the Gaps in Medication Safety in British Paediatric In-patient Units using Work Domain Analysis.

5.1 Study background

Healthcare has been described as a complex, dynamic, adaptive system.[218,319,320] Multiple components interact in unpredictable ways which leads to workers in the system to re-evaluate and adapt their actions in order to maintain normal system function. Subsequently, there is a need to understand how components within a system interact in order to identify potentially modifiable factors to further minimize ADEs for hospitalised children and young people.[321] This study aimed to explore medication systems in paediatric in-patient settings, using Work Domain Analysis (WDA) to identify contributory factors and control elements, and to propose systems-focussed interventions to improve medication safety for children and young people.

This chapter was submitted to the Journal of Patient Safety in November 2022 and was accepted for publication in July 2023.

5.2 Methods

The study was conducted between October 2020 and May 2022). Sites were selected using the sampling strategy described in section 4.6.1.

The characteristics of each site has been presented in Table 4.2.

The WDA was undertaken using documentary analysis (DA) and 20 hours of ethnographic observation at each site

5.2.1 Documentary analysis (DA)

Documents were selected in collaboration with local site collaborators using agreed inclusion criteria: that they were policy or procedural documents relevant to medication processes; that they had evidence of organisational approval; and were within their expiry date. These criteria are based on the markers for document quality described by Prior.[286] These documents included the medicines policies, medication errors policy, and incident reporting policies, medicines management committee terms of reference and other general medication-related policies. Between 15 and 20 documents were included from each site. Documents were analysed by the lead researcher and a chartered ergonomist deductively using the five levels of WDA as described by Naikar [195] and the CWA prompts from Read and Salmon [304]: namely functional purposes; values and priority measures; purpose-related functions; object-related processes; physical objects. The prompts within these levels are presented in Table 5.1.

Functional Purposes	Values and priority measures	Purpose-related functions	Object-related processes	Physical objects
Why does the system exist	How do we judge whether the system is working?	What functions deliver the purposes of the system?	What can the objects do?	What are the physical objects and processes in the system?
What role does it play?	What are the priorities of the system?	What do individuals and teams do within the system?	What are they used for?	What are their characteristics?
What are the demands the environment places on the system	How are resources allocated?		What things need to be done so that functions can be delivered	How are they organised?

Table 5.1 – Definitions and prompts for abstraction hierarchy levels adapted from Naikar and Read by Phipps et al.[299]

An initial draft WDA was created using the CWA Tool v0.9.[322] This was then reviewed and amended iteratively by three subject matter experts (SMEs) at each site (including a pharmacist, a nurse and a paediatrician) for accuracy and completeness. The final WDA was agreed when no more changes were suggested by the SMEs.

5.2.2 Ethnographic Observations

Observations of medication processes (prescribing, dispensing, administration, monitoring) were undertaken by the lead researcher as an open observer, independent of clinical care provision. He was not employed by any of the participating organisations and his status as a pharmacist was

only shared with participants in the field if asked. Ward staff were made aware of the presence of a researcher studying medicines safety with posters and short communications in the week prior to arrival. Further, he wore clinical attire matching those of other members of staff.

The total-observer posture was taken,[323] making no interventions or suggestions, and he maintained an innocuous position in the ward permitting view of work. He was open about his purpose with all staff but careful to stress that there was no evaluation or judgement of their work or practise. Observations were structured around medication processes, and the work of a nurse, a pharmacist and a physician were observed in each site. A convenience approach was used with activities and interactions observed as and when they occurred (hence the relatively prolonged observation period.) The timing of these observation sessions were pre-defined with site gatekeepers with the intention of capturing as much routine medicines work as possible. Contextual enquiry was used to clarify observation and interpretation.[324]

For the WDA, observation sessions were carried out over a five day period in each site, for no more than four hours per day. To facilitate observer entry, a one-week non-observation period took place at each site immediately before the first observation period, during which the observer became embedded in the clinical area. No personal or protected data was collected through this study; therefore, a pragmatic consent process in line with British

Psychological Society guidelines was used to minimise burden on participants.[325] Participants (staff, patients and their carers) provided verbal consent to observation which was verified regularly. All field notes were written in gender neutral language, and no identifying details research sites were included. Field notes were kept electronically on a secure tablet device and were typed up into a detailed narrative shortly after each visit. Once field notes were typed up they were destroyed. Only the observer had access to the detailed observation notes, but these were shared with members of the research team for analysis.

5.2.3 Data analysis

Observations were analysed deductively by the lead observer, to relate observed events and issues to contributory factors within the system that could be derived from the WDA. Data from observations was encoded to the WDA taxonomy proposed by Read *et al.*[304] A data dictionary was also created to support the population of the different levels of the WDA.[305] To support reflexivity, the researcher maintained a diary of thoughts and questions, and underwent regular debriefing with members of the research team. Overviews of the data were also shared and discussed with site research teams at regular intervals to provide participant validation of the WDA.

5.3 Results

Data from two observation periods (60 hours) over three months in each site were included in the WDA. The activity during one night shift, and two weekend days were observed. A total of 72 documents were also analysed (Appendix 2). The final abstraction hierarchy is presented in Figure 5.1 and the abstraction-decomposition space in Table 5.2.

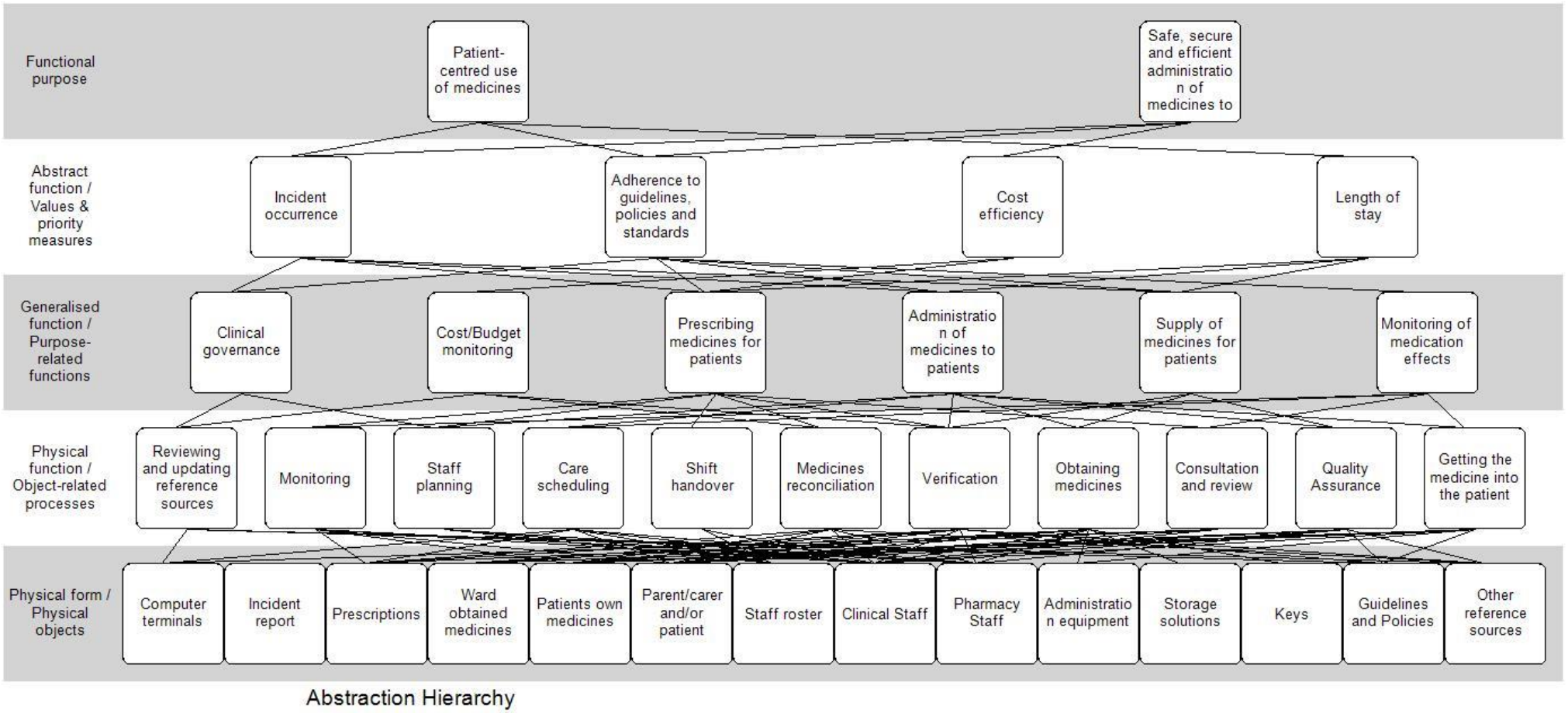

Figure 5.1 – Work Domain Analysis of medication processes in acute paediatric in-patient care

<table>
<tr><td></td><td>Organisation</td><td>Ward (including nursing staff and parents</td><td>Medical Team</td><td>Pharmacy Dept.</td></tr>
<tr><td rowspan="2">Functional Purpose</td><td>Safe, secure and efficient use of medicines</td><td colspan="3" rowspan="2"></td></tr>
<tr><td>Patient-centred use of medicines</td></tr>
<tr><td rowspan="3">Values & Priority Measures</td><td>Length of stay</td><td colspan="3" rowspan="3">Adherence to policies, guidelines and standards</td></tr>
<tr><td>Incident occurrence</td></tr>
<tr><td>Cost efficiency</td></tr>
<tr><td rowspan="2">Purpose related functions</td><td>Clinical governance</td><td>Administration of medicines to patients</td><td colspan="2">Prescribing medicines for patients</td></tr>
<tr><td>Cost/Budget Monitoring</td><td colspan="3">Monitoring of medication effects</td></tr>
<tr><td rowspan="10">Object-related processes</td><td rowspan="10">Reviewing & updating reference sources</td><td colspan="3">Monitoring</td></tr>
<tr><td colspan="3">Staff planning</td></tr>
<tr><td colspan="2">Shift handover</td><td></td></tr>
<tr><td>Care scheduling</td><td></td><td></td></tr>
<tr><td></td><td colspan="2">Consultation and review</td></tr>
<tr><td>Obtaining medicines</td><td></td><td>Obtaining medicines</td></tr>
<tr><td>Verification</td><td></td><td>Verification</td></tr>
<tr><td></td><td colspan="2">Medicines reconciliation</td></tr>
<tr><td>Quality assurance</td><td></td><td>Quality assurance</td></tr>
<tr><td rowspan="15">Physical objects</td><td rowspan="15"></td><td colspan="3">Computer terminals</td></tr>
<tr><td colspan="3">Prescriptions</td></tr>
<tr><td colspan="3">Incident reports</td></tr>
<tr><td colspan="2">Clinical staff</td><td></td></tr>
<tr><td>Patients, parents and carers</td><td></td><td></td></tr>
<tr><td></td><td></td><td>Pharmacy staff</td></tr>
<tr><td colspan="3">Guidelines and Policies</td></tr>
<tr><td colspan="3">Other reference sources</td></tr>
<tr><td>Patient’s own medicines</td><td></td><td>Patient’s own medicines</td></tr>
<tr><td>Ward supplied medicines</td><td></td><td>Ward supplied medicines</td></tr>
<tr><td colspan="3">Staff rosters</td></tr>
<tr><td>Keys</td><td></td><td>Keys</td></tr>
<tr><td>Storage solutions</td><td></td><td>Storage solutions</td></tr>
<tr><td>Administration equipment</td><td></td><td></td></tr>
</table>

Table 5.2 – Abstraction-decomposition space. Cells filled in grey do not apply to this level of abstraction.

Functional Purposes

Both the contents of the source documents and SMEs agreed that there were two overarching purposes of the systems: patient centred use of medicines, and the safe, secure and efficient use of medicines.

Values and Priority Measures

Documentary analysis suggested seven methods of monitoring the overall functioning of the system classified into three groups – service delivery, professional integrity, and patient outcomes. However, discussion with SMEs identified that these were more appropriately labelled according to monitoring parameters used by the organisations thus “Incident Occurrence;” “Adherence to Policies and Guidelines;” “Cost efficiency;” and “Length of Stay” appear in the second level of the WDA.

Purpose-related functions

Six purpose-related functions were identified from both the documents and SMEs. “Clinical Governance” included the routine assessment of performance of the work system using audit and spontaneous reports (incidents and complaints.) “Cost & Budget Monitoring” encapsulated the mechanisms of the organisations to contain costs associated with medicines. There are then four separate headings relating to the clinical use of medicines related to the process described by Sutherland et al.[132] –

prescribing, administration, supply and monitoring of medicines for patients.

These are presented in the third level of the WDA.

Object-related Processes

11 elements were identified as object-related processes (Table 5.3)

Reviewing and updating references sources	The work required to maintain and ensure that medication references and procedures were up to date and reflected best practice.
Monitoring	Assessment of patient response to medicines but also the routine work to ensure compliance with local policy and procedure.
Staff planning	The process of skill mix determination through staff rosters.
Care Scheduling	The processes required to plan the work to be done during a shift, including the allocation of patients to medical and nursing staff.
Shift Handover	The process of passing on information about patients-of-concern and to identify actions that needed to be followed up during the shift.
Medicines Reconciliation	The activities around obtaining and validating the medication history of each patient.
Verification	The physical process of checking to ensure that the medication prescribed is safe and appropriate for the patient and is undertaken by all members of the care team.
Obtaining medicines	The process involved in accessing medicines at ward level, from home and from the pharmacy department.
Consultation and Review	The ongoing process of prescribing review and follow up during clinician, nursing and pharmacy rounds.
Quality Assurance	The process of assessing the physical quality and utility of medicines and medicines information in the clinical area.
Getting the medicine into the patient	The processes involved in physically administering the medicine to a child under their care.

Table 5.3 – Summary of object related processes and their characteristics

Physical Objects

The 14 objects identified in the system are summarised in Table 5.4.

Devices	Computer terminals Ward obtained medicines Prescriptions Patients own medicines Administration equipment Storage solutions Keys
People	Clinical Staff Pharmacy Staff Patients, parents and carers
Resources	Guidelines and policies Staff rosters Other reference sources Incident reports

Table 5.4 – Summary of Physical Objects and their characteristics

Means-ends connections

Working with SMEs in each site, the connections between elements at each level of the abstraction hierarchy were mapped. These means-ends connections supported the identification of dependencies of the functions of the system with the processes and objects within. For example, it would not be possible to administer medication (a purpose-related function) without access to appropriate information resources (an object-related process) and medication administration equipment (a physical object). We have also identified that though parents and caregivers are explicitly excluded from the system at the functional purposes level, it is challenging to administer medicines safely to children without them (Figure 5.2).

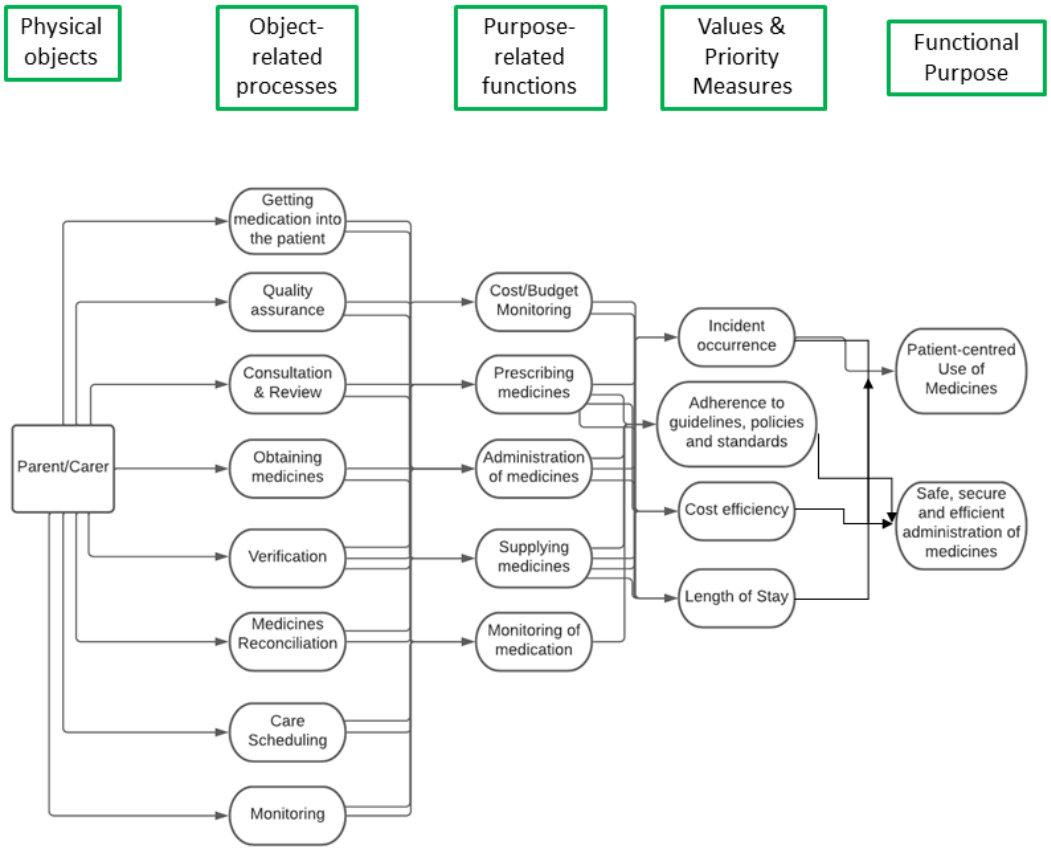

Figure 5.2 – Parent/Carer roles and participation within the medication safety system identified through the WDA.

5.3.1 Systemic vulnerabilities to DRPs

The WDA offered a graphical representation of how the components of the system interacted through the means-ends links facilitated the visualisation of processes and their constituent actions and resources. However, the observation of the process "in the wild" facilitated the identification of potential vulnerabilities within the system that may contribute to DRPs.

Resource limitations (inaccessible devices, materials, staff, and knowledge.)

It was noted during observations that some tools required to undertake tasks were often difficult to access. The keys to medication storage cupboards are emblematic to this, with frequently observed calls from nursing staff for the keys. Two sites had instituted technological interventions to improve access to medication - one site used an automated dispensing cabinet and another an audible tag that could be activated from the nurses' station. However, these interventions were incomplete as there was still a need for physical keys for refrigerators and the controlled drugs cabinet. Keys, being physical artefacts were sometimes broken or misplaced, which further added to the frustrations of staff seeking access to medicines.

Knowledge and expertise were also often accessible only to people who knew who to contact, or where to look. Despite there being telephone systems and radio pagers in all sites, practitioners were dependent on personal cell phones and messaging platforms. Some participants spoke of "...phoning a friend…" when lacking experience or knowledge, while others demonstrated how official hospital contact lists were often out of date, thus they relied on personal contacts and the recommendations of others.

Medication information was available on hospital computer systems, but many practitioners relied on their memory or that of those around them. “Pharmacy” would typically be contacted only as a last resort. It was often stated that information was impossible to find at the point of need and thus it was easier to just ask someone else. However, “pharmacy” was often poorly accessible at all sites, usually only by telephone or radio pager, and even then connected to a pharmacist who may not have been working in that ward on that day. Pharmacy services were highly dependent on wider service pressures within the pharmacy itself with ward cover reduced or removed on some days. Thus the pharmacy service was not clearly a part of the ward ecosystem except in the context of medicine supply. In those sites with electronic prescribing, pharmacist activity was carried out in offices or remote areas of the ward. At times of staffing pressures, services could be provided remotely which had been introduced as a new practice during the COVID pandemic. Across all sites, pharmacy service provision was focussed on the verification of prescriptions, ordering of medicines and processing discharge orders.

Cognitive demands on the operators in the system

All participating wards in this study were acute admissions units, with high patient turnover. Nursing rotas were all broadly comparable with a fixed ratio of staff to beds. During the study one site decreased its nursing ratio from 1:4 to 1:6 to cope with high absence rates. This increased the workload on

nursing staff resulting in them being unable to keep track of their patients in different areas of the ward, and missing information or tasks determined by medical teams.

Wards were busy and dynamic environments with multiple teams working on their own tasks and towards their own objectives and no team functioned together – medical, nursing, pharmacy and parent groups were autonomous and independent. Medical staff were responsible for the majority of prescribing, nursing staff operationally responsible for administration and pharmacy services responsible for supply. Monitoring of medication effects was not allocated to any specific group of actors and was rooted in subjective clinical assessments of “improvement” in patient condition, to which all actors contributed. This led to distraction and interruption as members of teams reached out for additional information, advice and opinion. Because of the disjointed goals and objectives of each team, these interruptions were inevitable because tasks could not be completed without them. Communication within teams was conducted in formal handover settings, but between team communication was transactional and informal.

Medication related tasks were undertaken on an ad hoc basis according to when medicines were due. Nursing staff treated these individually prescribed medication times as fixed time points, and deviation was discouraged. In some sick patients, nursing staff would group tasks together. For example, a patient on frequent nebulisations would receive their treatment at the same time as observations and blood tests needed to

be taken, to make their work more efficient. At an organisational level this was managed and acknowledged through elements of the medicines policy that focussed on the timeliness of medicines administration and expressly permitted a one-hour window either side of most medicines. In hospitals with CPOE, this was embedded within the systems to permit early or late administration within these bounds, but no administration was permitted outside those bounds. On paper-based medication systems there were no controls to ensure on-time administration.

Organisationally, all medicines administration had to be undertaken by registered staff (primarily nurses) or, in two sites, parents could administer medication when assessed as competent to do so and under nursing supervision. This nursing-centric approach to medication administration created problems for families, particularly those on established medicine regimens. Some parents with children admitted to the wards reported that medicine doses were missed or delayed because they were prescribed at times that did not reflect the family schedule at home. However some accepted that disruption was inevitable when their child came into hospital. Two of the three sites had parent self-medication policies, but in one site this was an assessment involving mental capacity and psychiatric safety as well as the technical competency to administer medicines, that required the approval of a doctor, a nurse and a pharmacist. Given the high patient turnover and the sensitivity of the information assessed, the policy was often unused. The other site used a more pragmatic approach asking parents to

self-certify their competence to administer their child's medicines, and asking nurses to confirm that there were no safeguarding concerns.

"Because if the parents are doing it, it's one thing less for me to worry about… they know what they're doing because they do this every day at home." (Fieldnote, Observation discussion, Nurse, CH2)

Adaptation and non-adherence to safety critical processes.

There was considerable suggestion that interventions to support medicines safety were ineffective because there was no underpinning consideration of how operators undertake their tasks in reality. One site had introduced an electronic barcode verification system to reduce medication errors. This barcode system was consistently overridden, because nursing staff did not perceive it fitting with their routine tasks.

"We know we need to do these checks, but we just don't have time and there are so many problems with it – wristbands, medicines from home, infection control…" (Fieldnote, Observation Discussion, Nurse, CH1)

On the other hand, nursing staff also admitted that they didn't know why they were being asked to use it. Barcode devices were frequently inoperable, or commandeered for other tasks such as scanning enteral feeds and default software updates initiating at inconvenient times. Furthermore, many medicines for children and young people did not have barcodes on the final

vessel for the medicines, but they were on the outer packaging. These outer boxes were often discarded.

5.3.2 Resilience features of the system

As well as identifying potential contributory factors to ADEs within this system, the WDA has also supported the identification of potential resilience features. Our selection of the parent/carer means-ends relationships demonstrates how involved parents are in the process of medication prescribing and administration. During observations it was found that parents held a large quantity of information about their children and were often engaged in correcting discrepancies in medical or nursing plans, and co-ordinating care between other teams and the acute team. Further, nursing staff would often delegate medication administration to parents to make best use of their time, and because assessment policies were perceived as invasive and excessive. Further, some parents would refuse to submit to hospital policies and procedures to surrender their medicines and subsequent autonomy over their children, and chose to continue self-medication throughout the in-patient period.

"…I know everyone's busy and stuff, but she's got a life-long disease, is immunocompromised and having medicines given an hour late just isn't good enough, so I do it all myself…" (Fieldnote, Observation discussion, Parent, CH2)

Yet the resilience against ADEs in this setting was often reflected against the perceived risks of parents being involved with medication processes. There was an organisational distrust of parents as good-faith actors in the system,

and an assumption that their recollection of patient histories or medication lists was in some way defective.

"Yeah, we ask the parents but sometimes you've got to understand that that's what they think but it may not be right…" (Fieldnote, Observation discussion, Consultant, CH1)

Furthermore, there were no organisational policies or procedures for involving parents in discussions and decisions about medication choices. Decisions were made by medical staff on ward rounds and usually presented to parents at the bedside as a foregone conclusion. Parents were able to advocate for their children when these medicines choices were not appropriate or inadequate. This was apparent when issues of palatability and individual patient acceptability emerged.

"Have you ever tasted that medicine… it's vile. We tried another one because apparently that was a "nice flavour" but when we both had it… [wretching noise]… in the bin!" (Fieldnote, Observation discussion, Parent, CH1)

All units had centralised medication stores with extensive lists of "stock" medicines that could be called on for most patient therapy. Parents of patients with long term therapies were also encouraged to bring medicines into hospital with them, which then continued to be used during the inpatient period. These centralised store spaces were located as near to the centre of the ward as possible and meant that the majority of treatment could be offered to patients quickly, without incurring additional delays relating to

dispensing of medicines via the pharmacy service. That being said, it was not uncommon for medicines to be unavailable (because supplies had been exhausted and replacements not ordered) requiring nursing staff to then contact other wards and departments to “borrow” new medicines, but this was still seen as preferable over contacting pharmacy services because it was quicker. This trading of medicines between wards was seen to occur at all times of day or night, whether the pharmacy was closed or not, despite exhortations in organisational policies not to do it.

5.4 Discussion

This study has developed a representation of the complex medication safety systems in place for hospitalised children and young people. There are considerable interactions between different teams, different services, different wards and different hospitals. This representation has identified disconnection between organisational goals and values regarding medication safety, and the tasks, equipment and knowledge needed to achieve those goals. The disconnections in these provisions lie within the way the system is constructed around the patient, whereas the nature of human work observed is not patient-centred. The expectations and provision of patient centred care appears to differ between patients. Furthermore, there are numerous ward- and professional-related tasks and expectations that have no bearing on patient-facing care but detract from the provision of care in this way. Therefore, there are elements of the system that might be amenable to intervention to improve safety. These may include a more flexible approach to established medication safety procedures, the involvement of families in

the medication administration process, and the optimisation of the skill mix and workforce in the clinical area.

Importantly thisstudy is currently the only multi-centre WDA for paediatric medication management systems that we can identify. Abebe et al. undertook a similar study in a single paediatric ambulatory care programme in the United States, focussing on the work of parent carers to keep medicines safe for their children.[326] This included similar components to our findings, with cognitive elements and management of resources central to safe medication practice for children at home. Additionally, this study has provided insights into how medication errors may evolve because of the way processes are implemented and provide insight into why previous interventions may be less effective than expected in empirical study. While there are many opponents to such a visual representation of complex systems, our study supports the position that the representation of a complex system is useful for subsequent systems design because of its theoretical foundations and the involvement of all within the system.[303,305]

5.4.1 System Reflections on Medication Safety

The ability to deliver many of the functions and tasks is assumed to be the singular responsibility of the organisation but there is a reliance on external networks and parents for much information and expertise about the management of some medicines. Communication networks are informal and transactional which may lead to failures of communication and decision

making potentially leading to medication errors.[327] We have identified that the professional groups in this system do not work together unlike that seen in high-performing areas such as emergency departments and maternity units where teams are allocated to the same environment.[318,328] Thus there may be an environmental aspect of medicines safety which this representation of the safety system may not be able to identify. However, this study has been able to identify a key role for *families* as a key resilience aspect of the safety system, yet at the higher levels of the system they are often excluded. This should be explored in more depth to consider how the work of parents can be safely acknowledged and supported, in the same way as the work of families in other care settings is being acknowledged and harnessed.[329]

All participating sites had ongoing campaigns to reduce interruptions in medication processes. Interruptions are associated with procedural and clinical errors, but probably where communication is impaired.[330,331] Therefore we posit that the lack of effective teamwork in the acute paediatric ward could be the systemic cause of these interruptions and distractions, which leads to degradation of system safety. This study suggests that consideration be given to the structure and function of the wider care team in these settings, with a view to exploring how skill mix may improve safety outcomes. For example, there has been evidence that pharmacist participation in ward rounds may lead to reduced medication errors [87,89,187,332] but the framework for this participation in the UK setting is unclear.[333] All research into pharmacist impact on ADEs is through a lens

of retrospective prescribing interventions rather than proactive clinical activity thus there are also economic and workforce considerations to acknowledge around staffing and outcome measures.

This study also identifies important evidence to support the impact of these workforce deficiencies through the identification of “efficiency-thoroughness trade-offs” (ETTOs).[334] ETTOs are endemic throughout healthcare, and this study has shown that ETTOs were imposed by organisational factors including workload, skill mix and lack of resources.[334,335] This study has also shown that medicines safety work is reliant on human-based checks and a great deal of human resource is expended in these processes. However, the effectiveness of checks to prevent ADEs is disputed with mandated independent checks often violated, while spontaneous checks as a result of nursing uncertainty were associated with a reduction in medication error incidence and severity.[330] Similarly in our observations, most of the medication administration checks observed were primed with only true independent checks for calculations, or where a nurse actively sought a second opinion because they had doubts. Yet nurses in all sites were clear that independent second checks were vital to prevent medication errors, often in spite of their personal and professional experience. There was a concerning culture in all sites towards reliance on the second check model to catch all errors, without considering the dynamic and distraction-rich environment.

Next steps

This study has provided a robust basis on which to consider further the medicines safety systems within acute paediatric care. There is a clear role for parents and carers in the system. Children (unlike adults) are admitted to hospital with advocates who are expected to competently make decisions about their child's care but are not formally permitted to continue providing care to their child. While this study has not explored this phenomenon in great depth it does demonstrate the importance of parents and carers as a source of resilience for the healthcare system. The concept of family-centred care is gaining increasing importance in neonatal care, but this has not translated into acute paediatric care.[336] We recommend that additional exploration of the role and perceptions of parents around medicines safety for their children in hospital and consideration of the concerns and opportunities in healthcare services for involving them on a more equitable and formal basis be undertaken.

There is also a need to understand how the various actors in the system work together practically, and to observe how people respond to emerging situations and adapt. This will provide considerable insights into how professionals and parents work together and separately to maintain patient safety while in hospital.

Strengths and limitations

This is the first multi-centre observational study of medication safety in children's' in-patient services to focus on systems and processes, rather than ADEs as outcomes. The use of sustained observation ensured that rich, deep data was obtained. Where we differ from previous research is that we have presented a systematic representation of medicines management processes using robust methods that can be used by researchers and practitioners to potentially support onward service redesign, which no other study has presented in this field before. Further our multi-centre design and careful selection of units in hospitals of differing sizes and organisational structure offer a degree of generalisability in our findings across the NHS that could not be offered from single-centre qualitative or quantitative studies. Our inclusion of the wider healthcare team in the analysis and validation of these findings also provides some assurance of the veracity of our findings.

An important limitation is that this study used a single observer across all three sites. The observer is an experienced pharmacist with knowledge of medicines safety processes, it is difficult to control for their own subjectivity in the analysis. However parental and professional perspectives were included in the analysis, and local subject matter experts validated the WDA. The generalisability of our findings outside of the NHS in England may be limited because of the English focus of our study. No internal comparison between sites was undertaken but the data could be reanalysed as a comparative study and will be deposited in a suitable repository.

5.5 Conclusions

Many interventions in the system intended to support medicines safety are poorly designed around existing processes. Further, the exclusion of families and other caregivers from the system may contribute to medication related problems, but this requires further investigation.

We have identified a complex adaptive system where the demands of the organisation conflict with the work that needs to be done. Our analysis has identified important systemic contributory factors for ADEs. Pharmacy professionals and families are important parts of the system but their input is limited. Controls against ADE in clinical areas are checks; of information retrieval and entry, and of medication administration. A lack of team working creates an interruption rich environment. Control processes are vulnerable to interruption and resource limitations. Furthermore, the way information and equipment for medication processes is presented predisposes the system to work-arounds and the evolution of informal networks.

However, because of the limitations associated with using representations of complex systems to support decision making, further in-depth exploration of these phenomena are required.

6 Insights into Resilience and Risk in Paediatric Medicines Safety – A Multicentre Ethnographic Study

6.1 Chapter Introduction

A sustained ethnographic study of three acute paediatric in-patient units in the North of England was undertaken between October 2020 and May 2022. The methods used for this study were described in Chapter 4.

6.2 Results

A total of 230 hours of observation were undertaken by a single observer during the study period and 404 participants consented to be observed. These are summarised in Table 6.1 below. No-one declined to participate in observations.

Site	Staff	Parents	TOTAL
CH1	104	28	132
CH2	110	7	117
GH1	107	48	155

Table 6.1 – Observation participants by study site

In addition, 19 participants were recruited to semi structured interviews with a broadly representative sample (Table 6.2). Interviews lasted between 40 and 95 minutes.

Designation	**Number (%)**
Nurse Ward Managerial (e.g. MSO)	5 (26%) 3 2
Doctor Junior Consultant	5 (26%) 2 3
Pharmacist	5 (26%)
Parent	3 (16%)

Table 6.2 – Characteristics of interview participants

As well as outlining the recruitment patterns of participants in our qualitative procedures, I have also created a stylised representation of a "typical" acute paediatric ward to help orientate the reader of this thesis with the landscape. Though all the wards looked different there was a common layout to the workspaces, storage and social facilities. This representation is provided in Figure 7.1, and should be used in conjunction with Chapters 7 and 8.

Data collection concluded in April 2022, and the analysis was undertaken concurrently and concluded in November 2022. Three core themes were identified – environmental influences, cognitive aspects of medicines safety for staff, and the involvement of parents as sources of resilience and risk. Because of the breadth and depth of data obtained, these will be presented and explored in separate chapters.

7 The environment for medicines safety work

The environment in which people worked exerted considerable influence over the way medicines safety was enacted in the clinical setting. This environment was composed of the physical space including near-patient areas, workstations and storage facilities and the social spaces in these areas where people would gather. There was also a less clearly defined environment which I have described as the "professional space." This was constructed from the structure of services and professional hierarchies, and the way these discrete structures interacted. Finally, there was an organisational space – these were how the constraints of the expected work influenced the physical and professional spaces, and how these constraints were managed.

7.1 The Physical Space

At a macro level all clinical areas studied looked different but their layout was essentially the same. Children and young people were nursed in side rooms with their primary carer (usually their mother) resident in the same space. There was a central workspace referred to as the Nurses' Station which also accommodated a ward clerk or receptionist. In two sites there was a doctors' office within the ward which was situated away from the nurse's station. These offices would accommodate two or three people but also served as a storage space for personal effects and a social space.

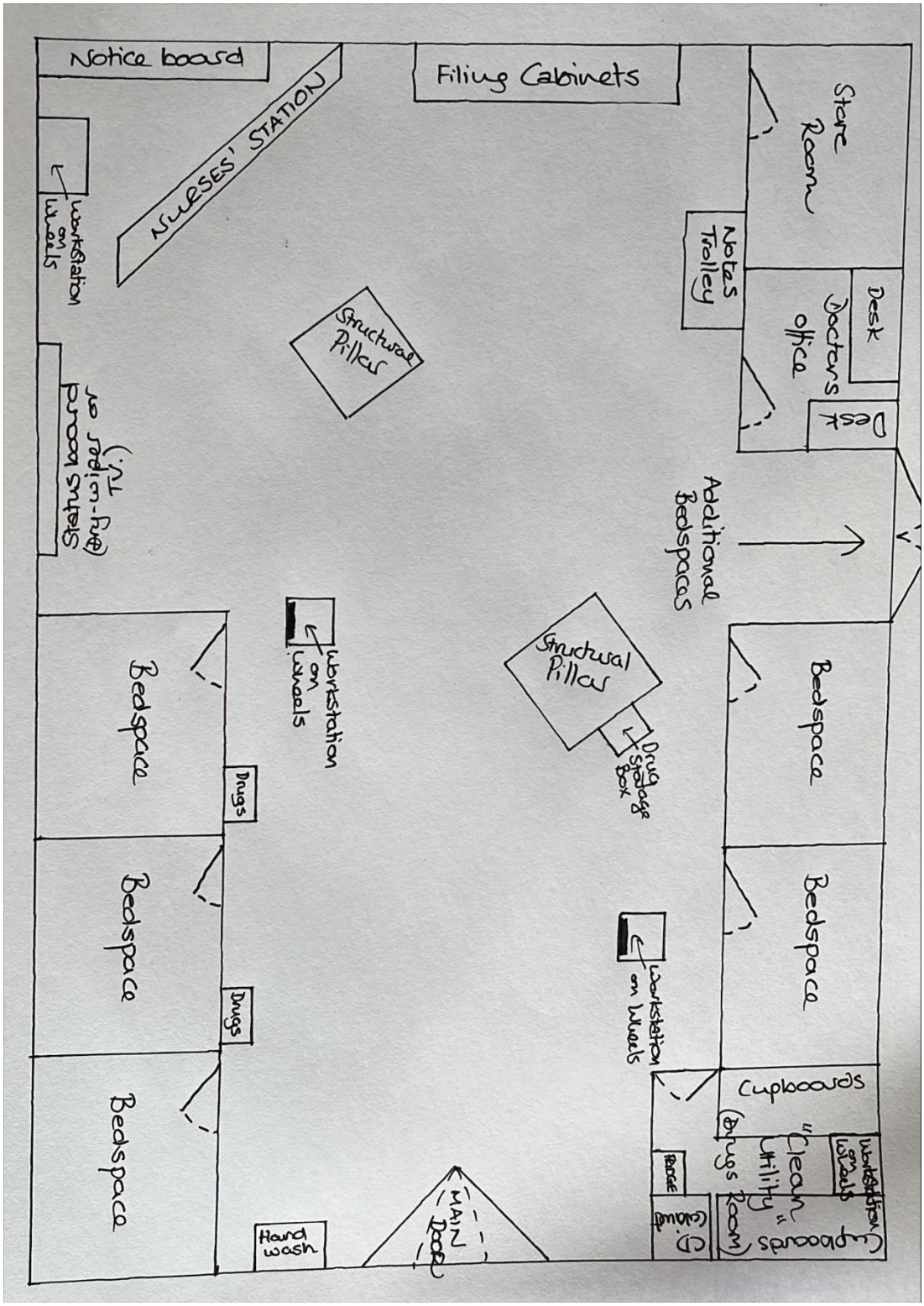

Figure 7.1 - Graphical representation of the layout of a "typical" acute paediatric ward in an English hospital.

All units had an administrative space usually referred to as the ward manager's office but for other members of the nursing team, there was no such administrative space. The ward manager's office was only used for managerial functions and reserved for the ward manager. This person was not counted in "the numbers" – the available nursing complement for each shift, though this was flexible when the staffing complement was low or patient acuity was high. Routine clinical communication such as nursing handovers, and the work of managing the shift resources was expected to be done on the open ward. Computer terminals and ward information boards were all in this space. All wards had a social space or break room. This was largely reserved for nursing staff and would be where they took their breaks. Doctors would take their breaks off the ward, either in their office or during a handover ward round. There was a large complement of student nurses in all sites across the studies. These team members were expected to store their personal effects (bags and coats) in the clinical area but were encouraged to use the break rooms.

Medicines were stored and manipulated in various spaces. There were trolleys next to nursing stations, wall mounted cabinets or lockable drawers in patient rooms, and specific medication storage rooms. Although organisational policies directed that all medicines be prepared in a specified enclosed room referred to as a "clean utility" these were often spurned by nursing staff in favour of the nurses' station. Medicines preparation was

observed to be a social task, with a preparing nurse sat or stood at the nurse's station referring to a computer screen or a hand-written prescription chart drawing up medicines that were due with in-process checks offered informally, usually on request.

There were relatively few dedicated spaces to other services or staff groups. Only one site had a specific space for the pharmacy team to work from, which was arranged with shelving and computer terminals to support medicines review and supply. Systems for the labelling and issue of medicines to patients were also provided in this space though these were infrequently used with pharmacy staff preferring to send items to the dispensary for processing. This space was exclusively for the use of pharmacy teams and was secured when not in use. Ward staff had no access, as proximity security systems were not enabled for this space. In other study sites, pharmacists and other allied health professionals based themselves at the nurses' station or at the notes trolley using laptops or paper notes.

7.2 The Professional Space

I observed that the work in these settings was highly social, with close personal relationships between staff within different groups. However, there was little shared relaxation in the work environment. Meals and breaks were taken separately. There was an informal "teatime" culture in all the units, but during the study this became increasingly infrequent and associated with

quiet times on the wards. On these occasions, nursing and administrative staff, occasionally medical staff and on two occasions myself would come together to relax, reflect and have some refreshment. Social conversation would mingle with work related discussion with transfer of clinical information that was not discussed during formal handovers, or to update progress for specific patients. However these social interactions were almost monocultural – primarily nursing. Other staff would fleetingly join these social moments to impart service information or obtain further information on a specific issue but they would not be part of it, they would join and then leave once their task was complete.

There was no space in the ward for teams to mix socially, and while there were clear parent spaces (kitchens or TV rooms) these were all closed "…due to COVID…." The impacts of COVID-19 may also have had other impacts on professional and parental boundaries, interaction and communication. Social distancing regulations led to restrictions on how staff could gather (though this was observed to be flexibly applied.) The doctors' office door was usually closed, both to maintain some containment of potential infection but also to protect the privacy and confidentiality of patients and discussions therein. This created a barrier to other teams seeking or providing information. It was often seen that nurses would "…wait until they come out of the office…" before raising an issue or asking a question. More senior or more confident nurses would knock and enter (or just enter) when grappling with a problem, but largely the problems requiring medical intervention were prioritised and banked for later.

Staff groups were not homogeneous. Within the medical teams, there were consultants, doctors-in-training, advanced practitioners (APs, healthcare professionals who have undertaken additional training in diagnosis and treatment who work within medical teams to support them) and physicians associates (PAs). PAs were only evident in one study site, where they undertook similar roles to doctors-in-training but were not permitted to prescribe medicines.

Medical teams were also arranged into “teams within teams” which formed and dissolved periodically, with tasks and responsibilities changing throughout the day. These teams were led by a consultant, who would work either 24 hours or three or four days “on-call” where they would take responsibility for all patients admitted during this period. Junior doctors were arranged into a day team, an evening team, and a night team. New members of the team would join and depart during the day. The day team was the largest and managed all patients admitted and discharged, but also attended to out-patient clinics. In the evening there were no outpatient clinics, so it was just referrals and reviews, and the night team admitted new patients and responded to changes in existing patients. The construction of these teams often made contacting the “right” doctor challenging for other staff members. Further, a great deal of time and effort of these doctors was taken up in dealing with referrals such that in one study site a dedicated consultant had been allocated to referrals from outside the hospital.

"…because our juniors are busy enough already on the wards, and a consultant working from home at the end of a mobile phone is much better placed to decide if a child needs to come in or can provide safety netting advice and stop an unnecessary referral." (Field note discussion, Consultant, CH2).

Nursing teams consisted of registered nurses, healthcare assistants who provided close personal care and supported nurses and families with hygiene, and clinical nurse specialists. Clinical specialists had received additional training in a specific clinical setting (for example, gastroenterology) and provided technical and clinical support to multi-professional teams and families who were part of those services. However, it was observed that these nurses were not ward based and were not allocated ward patients. Instead, they were available on request for additional support for those families. They too would have formal handovers, but these were twice a day, included the entire nursing team for each shift (those coming and those going) and coincided with the start and end of shifts.

The work in ward spaces was hierarchical with power and decision-making priority assigned to the nursing team as managers of the patient care areas. The ward was managed and overseen by nursing staff. Each ward had a manager – a senior nurse who was not part of the clinical roster but charged with overseeing staffing and day to day performance of the ward. There was then a nurse-in-charge who managed the shift and the resources available on that day. Medical staff would make the decision to admit patients, but it was the nurse in charge who would allocate resources – beds, nursing staff – to these patients. The pharmacy team were not a part of the ward hierarchy,

acting as an external service that provided medicines-related support and advice on a routine basis. The role of the pharmacy service was unclear. Their activities focussed on the verification of documentation about medication (prescriptions and drug histories), through which they identified potential and actual problems which they then escalated through the ward hierarchy usually via nursing staff or directly with medical staff.

The structures within the ward exemplified the separation between the actors in the system. Parents were effectively kept behind closed doors, nurses worked from the nurse's station while doctors worked from the doctors' office. The only space where the professions and parents interacted was on the ward round. The ward round was focussed around a single point – usually three or four clinicians would gather around either the notes trolley or a trolley mounted computer. This was an important part of the medical routine occurring in the morning, was led by a consultant or a senior registrar and involved the review of each patient in depth. There were multiple other informal information exchanges, termed as "handovers" where doctors would congregate for a brief exchange of status and information for each patient. These were sometimes viewed as duplication of work.

"Some complain that the handover is repetitive, and we'll just repeat the same stories and the same work each day…" (Interview 4, Junior doctor)

However other participants worried that the handovers were too brief and failed to capture all the information needed to understand the current

situation for each patient. This was often expressed as frustration during the ward round.

"But here I am coming on call for a three day stretch and asking about medicines that have been prescribed and no-one can tell me why…" (Interview 9, Consultant)

7.3 The Organisational Space

These professional and physical structures reinforced the separation of roles between medical, nursing and pharmacy staff. It was observed that though all these groups worked often in the same space, they worked in isolation. This was because their goals and objectives were subtly different. Medical staff were concerned with diagnosis and treatment (prescribing of medicines), nursing staff were charged with ensuring that treatment plans were executed (administration of medicines.) and the pharmacy service ensured that medication was available and supported medical and nursing staff in their tasks.

Pharmacy teams were separate from the clinical environment in all sites. Pharmacy professionals were a part of "Pharmacy" as a separate and autonomous service within the organisational structure. "Pharmacy" was described as many things – it was a physical place within the hospital where medicines were stored and supplied; it was a theoretical construct used to describe medicines governance processes and policies, and it was also used as a term to describe pharmacy professionals. While most ward staff knew

the pharmacy professionals by name, they were referred to amongst colleagues and to families as “pharmacy.”

“We’re waiting for pharmacy to do your TTO (discharge medicines).” (Field note, observation, GH1)

“How do I prescribe this medicine, do I just ask pharmacy?”

(Field note, observation, CH1)

“We’re waiting for pharmacy to approve that medicine.”

(Field note, observation, CH2)

The pharmacy service was charged with providing medicines to patients throughout the hospital and beyond, via the in-patient dispensary, outpatient clinics, home delivery services and aseptically prepared products. This led to demands on pharmacy staff to support not just the wards but also the other services within the pharmacy itself thus ward-based pharmacy services were prioritised alongside other pharmacy services.

There were enormous pressures laid on pharmacy services to turn around discharge medicines as fast as possible because there was an organisational perception that “pharmacy” slowed things down.

“The amount of time we spend chasing discharges when actually, the kids told they can go home, and the discharge letter’s not even written yet. Or we’ve done all our bits and they’re just assuming that because the discharge letter isn’t done, the meds haven’t been done. It’s never meds that delay a discharge and always tests, or letters, or reviews…” (Field note discussion, pharmacy technician, CH1)

“Yeah so we have this “Home by Teatime” thing, but discharge letters are always being written late, or one of the teams change the meds late and we need to get it all relabelled and redispensed.” (Interview 12, Pharmacist)

All pharmacy services to the participating wards comprised a pharmacy "visit" which lasted between two and three hours, was focussed on the morning.

"…because that's when most of our work is needed with medicines reconciliations and supply…" (Interview 7, Pharmacist).

The pharmacist would usually arrive between 9 and 10am, would ask the nurse in charge about any potential discharges and then review all the new patients. Two of the research sites also had pharmacy technicians who would conduct the drug histories on the new children leaving the pharmacist to focus on the clinical review of the medications. In all sites however this predictable arrival of the pharmacist led to the formation of occasional queues for advice and assistance. Again as with their approach to medical enquiries, nursing staff would gather their issues and hold them until a pharmacy professional arrived and then go through each issue line by line.

"I mean, you see what happens when I come onto the ward… I'm just mobbed and it really delays the other stuff I have to do." (Interview 14, Pharmacist)

After that pharmacy visit, the service fell back to a remote service via a bleep or direct telephone, but this was rarely used by ward staff. Where it was used it was usually to source medicines. It was observed that for clinical questions around the use of a medicine – dosage, preparation or

administration - when the pharmacy team were not around, there was a propensity for ward teams to work things out for themselves, and only contacting pharmacy services when there was no agreement on a course of action. When a decision to escalate to the pharmacy service was made, it was rarely to the bleep number that was available on the door, but a direct call to the pharmacy department using the telephone number that was invariably accessible next to telephones, or that people could remember.

"What's the number for pharmacy? Is it 1234?" (Field note, observation, CH1)

Despite the observed absence of pharmacy support, they were viewed as important elements of the team. Practitioners often described pharmacists as "lifesavers" or "walking BNFs" yet when asked what an "ideal pharmacy service" would look like, there was a focus on medicines supply ("…get the TTOs done quicker…") from consultants and nursing staff. From more junior doctors there was a desire to have them on the ward round "…to help us make safer prescribing decisions."

Pharmacists themselves often complained about not being "…in the loop…" on prescribing decisions and consequently many of their "interventions" were retrospective, after doses of an inappropriate medicine had been given. This complicated some reviews because it was observed that decisions around medication were often made verbally during ward rounds, or between medical and nursing staff and then acted on but not documented in great

detail. When a pharmacy professional came to review these orders, they were unable to find a justification or rationale for those choices, and this sometimes led to challenge and conflict between professional groups

"So on this occasion a pharmacist e-mailed me … highlighting that something had been prescribed incorrectly … and I was very quick to point out that the intention was such-and-such and so it wasn't incorrect…" (Interview 12, Consultant)

"Honestly, I just wish they would ask us before they prescribe something blind…" (Interview 9, Pharmacist)

"But we have discussed that medicine on the ward round, we've written our assessment and plan in the medical notes… For us to go back and write the indication or justification of every order on the prescription… no it would take too long." (Interview 18, Junior Doctor)

Medical work was structured around handovers and ward rounds. Handovers were informal short duration exchanges between shifts for the transfer of key information and progress from the previous shift between the junior doctor pool. They were strictly timed to less than half an hour and were often held in an office or other discreet non-public space. Ward rounds were formalised, and conducted in public and were of variable duration being dependent on the acuity of the patients admitted and the extent of review required. They were intended to provide a global evaluation of diagnosis, progress and decision making led by a consultant. From the ward round specific patient tasks (discharge letters, blood tests, booking investigations) were allocated to individual doctors on the team. Subsequent "jobs" were discrete tasks intended to answer specific questions raised in the ward round. Handovers were brief and focussed to specific issues, while ward

rounds were often more involved, in the patient space and involved the parents and other professionals in a haphazard way.

Ward rounds in all sites were entirely medical, led by a consultant or senior registrar with medical team alongside. Whether reviews were conducted in an electronic setting (using an electronic patient record) or traditional paper medical notes, there was always a consultant conducting the assessment and formulating the plan, and they would often dictate directly what the doctor should write, while offering explanation of the terms and approach through the writing. This formed part of the educational role of the ward round, as many consultants were observed to challenge and explore medical knowledge during the round and would often canvas alternative opinions of the problem and potential solutions.

Nurses would only participate in the ward round if requested by one of the attending clinicians, or where there was a problem. Occasionally a nurse would proactively join the ward round to participate in the discussion of one of their patients to influence the plan and offer their assessment, but this was dependent on the nurse and other ward demands. This absence was often observed as a weakness of the process. A consultant in CH1 observed that "… if the nurses were here on the ward round they'd know the plan and then not bleep us later to find out what the plan is…" but there were also other rounds ongoing in that site that there were insufficient nursing staff to undertake care tasks and follow the ward round.

This lack of nursing participation was exacerbated during the study when CH1 widened the patient allocation ratio from one to four to one to six. This was to deal with high nursing vacancies and sickness absence. While this was a pragmatic management decision to maintain safe care within the constraints of available staffing, it created issues for nursing staff in how they would organise their care scheduling for their patients. The ward environment had been designed with a 1:4 allocation in mind, and nurses were grouped in pairs within a "pod" of eight beds, and would manage four patients within this pod. Moving to 1:6 introduced patients outside the defined space of the pod and led to nursing staff moving between different sectors of the ward.

"I got bollocked by a doctor last week for not getting some bloods done in time for the ward round, but the patient was in blue pod and I was based in yellow and had two sick patients… I just can't keep track."
(Field note discussion, Nurse, CH1)

All wards kept supplies of medicines as stock that were stored in a centralised space (the "Clean Utility"). These rooms were of varying space and layout. Broadly they consisted of a system of storage cabinets, a refrigerator and a hand wash basin. There was also storage for drug preparation paraphernalia – syringes (parenteral and enteral) supplies of water (for reconstituting oral liquid medicines) and vessels for the preparation and administration of these medicines. Consequently the rooms were often cluttered and nursing staff (for they undertook all medicines preparation work) would have to move things claim some space for their work. None of

the observed rooms had hardwired computer terminals within because of space constraints. In CH1 a computer-on-wheels (COW) was based in the room, plugged into the wall. In CH2 nursing staff relied on handheld tablet computers to undertake their work. It was clear that none of these spaces had been constructed with an electronic patient record in mind, and consequently there was no space for well positioned ergonomic computer workstations.

It was also seen that these storage rooms were insufficient or ill-suited to fast and efficient access to medicines, or storing medicines specific for patients. Thus there were drug trolleys at nurses' stations, metal boxes with digital locks mounted outside patient side-rooms or drawers in bedside cabinets that were also locked that were also used for storing medicines. In one ward, there were over 10 keys required to access medicines from fridges, cupboards, lockers and drawers,

It was not uncommon to see cabinets heaving with medicines. Each ward maintained a stock of drugs which essentially captured a core formulary and then some additional medicines that would be considered "routine" in that area. Nurse leaders doubted the necessity for such exhaustive stock lists.

"Let me tell you, no ward needs a stocklist of 200 items. That's why they can never find anything…" (Interview 14, Nurse)

This perception was support by my observations. Medication that was available in the ward was often obscured or overlooked because of the clutter.

"Sometimes it's just easier to order it from pharmacy…" (Field note discussion, Ward Manager, CH2)

Pharmacists similarly complained of missed doses of essential medicines when the product was stocked on the ward.

"They just don't look for it, and if they can't find it they just skip the dose." (Field note discussion, pharmacist, CH1)

The hospital policies in all sites was that medicines administration checks had to be "independent" – one nurse would draw up and prepare the dose and then a second nurse should independently verify the preparation and calculations. In all sites, people told of many previous medication errors were attributed to nursing staff not undertaking the checks properly.

"If they'd just done their checks properly, then that error could have been avoided." (Interview 10, Pharmacist)

Yet truly independent checks were only observed to be undertaken a handful of times because there were insufficient time and nursing staff available to support them. There was some debate among nurses about them. Some wanted to adhere at all times, but couldn't partly because of workload and accessibility, but also because they felt pressured by their peers to pare back

the checks. However, other nurses considered independent checks as performative and offering little value.

"The dose hasn't changed in the last three shifts I've been giving it, so why do I need to go through the process of checking it in the BNF…. It was right on Wednesday, it's right today." (Field note discussion, Nurse, CH1)

Medicines were routinely "signed for" at the completion of preparation rather than on completion of administration.

Nurse 1: "Right love, I've got amoxicillin, 125mg in 5ml, 5ml due now at 8 o'clock…"

Nurse 2: Reviews bottle, syringe of yellow liquid and prescription chart with Nurse 1 stood next to them. "Yep, that's right. I'll just sign that off for you.." (Field note observation, Nurses, GH1)

All research sites had acknowledged the resource burden in mandating independent second checks, and had introduced limited lists of "single check" items, where the product could be legitimately checked by a single nurse. Yet the selection of these products was occasionally perceived to be illogical and unpredictable.

"So, ibuprofen isn't single check because apparently the renal team worry that we'll give it to a kid with renal failure, but I'm not sure how that'll stop that… we give it to pretty much everyone. Oh, and here's a good one… salbutamol inhalers absolutely fine single check, but the minute you want to use a yellow spacer… double check…" (Field note observation, Nurse, CH2)

To help nursing staff awareness of these products, visual prompts were appended to electronic orders to signify those items where a second check was still required. However with paper based prescribing systems such signifiers were not present, and nursing staff relied on their memory or laminated lists of "single check" medicines that were appended to walls.

This lack of time and resources to undertake full independent checks presented another condition in the work environment around distractions and interruptions. Distractions were everywhere in the environment. Devices would alarm constantly, the doorbell would ring requiring attention, or parents and patients would seek information or support. There was a clear view from all the professionals involved that "distractions" were a major cause of medication errors but distractions were poorly defined among those observed or interviewed. There was a range of views, from the "… leave me alone, I'm checking medication…" to a more pragmatic "You'll stop if someone's about to arrest, or there's an emergency…" There were stories of interventions to mitigate these "distractions" on all sites. Doctors told of the use of noise cancelling headphones and experiences of dedicated "prescribing areas" to support safe medicines prescribing, but none of these interventions were observed as being actively in use during the study, and no participating area had any easily identifiable space for a dedicated medicines area, other than those organisationally determined spaces described above, to which medical staff had no access.

Most organisational interventions were to support nursing staff in medicines administration through the use of specific aprons or tabards to mitigate interruptions during medication preparation. One site had purchased specific red plastic disposable aprons with "Do not disturb. Medication round in progress" printed on them. They were never observed to be used despite

being available directly on the medicines trolley at each nurses' station. Several boxes of these aprons had laptop computers balanced on them. Another site had adopted these aprons into practice but they were not seen to be used and this had been observed by the management team.

"…but we never have them when we need them. If we run out of white pinnies, we'll just use those and then won't have them." (Interview 14, Nurse)

None of these interventions were in place routinely because they were not available in the right place at the right time, they were inoperable or new staff came through and were not aware of the intervention. In one site, the red aprons were provided in the nurses' station on top of the medicines trolleys or in medicines storage rooms, but were not available near patient bed spaces. There was a conflict between the use of red aprons and established trust infection prevention and control measures during the pandemic which required all staff to gown up on entry into side rooms – either a clean apron, gloves and face visor, or full personal protective equipment (PPE).

Medication processes were performed in the open in a social setting. Parents would interrupt for updates or to advise that their child required some help or intervention. In some circumstances, parents would also request medicines for their child that were due, arguably a supportive interruption, but an interruption nonetheless. Medical staff would interrupt processes to seek information and clarification on progress. A nurse observed that whether they were wearing a red apron or not:

"…someone needs something off you and they're going to interrupt you whether you want them to or not." (Interview 02, Nurse)

Everyone had specific tasks and responsibilities and were focussed on those, with scant consideration of other people's priorities.

The day-to-day life of a busy children's ward was also a source of constant distraction and interruption. Broadly speaking, all participating units employed receptionists or ward clerks – administrative support roles to provide front of house and back-room functions (for example ordering stationery, signposting staff and patients to hospital services, and answering phones.) However, the way these staff were utilised appeared quite variable. In CH1 the ward clerks and receptionists were based in a closed office at the back of the unit and the nurse in charge based themselves at the nurses' station at the front of the ward nearest the main entrance. This meant that nursing staff were essentially acting as the meet-and-greet of the unit, while administrative staff were largely absent. Meanwhile in CH2 and GH1, receptionists were the first person anyone arriving on the ward (including myself) would meet. They managed the access to the ward and handled many more mundane enquiries.

"Between 8am and 4pm, we don't answer the buzzer. The ward clerk does it for us." (Field note discussion, Nurse, GH1)

But then at all other times the burden of answering the door and identifying visitors fell to the nursing staff. There were many times that I was kept waiting at the door while someone answered the intercom. Occasionally

other members of the care team would assume this duty, but this was opportunistic related to whether or not they were sat next to the intercom at the time.

The organisation itself created frequent interruptions to care provision. In one site, in response to capacity pressures in the emergency department the hospital management requested that several patients be transferred to other wards simultaneously, which demanded reprioritisation of work and rescheduling of care across the entire ward.

The allocation of patients and the levels of care that were accepted in each unit were unpredictable. It was not uncommon for these wards to care for extremely sick children. Teams would manage these patients well, but would frequently have to sacrifice other care duties for other people to accommodate them. In one site a patient who in the view of the managing nursing and medical team needed escalation to paediatric critical care continued to be managed in the general ward. While there were wider concerns about "best interests" of the patient, there was a stated view from the lead nurse for the unit that

"…the ward are providing exemplary care, and therefore this is the best place for them…" (Fieldnote observation, CH2)

The patient consumed a whole nurse each shift in managing their care and maintaining their safety, which placed strains of the remaining nursing staff. Similarly in another hospital it was common to nurse patients with relatively severe asthma in the general ward "…because we've coped before…" But

this placed massive burdens on the caregivers around them, with no change in allocation to account for it.

"If you get a sick asthmatic on aminophylline, you're going to be there all shift doing hourly nebs and blood gases and cares and you'll still have three other patients to look after… you'll just be chasing your tail all day." (Fieldnote discussion, Nurse, CH1)

Work within these complex settings was supported by a considerable library of clinical policies and procedures for the use of medicines which established the practice boundaries within which professionals were expected to work. All sites had an overarching medicines policy, which in two of the three sites did not carry specific references to children or children's medicines, but instead was held as an abstract statement of minimum standards of practice for medicines regardless of location and nature of the patient. This generalised approach was viewed with suspicion by clinical teams who perceived that it meant the organisation had no understanding of the "unique" needs of children and young people. However, it was argued that children

"…are no different to a 90 year old with dementia in one of our rehab wards, and we need to account for that…" (Interview 14, Nurse)

Policies were intended to offer professional and procedural flexibility to nursing and medical managers when dealing with their patients, but created ambiguity on the shop floor. For example, pharmacists mentioned problems that occasionally occurred because of nursing staff not using the "prescribed" formulation on the electronic order entry system. Where a medicine was available on the ward, but not in a formulation that was stipulated in the

medication order (for example, omeprazole as an oral liquid suspension prescribed, but only omeprazole dispersible tablets available) nursing staff would use what they had on the shelf "…because it's better to give something than nothing." Sometimes this led to negative patient outcomes.

"Yeah, so they used an omeprazole tablet and it blocked the poor kid's gastrostomy and they had to go to theatre to have a new one placed…" (Interview 9, Pharmacist)

However these problems emerged because the formulation switch was enshrined in a policy which permitted nursing staff to administer a different formulation to ensure medicines doses were not missed. A policy designed to prevent unnecessary omitted doses indirectly contributed to other adverse outcomes. This policy-driven need to give "something" created conflict with families with specific needs that were often ignored or overridden by nursing staff trying to avoid a missed dose which contributed to patient anxiety.

"So they know that she only has tablets, the liquid makes her sick, but every time I'm here I see them using a liquid and they've gotten it from another patient, or they've gotten the doctor to represcribe it and it's just… it's because it's quicker and easier for them to do that." (Interview 19, parent)

Clinical guidelines were constructed to support work within stated clinical situations and conditions. There were guidelines for epilepsy, asthma, and other common presentations on all sites, and technical directions on how to prepare and administer medicines. They were all structured to direct action in specific situations, and requested specific actions, investigations and treatments. Sometimes, the guideline did not offer appropriate information in order to make a decision, and in these circumstances professionals were

seen to fall back on their own previous experience or those of others around them. If that was not possible (for example on a night shift when there were fewer people around) then people would reach for the internet.

"Oh, always phone a friend if you're stuck and I keep a WhatsApp group for these sorts of things. And then Doctor Google is quite useful."
(Fieldnote discussion, CH1)

Yet some professionals frowned on this approach to obtaining information.

"I don't like having my phone out on the ward… it looks unprofessional… maybe that's just me and an experience I've had…" (Interview 7, Consultant)

The issue of access to these guidelines and processes was a common theme in all sites. In the main they were held on local servers, accessible through an intranet but in all cases practitioners had to know where to find these documents either by location or through a title. Titles were often not predictable or logical. In one situation, the junior doctor on duty was unable to locate the sepsis guidelines for children.

"We searched for it on the intranet everywhere. We found the adult one no problem, but couldn't find the children's one anywhere. It was the nurses who told us what we should do and I think someone on the nightshift has now printed off the summary page and pinned it up in the doctors office." (Interview 15, Junior Doctor)

Unsurprisingly, the internet was the single most important space for holding information. As well as guidelines and resources, patient record systems were often web-based and there was a clear reliance among workers to communicate with colleagues using internet-based platforms. While all sites

provided various ways of accessing these resources, most staff used their own personal cell phones.

Given the organisational reliance on internet-based information storage and access, most sites had introduced technological interventions to support "medicines safety." Two sites had complex electronic health record systems (EHRs) that included a prescribing module. The interfacing for these systems required access to computer terminals. On one site this was facilitated through computers on trolleys, and hard-wired desktop stations. In another there were computers on trolleys, hard wired terminals and a library of handheld devices. These devices were available on a common-use basis with professionals using the first available device when needed. This inevitably led to issues with maintenance and upkeep. It was not uncommon for devices to be low on battery, or in need of a restart for the installation of updates at the point of use. This would add on considerable time to task while waiting for the computer to log in.

However, in one site there was some suggestion of inequity in the provision of IT equipment. Some other teams were observed to have their own mobile computers which were configured to their preference. A clinician inadvertently left their laptop on the study ward when leaving to attend another patient and returned some time later to reclaim it.

"Oh thank God that's here… I didn't want to use one of the ward machines because I can't find anything." (Fieldnote observation, CH1)

These laptops offered some physical insights into the work being done. They were 40cm long and 17cm wide, and weighed around 2kg yet they were carried around under arms, in hands or in satchels. Laptops then required a surface on which to be deployed on use. Again, this would be any free surface and it was often seen that a computer on wheels was used as the rest for the laptop while rounds and reviews were conducted, which removed this resource from the pool.

One study centre had also implemented bar code medicines administration (BCMA) to support a closed loop medication administration process, with external independent verification of drug, patient and time using medication barcodes. At the time of study, these barcodes were the proprietary barcoding applied by the manufacturer to an original pack. New handheld barcode scanners had been procured to support implementation. A single hardwired scanner was made available at each nurses' station which staff were expected to share between their other barcode related tasks – blood products and feeds. During each observation period at least one of them was inoperable. Consequently I frequently observed scanners being disconnected and moved between workstations and other devices.

During the study it was reported that "compliance" with BCMA in the study ward as <5%. I was able to present a brief precis of the operational issues observed to the medicines safety team to support them in making later improvements. Following this, specific barcode workstations were created

using a trolley, a laptop and a specific barcode scanner (in addition to those in the nurse's station.) However, the perception among nursing staff as the only staff who used BCMA was that little had improved.

"Now you've gotta wheel this thing to the patient's room, but we can't take it into the room cos of covid. And we still need two nurses to do it because of the double checking policy." (Fieldnote observation CH1)

One of the trainee APs who was formerly the ward manager walked me through the BCMA process. Once the patient and the medicine were identified, the nurse would locate the medication from the ward store. They would then scan a barcode on the packet

"…but not all the medicines have a barcode on the actual container. See this here – the barcode is only on the outer box and not on the bottle inside so we're all nervous about someone putting the wrong bottle in the wrong box – it happens all the time. And if there is a barcode on the bottle inside there's no guarantee that there won't be slicked residue down the side of the bottle obscuring it." (Fieldnopte observation CH1)

They talked through the scan process, and on this occasion the barcode wasn't recognised.

"So this happens all the time, when its parents own medicines and it's something that we don't keep here, or just if the pharmacy haven't caught up registering all the barcodes…" (Fieldnote observation CH1)

It prolonged the checking process, and busy nurses predictably chose not to comply with BCMA. During a live administration process, I watched as two nursing staff were drawing up a dose of amoxicillin.

"Right, does it have a barcode on the bottle?"
"No, it doesn't."

"OK, and someone's thrown the box away so I'm not fannying about finding another one. I'm going to override because it'll delay care."
"Override away. Happy for that." (Fieldnote observation CH1)

They had also prepared two nebulisers of ipratropium and salbutamol "…and none of the amps have a barcode so off we go…" The checking nurse entered their identity credentials manually and the process was completed.

This was the second time the ward had attempted to implement BCMA. One of the ward nurses who was part of the implementation team described the initial failure of implementation.

"They just launched it last year and it fell on its arse. No one used it, so we stopped and reviewed and then we're trying it again." (Interview 2, Nurse)

When discussing casually with nursing staff, it was suggested that no one in authority had considered their workloads or workflows

"…so they introduced this thing telling us it was safer, and we get that but we just can't use it because the scanners never work, and you can't take these massive laptops into side rooms…" (Fieldnote discussion, Nurse, CH1)

During observation it was also possible for me to get other perspectives from other professionals. I was able to have an informal conversation with a senior pharmacist who was covering the ward that day.

"Oh God… it's just going to the same way as last time. It's shit. Nothing works, pharmacy don't put barcodes on everything so… it's no surprise. The chief nurse is asking if we should just bin it if it's not being used, but the nurse managers want to keep using it because it's almost a monitoring tool – they're using it as a surrogate for second checking…" (Fieldnote discussion, pharmacist, CH1)

Throughout the study it became apparent that while technology was espoused as a method of improving the quality, safety and efficiency of care, it was also used as a monitoring and measurement tool for staff and their work. This was evident in all sites, from the barcode compliance referred to above, to ward "dashboards" and quality review statistics EHRs generated huge amounts of data to measure and manage work. Work was governed in CH2 by a large flat screen television on the wall beside the nurses' station that provided real time information on patient status and early warning scores, but also gave visual alerts to "overdue" tasks.

"Yeah so when something's red it means it's overdue, amber means its due. When a kid comes to us from somewhere else it automatically changes to red…there's a policy that when a child is admitted to us from another area, their obs need doing within 15 minutes, even where they were done just before they left the other area… so it automatically goes to red. It creates some anxiety for the more junior nurses if we're busy, but we just do it when we can." (Fieldnote Discussion, Nurse CH2)

The ward manager took me through a large blue folder on their desk labelled "Audits" and flicked through the pages and pages of data that they were expected to collect on a daily or weekly basis.

"So for medicines we have these eight questions – is everything locked away, are the drug rooms tidy, are the fluids off the floor – which we go through every week, and then I send them back to the matrons every month. Pharmacy have their own medicines audits which they do every quarter…" (Fieldnote discussion, Nurse, CH2)

The reasons for these duplications of data collection were explained by a nurse manager.

“You get real insight when you have different people auditing the same thing. If there’s an event we’ll often send one of our colleagues down to do some fact finding and you’ll often uncover issues that aren’t picked up in the regular audit...” (Interview 14, Nurse)

Altogether, the motivations for implementing technological interventions for medicines safety and quality were admirable and for the right reasons. However, there was a systematic lack of consideration of the impact these systems had on workflow, and on the way people interacted with them in the live work environment. While there were assumptions that mobile phones could be used to access information on demand, reflections on the challenges to professionalism that this assumption overlooked were surprising. What wasn’t surprising was the reluctance of staff to have work-related applications on their personal phones. This exemplifies real issues with provision of equipment to support interaction with technological interventions, with a clear drive to the absolute bare minimum amount of kit needed to get the intervention into place, rather than what would be needed to support the intervention’s implementation (including redundancy and device design.)

The drive to use technology as a way of monitoring care and clinical service provision was also a predictable outcome of these interventions. What was unexpected was the suspicion that these interventions generated among shop-floor workers around performance management and monitoring which further eroded trust and compliance with the interventions.

7.4 Chapter Conclusions

It is clear that the space in which work is done both defines how the work is delivered, and is defined by the assumed nature of the work. While healthcare work is complex and social, requiring the development of relationships between multiple actors including healthcare professionals, patients and their carers, the environment is designed such that these groups of people do not naturally share space, or work together except in relation to specific tasks. The presence of specific workspaces for these different groups reinforces professional boundaries that only more experienced colleagues will breach. These spaces are maintained when actors are working in shared spaces because of differing objectives and priorities.

Furthermore, the working environment may be said to reflect the way services are structured in modern healthcare systems. Medical, Nursing and Pharmacy teams were all separate and had defined and discrete objectives, and there is a suggestion in this chapter that these objectives are not fully understood by all actors. Consequently it can then be seen that communication between all the players in this space was compromised which led to specific adaptations in the way teams worked together with the development of “huddles” in some centres which presented a fixed and formal opportunity for sharing plans and objectives for the coming shift.

The space in which this work is delivered also created a constraint on work that most actors adapted around – the movement of medication preparation work to nurse's stations appears to be related to multiple drivers - the proximity of computer terminals; being present and visible; and because designated medicines preparation spaces were not of sufficient space to support the extent of medicines preparations required in them. That being said, in the sites with portable medicines interfaces (either paper prescriptions, or tablet computers) there was more preparation work undertaken in specific spaces. It was clear that medicines preparation was undertaken wherever there was co-location of supply and information.

Alas, those sites that moved towards technological intervention to support patient safety didn't appear to consider how those technological interventions would fit within the environment constraints. The move to BCMA in one site didn't appear to have been designed around existing workflows and presented more barriers to successful integration than it was perceived to resolve. Technological interventions such as these have also been used as an assurance tool that policies and procedures are being followed, and there is little sign that these are interpreted in the broader systems context.

What we have demonstrated in this study however is that distractions and interruptions in medicines processes are constant events. These interruptions are related to the disjointed way in which services and spaces are designed – people have jobs to do in a defined period, with only limited

information to deliver the task and there is a need to get information as quickly as possible. Key information transfer points were not multi-professional, and are not scheduled at times that suit all services. The environment – the physical, professional and organisational space – means that actors within the space have to communicate and build relationships. Some of these may be considered as distractions and interruptions, but they are essential to getting the job done safely and effectively. In the next chapter, I will explore how communication “works” within the system.

8 Cognitive Aspects – How Healthcare Workers Work Together

The patterns of communication and interpretation of information between actors in the system was seen to be an important theme in the way medicines safety work was enacted. In this chapter, I will explore the features of communication seen during this research – the effect of training and expertise, how teams problem solved, and how components of the system interacted. This chapter will also consider organisational aspects of communication including documentation, the presentation of practical guidance, and how "patient flow" through the system impacts communication and safety.

The system in each study site was characterised by multiple teams working together – medical, nursing and pharmacy teams. As we identified in Chapter 7, they shared resources and equipment. These resources included space, and information. There were discrete and defined tasks associated with specific staff groups. Medical teams managed patients, their diagnosis and treatment. With regard to medicines, this essentially meant that prescribing was largely done by medical staff and members of that team. Nursing staff provided personal and holistic care to patients and ensured that treatment plans determined by medical teams were implemented and completed on time. Pharmacy teams reviewed prescribing and medication supply, and supported the movement of patients through the healthcare system ("flow") by ensuring medicines were supplied promptly when

requested. Flow was the term used to describe the movement of patients through the system, from admission to discharge. Expected discharge dates (EDDs) were calculated on first admission based on the presenting complaint and initial diagnosis and were prominently displayed on patient dashboards and medical and nursing documentation. It was often seen that bed co-ordinators in each hospital would refer to these EDDs when enquiring about patients approaching or ready for discharge.

8.1 Training and Expertise

The apparent head of any patient admission was the consultant paediatrician. The role of the consultant was one of leadership, overseeing the management of their patients and supporting their more junior colleagues in assessment and decision making. Medical staff had a range of experience, from their first years of post-graduate training (Foundation Year (FY)) up to near-consultant level training. One site stated that the most junior FY trainees were “supernumerary” – they were not part of the formal staffing establishment - however they were seen to work and be used as substantive members of the team. They were allocated patients and on occasion held the on-call pager and the cardiac arrest bleep. It was apparent that their supernumerary status was in name only, as without those team members the service would struggle to manage its caseload. There were a small number of specialist trainees (registrars) but for the most part medical care was provided by doctors who did not have paediatrics as their primary interest – general practice trainees and emergency medicine trainees.

The undergraduate exposure and experience of medical students to paediatrics appeared to be quite limited.

"I think because we have fairly limited training in paeds…, I mean… when I say limited, in year three we have a four week rotation, in year four we have a four to six week rotation, and then in year five similar again, but the rest is adult medicine." (Interview 9, Junior Doctor)

"I haven't had my degree here in the UK, I don't know really how much of pharmacology people study. I had a pharmacology course in year four of medical school, it was a long course… I think doctors mainly need more pharmacology teaching, to be honest. We need to know what we are prescribing…" (Interview 18, Junior Doctor)

In GH1, an American resident paediatrician was participating in the service as an observer and over the post ward-round coffee break opened up a little about his experience. "I mean, it's really weird seeing how you work here, compared to me back in California. You guys know how to site a cannula, suture, but where's the science? I can't do any of those things, but I know pharmacology inside and out, and can't pass my board certification without it…" A local doctor asked about the cannula. "Oh, the nurses do that, to the point that I'd probably be fired if I tried to do one myself…"

Nursing teams were described in Chapter 7, but it should be noted that while very few medical staff were specifically qualified in management of paediatric patients, all nurses held specific qualifications and registration (Registered Nurse (Child), RNC).

Pharmacy teams were less easily defined. Each ward received a visit from a clinical pharmacist, and this pharmacist varied depending on the availability of staff in the pharmacy department. One study site had a single dedicated pharmacist. When they were not available there would be a visit from another pharmacist who had received in-house training regarding paediatric pharmacy and had had an introduction to the ward but it was not their primary area of work. In CH1 and CH2, the ward pharmacist was a relatively junior pharmacist who would spend three and four months in this space to "learn the ropes." They were "rotational" and would move on to another service after they had completed their time in this area. The pharmacist was usually a lone representative of the service and was supported either remotely by a senior team based in the department, or on a more formal basis through direct supervision and assessment. There were other pharmacy teams that participated in the ward service, in the form of pharmacy technicians. These teams were either ward based, or based in the dispensary and would focus on taking medication histories from patients, and supplying medicines.

All pharmacists observed in this study had other responsibilities within the wider pharmacy department which meant that their time in the ward was limited. It was observed that most pharmacists would fit their ward commitment around their other jobs and roles. During this study, there were considerable workforce pressures, and in some cases there was no pharmacy service provided to the children's wards with the expectation that if the ward required anything, they would have to contact the pharmacy for it.

In observations, none of these teams really worked together formally. There was no formalised space for nursing or pharmacy representation on the ward rounds or handovers, though those staff members would attend a round or handover in order to deal with a specific issue or seek information. However, these occasions were few and far between, but did present some interesting reflections on how the teams managed challenges and uncertain situations particularly around medicines.

8.2 Problem solving

The systems within these units was hierarchical, and where challenges were encountered problems would be "escalate" to the next rung on the hierarchy to identify the right person to deal with the problem. With medication, this was often to the medical staff, in part supported by policy drivers to "…refer to prescriber…" to clarify ambiguity and inconsistency. As noted by two experienced registrars in CH2, many of these "escalations" were observed to merely pass a problem from one person with limited experience of the situation to another with a similarly low experience base.

"Yeah, doctor informed… that's a great one to read in the notes. Informed of what? You've often got less understanding of the problem than the nurse who "informed" you…"

"It's just a way of passing the buck isn't it really?" (Fieldnote discussion, Doctors, CH2)

It was commonplace in observed escalations like these that the doctor would ask the escalating nurse “Okay, and what do you want me to do?” (Fieldnote observation, CH1)

This reflects the nature of how medication related problems were identified. These issues were seldom identified as primary problems but were incidental findings. Medicines were prescribed by medical staff or APs with reference to dosing guidelines and manuals (e.g. the British National Formulary for Children (BNFc)) but there was often inconsistency between these documents and practice. Further, there were also the expectations of parents about their child’s medicines which often did not reflect the practice of prescribing and administering that was recommended within the hospital. And finally, there were situations where acute changes in the patient’s status had an impact on the medicines for those patients and required some form of action.

These problems were described as “emergent” – they were frequent, but often unpredictable. They were rarely picked up by the prescribers, so they were mostly intercepted and identified by nursing staff or parents. They were then escalated through the shift co-ordinator or “nurse in charge” or through the medical team. Most nurses would escalate medicines related problems directly to the doctor, who would then fall back on their past experience and knowledge to evaluate and determine the course of action. Where the doctor lacked the requisite knowledge or experience, they would reach out for

"advice" to the people around them – sharing their experience and knowledge. One junior doctor described how it worked;

"Yeah, so, I've been around a bit so I'll think if I've seen something similar before. If I haven't then I'll ask my colleagues on the ward with me, as someone might have seen it. And then if that fails then we'll reach out to the nurses who have seen and done a lot, or we'll go to Google." (Interview 6, Junior Doctor)

These issues were often resolved quickly and locally. Where there was uncertainty or a reluctance to make a decision, then the junior staff escalated their questions to the consultant. Medical staff were confident of their boundaries and limits but some consultants worried that on occasion these boundaries were misplaced, or confidently overlooked. Some consultants wanted to be "kept in the loop" even when the junior medics on the shift perceived that they could handle the problem. It was likely that this was because sometimes small problems in isolation became bigger issues when viewed in the wider systems context, and consultants doubted that their junior colleagues had the systems view to spot when that was happening.

Acute children's wards were not isolated systems, and were affected by decisions and problems in other departments. For example, in response to high acuity in the Emergency Department (ED) at GH1 over a night shift, the ED consultant started directly referring children and young people to the Children's Ward in an attempt to manage capacity. The nightshift medical and nursing team got on with the work, and managed all the patients that were sent up. At the morning handover the on-call consultant was heard

complaining "…well no one called me to tell me this was happening." Following the handover and at conclusion of the ward round, it was possible to explore the concerns of the consultant privately. They perceived their role was to provide supervision and leadership but also to provide managerial capacity and authority to challenge potentially disruptive service changes, and to provide additional capacity to support the wider team. However, the view of the nightshift team were that the referrals from the ED were no different to patients coming for assessment from GPs or community teams which was a part of their normal day time work. They were supported by established processes through the daytime, and these had utility in the middle of the night as well. Thus the focus of the night shift team was on the immediate problem of each patient as a single entity, rather than on the impact that all these patients would have on the ward system as a whole. The consultant however appreciated the potential knock-on effects that the isolated decision from the ED had on the safe functioning of the Children's Ward as a system in itself, and would have intervened with ED to mitigate these risks.

This focus on the immediate "presenting medical complaint" was not restricted to crisis situations like the above. It was clear that this focus was the norm for practitioners on the shift. A relevant example for this research would be around the capture and documentation of medication histories during initial clerking. Especially for patients with medical complexity, medication histories were captured but only in the briefest of terms with the names of drugs and often the doses in a liquid volume which presented

issues in assessing appropriateness of medication dosing later during nursing or pharmacy rounds. Medical staff were aware of their roles with medication history taking but "…honestly we're just firefighting on nightshifts, so some things just don't get done…" The pharmacy service would often pick up the medication histories "as written" and then add more detail. Indeed, a consultant related that it was often "pharmacy" that unveiled medicines related problems that were not otherwise detected or considered because they didn't relate to the immediate medical problem.

"So we had a patient who was experiencing an adverse event for several days, and we didn't know why. And it was the pharmacist that identified that the reaction we were seeing was probably related to their doxycycline, so we stopped it and the reaction resolved." (Interview 9, Consultant)

By their very nature, these "interventions" were often reactive and many problems related to medicines were detected post hoc. Pharmacy professionals were not part of the ward hierarchy and were not present on ward rounds or handover. Consequently their role was one of secondary review which created tension between professional groups. When approached by a pharmacy professional with a question, medical staff would joke "Oh god what have I done wrong now?" and there were occasional examples of praise for doing a medication history well or prescribing something properly.

"I submitted an excellence report for a junior doctor who did a perfect drug history and scheduled all the medicines for the child's routine at home…" (Interview 8, Consultant)

Notwithstanding these examples, there is a clear suggestion that time is a clear issue in making thorough, detailed assessments and documenting

histories. Medical staff are capable of identifying and acting on suspected medication related problems when they have the time and capacity to do it.

"So we had a small baby, very sick with flu, and she had been started on Tamiflu (a specific antiviral for flu). Anyway, a day later we noticed that her liver function tests (LFTs) were deranged, and the consultant asked me to find out what was causing it, and if it was the Tamiflu. I could have asked the pharmacist, but they weren't around and the ward round was done quickly so I was able to go and read around on the case. At the afternoon handover, I said that it was possible that the Tamiflu was causing the deranged LFTs and we stopped it. A day or two later, the LFTs were normal again…" (Interview 18, Junior Doctor)

8.3 Interactions between teams and services

General paediatric care was a single service that was provided within a wider complex system of multiple services. While it is focussed on child health, it is recognised that children have a range of pathologies and diseases and thus there are myriad sub-specialities. It is not dissimilar to the wider model of acute care provided to adults. Many children and young people are admitted acutely unwell and are managed by the General Paediatric team. Some patients will then be managed under this service until they are discharged (which accounts for the majority of acute admissions). However, others may be transferred to a single speciality team (e.g. neurology, gastroenterology). Within large tertiary services such as CH1 and CH2 these referrals would be made concurrently and the specialist team would come to offer review and advice in the acute ward, or would accept their care from the acute service and request transfer to their ward. In GH1, there was no co-location of these higher services, and referral or requests for advice were made via telephone. Many referrals or decisions could only be made by the consultant which created problems with patient flow and information sharing.

A medical team had made a clear plan that the child could go home "pending micro advice…" but by early evening no advice has been offered. The trainee on call for the evening called the microbiologist asking if the culture results were through; "Right, so you'll only discuss with a consultant? The kid's fine, apyrexial, CRP normal… we just need to know what's in the blood cultures if anything… Right, okay but I don't know where my consultant is and the family need to go home." The "consultant to consultant" discussion was not unique to GH1. In CH2 the neurology team came to review a new patient that had been referred from the general ward round. When their team arrived, the general paediatric consultant and team had already left and the nurse looking after the patient received the team.

> *Neuro: "Oh this isn't good enough. Where's the consultant?"*
>
> *Nurse: "Just gone up to the other ward"*
>
> *Neuro: "Well I'm a bit busy so I'll just have a read of the notes and then I'll go find them. They did want the review didn't they?"*
>
> *Nurse: "They certainly did." (Fieldnote observation, CH2)*

This interaction was fairly typical of discussions between specialist services and the general services in all hospitals where the general service was considered to be less skilled or capable than the specialist service. There were episodes where specialist services would bring patients in for a detailed hospital review and admit them to the general paediatric service initially. This irritated clinicians.

"I just feel like there's been no discussion with me over this child. If that team wanted them to come in they should have admitted them to their own

ward, because now I feel like we're just doing the donkey work for them to come in and tell us what to do…" (Fieldnote Observation, CH1)

Conversely, In GH1 a patient needed to be transferred to the tertiary centre to have their implantable venous access device (referred to as a "port") reviewed as there was evidence of infection and tissue deterioration. The referring consultant however was unsure, not because they weren't sure of the diagnosis, but were concerned about the subjective assessment of the tertiary site.

"…Are we sure that this needs to go there, because I don't want us to be marked as just another DGH that can't manage a port…" (Fieldnote observation, GH1)

Because of this sensitivity to the actions and decisions of other services, which created uncertainty about the abilities of their team, there was some difficulty in asking junior doctors in this wider context to make "big" decisions, and senior clinicians felt the weight of responsibility such that the hierarchy within acute paediatrics was well defined. This was reflected by the consultants themselves.

"Y'know we have a really junior workforce – foundation year one doctors, GP trainees, early paediatricians… they need a lot of handholding and support, which is why we're around as much as possible. I always say "bring it to me and we'll discuss…" (Interview 6, Consultant)

"We had one doctor who subjected a child to all sorts of tests for diabetes because a blood sugar was raised. I reviewed the patient the following day and they had also been on high dose steroids – dexamethasone – which will raise your blood sugars so we discussed the tests and it was clear they hadn't considered that." (Interview 6, Consultant)

And yet it was observed that when specialities came to offer advice and opinion which differed with the treatment plan there was a difference in the way these were managed.

In the tertiary centres (CH1 and CH2) these speciality decisions were generally accepted without question and plans made regardless of the impact on patients. A child admitted with uncomplicated periorbital cellulitis had been stepped down from IV to oral antibiotics by the general paediatric team, with a plan to send them home. During the ward round, it was decided to ask the Ophthalmology team to review the patient "…out of courtesy…" and when they came to review the patient later in the afternoon they overruled the switch to oral antibiotics, and recommended a further 72 hours of IV antibiotics prolonging the patient's stay. The medical staff attending this patient was visibly frustrated by the change in treatment plan, and on the phone to their consultant were heard to complain "…because if it was earlier in the day I could have sorted them IV antibiotics at home and they could have still gone…"

At GH1 specialist referrals were treated somewhat differently. Where a need for specialist review was identified, there appeared to be two pathways. The first was for urgent referrals which required sending the patient with an escort to the emergency department of the accepting children's hospital to be reviewed and considered for acceptance to the speciality. The other route was more informal around a telephone or video conference discussion

among clinicians with an existing relationship either to the patient, or among the clinicians in the hospital. A patient had had a CT scan in GH1 and a neurologist was asked to review this remotely as part of the speciality radiology meeting. This was reported on the afternoon ward round "…they don't notice any obvious change to previous scans, but ask that they be kept in for monitoring and then a repeat scan tomorrow if possible." The consultant on duty took a definitive approach. "OK, well they can go home tonight – they're not getting anything here that they won't get at home. The kid's fine and we know them a bit better than they do so let's get a scan booked for tomorrow and I'll tell the family to come in in the morning for that…"

The same could be argued where medicines were concerned. In one site, it was observed by a neurologist during a specialist review that "there are no maximum doses of these drugs in neurology here" which led to a sarcastic response from the rest of the round. A junior doctor described how they had challenged a request that conflicted with their own internal knowledge.

"Yeah so they told me to just stop the Keppra [an antiepileptic drug], but I don't think that's really appropriate so I said I'd run it past my consultant."

"And thanks for that, you're absolutely right. Let's reduce the dosage slowly." (Fieldnote observation, CH1)

The difference regarding these three cases is how the advice and recommendations were captured by the team. In the case of the ophthalmological advice, documented recommendations in the medical record were not challenged or changed, but when verbal advice was sought

it was in immediate one-to-one conversational exchanges (“corridor consultations”) either in person or via telephone. This offered space to clinicians to contextualise the advice and interpret the recommendations to support their own decisions.

This is important as the COVID-19 pandemic had led to a rapid growth in on-line meetings and videoconferences to co-ordinate speciality care. This created easy access to teams that previously would have required a lengthy referral and acceptance process. The pharmacist in GH1 explained one of the specialist ward rounds that they were able to attend. “It’s great because they happen every day and we can just dial in and ask about our patients.” However while accessing the speciality teams was viewed as a positive move, there was confusion in the way that treatment plans and recommendations were communicated. It was not uncommon for tertiary centres to make decisions about patient care, and then ask secondary care to enact the plan; but because assumptions were made on both sides about the detail of the plan and the level of understanding and knowledge on both sides, there were occasionally rules-based mistakes as a result.

This was best illustrated with an example of steroid dosing for inflammation given by a pharmacist. A referral hospital had advised GH1 to start methylprednisolone for inflammation, but this was not something that was used in GH1 therefore there was no available guidance.

"So they referred to a book that we subscribe to which is from another area and they leafed through for a methylprednisolone dose and used, like 0.4mg/kg, which is the prednisolone equivalent dose. It looked right, it was the correct drug and it was written in a document that was trusted, but without the context of what the specialists would do they prescribed a dose that was extremely low. I came in the following day and picked it up. I've seen these patients with Kawasaki's before and we treat them with 10 or 20mg/kg so I was able to e-mail back to my colleagues at the children's hospital to check and we got the right dose prescribed." (Interview 3, Pharmacist)

No harm came to the patient, and this case presents a good example of how the system functioned in uncertainty. The normal process – referring to local guidelines and consulting the BNF – failed. An additional reference manual was available that was trusted and recognised among the team. This was not uncommon. Prescribers in this centre would frequently refer to other information that was unsanctioned, or uncontrolled. There was a suggestion of a superficial quality assessment when looking at information from non-typical sources.

"…so I just googled guidelines for (another disease), and sure enough there was one from another trust, and it looked legit – it was branded, had a date on it, and came from an NHS website, so I just went ahead and used it." (Interview 4, Junior Doctor)

What was lacking was the contextual experience of the use of this medication that would have signalled a different dose was required. In the moment of that particular event there were no specific dosing guidelines and no prior experience available within the wider team for those formulating the plan so they adapted. Action needed to be taken, and they sought action that roughly fitted the situation – in this case a dose of methylprednisolone that referred to inflammation. It was not the right course of action when viewed through the lens of someone with the requisite experience and

knowledge (the pharmacist), but also was not the wrong course of action in that the patient was not denied treatment, and there was broad consensus among the team at that time that was what needed to be done, in the light of poor access to specialist support.

8.4 Methods of communication

This difference of perspective confounded care provision. Multiple professionals were involved in patient care which led to the use of varied methods of information communication at handover. Documentation of patient assessment, diagnosis and progress was a central part of observed activity, with the medical record essentially the system's primary record of events. It was also occasionally the only reference to information on clinical intentions for courses of treatment. However, this record was not suited to day-to-day task management and communication. Verbal "handovers" were the central pillar on which information was transferred within teams and were built on a single document that was colloquially referred to by workers at all sites as "The Handover."

Each staff group had their own Handover. The Handover was a printed document that held standardised information for the needs of professional groups that were subjectively defined as essential for their own needs. They were maintained independently by the owners, and they were updated either "on-the-go" as things changed, or decisions were made, or at fixed points in the day alongside other formal processes, for example the lunchtime medical

handover. This information was structured around the minimum knowledge required to ensure task completion during each shift. They supported a shared understanding of the work that was meant to be done within each staff group and were seen to augment and synthesise the medical record and flag important issues. For example it was not uncommon to see a Handover with “Complex needs – see notes” or “Safeguarding – see [Named nurse].” Even in those sites with an electronic prescribing system, professionals continued to use paper Handovers to record information in a convenient way that fit into a pocket, or to refer to informally as an *aide memoire*.

The Handover was a focal point for staff to both provide information about individual patients but also to monitor and evaluate performance. Nursing staff would remark that they were “really behind” and show people their creased and pen-blotted Handover and the list of jobs that had yet to be crossed off.

However, The Handover was an informal device to support communication and transfer of information between staff. In CH1 there were anecdotal reports of The Handover being implicated in patient safety events related missed and omitted investigations and medication. Consequently attempts were being made to formalise The Handover for nursing and medical teams into a single unified technological system. The technological intervention

involved the electronic communication of “tasks” via a handheld portal so that tasks could be allocated and centrally monitored.

“Oh it’s supposed to reduce the number of bleeps that we’re sending to the doctors to get stuff done, but it relies on them using it as well and the last time around they didn’t.” (FIeldnote discussion, nurse,, CH1)

As we were discussing, one of the nurses needed a new cannula so had picked up the portal.

“I suppose I should give this a try again… we’re supposed to wait half an hour after we’ve posted the job and then bleep them but to be honest we’ll just end up bleeping them anyway just to check that they’ve seen the job…” They entered the job to the portal and a few minutes later the doctor from the team looking after their patient arrived on the ward. “Oh wow. You came!”

“I’m sorry?” came the reply.

“I’ve just allocated a task to you on The Handover thing…”

“Oh have you? I haven’t seen it. Was it for a new cannula? I was coming to do it anyway.” They showed the nurse the medical handover and pointed to “New cannula” handwritten against the patient. “We knew it was going this morning…” (Fieldnote observation, CH1)

When I asked one of the practice development nurses who was involved in rolling out the new task manager, they talked me through the organisational justification for the new intervention.

“…we have no idea what’s on those handovers because they’re not saved every time they’re changed, so have no way of understanding the situational awareness of the teams.” (Fieldnote discussion, Nurse, CH1)

Individual printed Handovers were seen as an uncontrolled way of recording and transferring information. They were subjectively populated with only “need to know” information (most commonly observed among nurses using

the SBAR structure – Situation; Background; Assessment; Recommendation.[337]) and were structured in this manner:

> Situation: the immediate problem of the child
>
> Background: often truncated to bare minimum both to save space on the sheet (it was sometimes noted that The Handover ran to two sides of a page, which was viewed as a surrogate for the busy-ness of the service.). For example, patients with complex medical needs were seldom described in The Handover with a list of all problems, just "complex needs…" When explored with practitioners in the field there was always a reference back to the primary medical record for a fuller picture of those needs
>
> Assessments and Recommendations: Usually specific tasks and instructions to follow up ("chase…") the outcomes of some tasks.

Progress of tasks and work were marked on Handovers in ways that facilitated evaluation of progress. Working to goals allowed staff to feel like they were "keeping on top of things". Medical staff were noted to use a system of boxes which would be shaded in over time. This was learned from those around them. I shadowed a trainee Advanced Practitioner on one occasion who showed me what the boxes and shading meant. "An empty box means it needs doing and I haven't started; a half shaded box means it's started and needs completing or following up; and a full shade means it's done and I can forget about it."

Nursing staff tended to list their jobs on The Handover by hour of their shift and would often group tasks (including medication) into a single interaction with the patient “cos it’s easier to get everything done in the room at once, so if there’s cares and obs and drugs to be done, we’ll do them all together.” (*Fieldnote discussion, nurse, CH2)* However, this reliance on The Handover and verbal transfer of information was really only as good as the detail entered onto The Handover. On occasion this summarisation of patient history, and focus on the immediate problems of the child led to some essential information being omitted from The Handover.

A child admitted to one of the research sites was treated with warfarin for a cardiac defect that had been repaired in early infancy. There was a clinic letter in the patient’s notes described a previous “Fontan Completion for Hypoplastic Left Heart” which is a procedure that requires lifelong anticoagulation. However the “background” on both medical and nursing Handovers described “Cardiac surgery – resolved” but no reference was made to the likelihood of on-going anticoagulation. During the formal medical shift handover that marked the end of the night shift and the beginning of the day shift the child was described as “…a ‘bronch’ requiring oxygen on the back of historical cardiac surgery…”. There was no immediate sense to me as the observer that the presence of therapeutic anticoagulation had been considered overnight, because the cardiac issue had been considered as a “past problem.” Consequently, there was no collective awareness that a child in their care might be on a high-risk medicine because it was not part of the reason for admission and the

immediate problem. The warfarin required monitoring, especially when the child was sick and there was no discernible account for this in the morning plan. Thus for the only time in this study I intervened to advise the wider handover group and the nursing team that the patient was likely to be on warfarin and therefore warranted some deeper scrutiny and attention.

Why did I decide to intervene in this case? I considered three issues as part of my assessment:

1) The clerking and medication history taken overnight was from a parent, via the grandparent on the 'phone. It was written on a Post-It note and stuck on the inside of the nursing folder. It was names of medicines and volumes written in millilitres (e.g. Lisinopril 3.5ml) which were transcribed verbatim into the medication chart.
2) I observed nursing staff struggling to reconcile the medication on the drug chart against this post-it note. The family had brought the child's medicine into hospital with them, and they were all labelled, but doses on the labels differed from those on the medication chart, because they had changed since the last dispensing. This was not uncommon and seen throughout the study however this created a challenge for nursing staff who then had no frame of reference against which to verify medication administration. Under normal function, this should have prevented administration until the ambiguity was clarified however, the nurse felt under pressure not to omit doses that were

prescribed, and the mother was very clear that the doses on the label were correct and appropriate and wanted them given on time.

When I asked the nurse what had happened overnight “Oh, Granny gave everything. The drug chart didn’t get written until this morning because we didn’t have one and mum was telling us that she needed to do his meds…” Thus there was a risk to my mind that all medicines would be administered whether there was accurate documentation or not, and if not by the nurse by the parents, and still no one had signalled an awareness that warfarin was part of this child’s treatment.

3) A pharmacy medicines reconciliation would have been undertaken but on this week of observation the pharmacy service had been erratic, with one observed visit happening at 4:30pm. It was currently 8:45am.

So at that point I considered that there was a risk that treatment would continue, plans would be made and potential interventions carried out that could have created a risk to the patient (e.g. prescription of a medicine that could have interacted with warfarin causing an adverse patient outcome.)

The pharmacist attended that ward about two hours after my intervention and I advised them that the “new bronch” was perhaps more complicated than the handover might suggest. They allowed me to observe the process of

their medicines reconciliation and I was careful to not provide more information than was necessary to prompt the review. They continued to refer to the medical Handover and the notes, where diagnosis and treatment were ambiguous. Surprisingly on review of wider NHS clinical records including the GP records, there was no record of warfarin or any suggestion of on-going monitoring. It was subsequently identified through the pharmacist's interview with the parent that the warfarin was managed and supplied by a tertiary cardiac unit in another city, that had no formal links to the hospital in question, and the parents managed the monitoring. Thus, the only functional barrier to the omission of the warfarin were the parents and in my view they were likely to have prevented prolonged omission of the warfarin through exercise of their own parental autonomy, however had that not been detected would anyone have known to ask? The experience of parents and the systems expectations of them warrants specific consideration which will be presented in the next chapter.

Once identified, there were systemic challenges in getting the therapy documented and continued safely, which has similarities with the steroid case presented earlier in this chapter. There was no paediatric anticoagulation guidance and no facility for prescribing anticoagulants for children whereas there were dedicated resources for monitoring and dosage adjustment and clear support for assessment and decision making in adult areas of the hospital. Again the service was reliant on the support and guidance of a remote tertiary unit. It required the intervention of the parent who produced monitoring records, and co-ordinated the anticoagulation with

the tertiary unit via WhatsApp and fed back to the site clinical team what the recommendations were.

Through the formalised shift handovers, and written Handovers there was seldom any reference to the official medical record for the patients in their care. Handovers appeared to support the recall and processing of important information from memory. Complex patient histories and task lists were synthesised into bullet points or a few words, and medicines were seldom considered except where specific tasks and operations were required. These tasks were also profession specific – medical tasks and problems were outlined on The Medical Handover and nursing issues on the Nurse Handover, which supports a suggestion that work priorities between staff groups were not aligned, and potentially counterproductive.

Communication between the professionals in the system – Medical, Nursing and Pharmacy – were often transactional. A desire for information from one actor led to the exchange of information with another. These exchanges were focussed on specific needs. Occasionally, there was an unprovoked discussion about plans between medical and nursing staff where a doctor would update the nurse on a patient's progress and the decisions made on the ward. For example, a doctor advised a nurse that they were going to have a conversation with a family

"…and after that they can go home, as far as we're concerned."

“OK, have you done the discharge letter?” A nurse could not discharge a patient without a discharge letter being completed and signed. (Fieldnote observation, CH1)

This exchange served as a prompt to the medical team to ensure the discharge letter was done and gives an example of how teams worked informally together to ensure completion of these tasks, but the physical processes themselves were not aligned. The process of discharging a patient required considerable documentation of information but it was not uncommon for a doctor who did not know the patient to be asked to undertake that process. In these circumstances, the doctor would draw on multiple sources of information including The Handover to draft a discharge letter.

In the sites with electronic patient records, these could be populated by transferring data rapidly between one section of the EPR to another and processing medication needs and follow up requests using the daily consultant review and The Handover. In the site without an EPR there was a need to review the paper medical notes and synthesise the history into something succinct for onward communication. The doctors who were writing the discharge letter also had to ensure that all follow up appointments were booked before concluding the letter.

The Handover also supported the population of transfer, referral or discharge letters as it provided some of the background and situational information

important in framing the reason for admission and the diagnosis and was then a useful short cut to reviewing the entirety of the patient's notes for those initial assessments and plans. It provided essential information that could facilitate a relative stranger to the patients on that list providing safe minimum levels of care. However, because of its limited medication related content, it was not uncommon for the entire medication history to be omitted from the discharge letter with only those medicines that needed to be supplied being appended to the letter "…for expediency…" This was criticised by some pharmacist respondents however.

"The discharge letter isn't just an order form for us to supply medicines. It's also about providing clear information to everyone about the patient's current drugs and doses…" (Interview 9, Pharmacist)

Discharge was also one of the most challenging processes both for ward operations and strategic hospital objectives – often beds were needed within a short time span, and decisions to discharge often delayed by other processes (for example lab results). There were numerous programmes in place to accelerate discharge processes. One site had a policy that all discharges had to be done by 3pm "…so children can be home by teatime…" but these targets were often missed

"…We barely manage 40% because, y'know, people are busy..." (Interview 14, Nurse)

The structure of ward work was one factor for this. The shift handover was usually followed with a formal ward round where the child was reviewed, further information required identified and jobs outlined. This finished between 10 and 11am and then jobs were prioritised by the receiving doctor.

It was rare that investigations were completed before late afternoon. In one site this was informally acknowledged as an insurmountable challenge.

"Basically, kids only go home at two points in the day – lunchtime or teatime. The kids who go home at lunchtime are the ones where all the tests were done yesterday so it's just the discharge letter what needs doing. The ones who go home at teatime are the ones told they can go home today but need a blood test or an inhaler review. If you don't make either of those times, you're not going home…" (Fieldnote discussion, Nurse, CH1)

Prioritisation processes were subjective, based on the doctors' perception of what was urgent. Nursing staff were not a part of the medical ward rounds, so these priorities were occasionally not aligned. Clinicians were very clear that they wanted nursing input on the rounds but also acknowledged that there were often too many ward rounds to support that. In the two children's hospital sites it was not uncommon to have multiple ward rounds led by multiple consultants running concurrently. In one centre this absence was felt strongly when a consultant remarked that "…without nursing staff on the rounds, we can't tell them what we're going to do and they keep bleeping us to ask about the plan…" *(Fieldnote discussion, Consultant, CH1)* However, the organisation of consultant rotas, ward round arrangements and allocation patterns of patients to clinical staff worked against nursing staff participation in ward rounds.

CH2 had addressed this by providing time and space for a specific medic-nurse handover – "The Huddle". This brief discussion took around 5 minutes, and was led by the nurse in charge, and involved the consultant for the day and the ward medics. Patients were referred to by bed number, and

medics were advised of any nursing issues emerging overnight, children who were considered ready for discharge and those patients who required additional review. It allowed nursing staff to influence prioritisation and decision making across the unit and advocate for their patients in a positive environment. It also appeared to create space to develop good relationships between clinical staff. Though the ward doctors worked within an office with the door closed, the engagement of the nursing staff with their processes promoted an open environment for cooperation and challenge that persisted outside of The Huddle.

8.5 Guidelines and Procedures

There was a suite of guidelines and procedures available that was described in Chapter 7, and while these were a reference point for many, there was sometimes a tendency among nursing staff to interpret documented guidance literally, which created a highly localised approach to certain medicines. For example, ceftriaxone is a common antibiotic and has a range of dosing instructions. Dosing was presented in such a way that doses “less than 50mg/kg” the medicine could be given quickly, while doses above this threshold had to be infused over one hour. In GH1 the standard dose for suspected septicaemia in children was 50mg/kg, however it was observed that orders for this dose were often adjusted to 49.9mg/kg because nursing staff interpreted “less than 50mg/kg” literally. In other sites, nursing staff were more pragmatic and would seek clinical verification that giving a slightly higher dose quickly was okay. This was supported by pharmacists in those sites who took a view that the intention in the documentation was “less than

or equal to" and that changing to 49.9mg/kg wasn't a practical thing to do "…because they can't measure that accurately anyway…" *(fieldnote discussion, pharmacist, GH1)* Yet there were cultural differences between the site that took a literal view, and those that were more pragmatic and this comes down to proximity to other more specialised units and what could be justified as "standard practice." In discussing this in CH1 one of the nurses advised "…oh God, they'd give that as a bolus down in PICU and it's in their guidelines, so we'll always refer to those…" *(Fieldnote observation, CH1)* In the smaller site with no other paediatric services, there was no other service against which to compare their approach.

Because of the relative ambiguity in available guidance, constraints around staffing and expertise, and the wide variation in how practice had evolved in different sites, there was tension between doing what was expected, and what needed to be done to accomplish the task. This is best described with the following case study. A doctor made a reasoned decision to use dexamethasone for a child with wheeze "…because they were puking up the pred, we used it in another hospital, and it was a single dose…" but the nurses refused to administer it "…because it wasn't in the BNFc and the only reference they could find was for croup and the child didn't have that." This led to a prolonged discussion between nurses and doctors at the nurses' station. There was clearly discomfort from the nursing staff at being asked to do something that they had no written confirmation of being an appropriate action, but also a pragmatic view that something needed to be done. "Well fine, we'll do it, but it needs to be approved by a consultant."

There was tension between the independence of medical practitioners as a special group and the need for nursing staff to be assured that what they were being asked to do was the “right” thing. Nursing staff (and to a lesser extent pharmacy staff) appeared to require a guideline or a piece of written correspondence to support all medication related tasks. A pharmacist complained that medical staff would seldom follow guidelines as she was familiar with them

“I just wish they would follow the guidelines… that’s all I ask.” (Interview 11, Pharmacist)

Many guidelines were available and yet not followed strictly. This was partially related to their perceived inaccessibility, but also because many practitioners were observed to use their memory and experience as their primary frame of reference. Documents were only referred to when practitioners recognised that there was a gap in their knowledge. Where these experiences aligned across professional bounds then things went smoothly and medicines were administered without challenge. However, it was noted that each professional group in the system assessed medicines within their own perspective. There were real issues with documentation of indication and intention when assessing orders for administration as outlined with the acyclovir example above. However medical teams were very clear that additional documentation of decisions was unnecessary. “We’ve been on the round, we’ve discussed this, that is our decision… it should be clear from the notes.”

This ambiguity permeated through guidelines and treatment plans which occasionally required considerable interpretation of the intention of the prescription of a particular medicine. In one situation two nursing staff were trying to understand the dosing of acyclovir while preparing an infusion in the clean utility room. One had a copy of the BNFc in their hand, while another had a PDF image of a guideline on their handheld computer. Both were flicking between two or three pages of the BNFc, the guideline, and the order on the electronic prescribing system. Aciclovir had multiple indications, potential dosages and two ways of calculating the dose based on age and weight (one was based on bodyweight, the other on body surface area.) The nursing staff calculated the dosage using each method, working backwards to identify the monograph that the prescriber had used to format the prescription, and then consulting the notes to make sure that the indication was the right one.

To mitigate this ambiguity around prescribing intention and dose selection, hospitals with EPRs had attempted to build their guidelines into prescribing protocols, as a form of "decision support." These protocols incorporated licensed dosing recommendations, alerts (but not stops) for excessive dosing, and in some cases rounding parameters (e.g. where a medicine couldn't be measured accurately, the measurable dose was proposed by the computer). These calculations were based on predefined dosing parameters such that "…when a prescriber selects the right protocol you get an

appropriately formatted order of the right dose, right formulation, right times…" but it was frequently observed that prescribers would pick the wrong protocol.

This was related to labelling whereby designers (generally pharmacists and consultants) had a different view on the meaning of these labels compared with the perceptions of prescribers (who were generally junior doctors or APs). For example, neonatal protocols were identified as a common issue. These protocols were intended for use in the Neonatal Intensive Care Unit (NICU) and reflected the practice and guidelines in that unit, which had limited utility out in the open wards. However, when presented with a neonate in general paediatric care, defined as a child who was an infant within the first month of life, prescribers in the paediatric service would select the neonatal protocols. It created issues with dosing and around scheduling of monitoring. Pharmacists gave examples.

"…like with gentamicin yesterday, the monitoring was scheduled for 36 hours after the dose because that's what we do in the Neonatal Intensive Care Unit, but here we check at 24hours… I knew straight away by the way the order was formatted that that was what the prescriber had done…" (Interview 12, Pharmacist)

"…but there are times where they use the wrong one. Like today, a kid is in who's a term baby on paracetamol but they've used the neonatal paracetamol protocol so the doses are all wrong…" (Interview 7, Pharmacist)

The infants in this case could be argued to be a neonate, but they are not "neonatal" in the organisational context – i.e. a baby admitted to the neonatal unit.

Further, these automated calculations required the population of weight and age measurements being taken on admission, and it was commonly seen that they were not. In an observed team meeting, a senior consultant made an exhortation to the wider team to "please ensure that all patients have a weight, height and age documented on the system on admission…" It was identified that the emergency department was using paper-based workarounds to save time. In CH1 the emergency department used a paper based assessment and documentation system and the reliance was on ward nurses to transfer this information into the electronic patient record on admission, which was often delayed by other patient care responsibilities.

8.6 Workload and Responsibility

It was apparent that the medicines related work did not happen in an isolated and controlled environment, but medicines safety policies and procedures assumed that medicines work was a discrete event. Medicines work was packaged with other tasks for convenience and efficiency. Where a child required observations or care interventions, and a medicine was due in proximity to that it was accepted practice that those tasks would all be delivered as one process. It was common to see nursing staff going into side rooms laden with bags of intravenous fluid, monitoring equipment and other

paraphernalia. In those hospitals with mobile workstations they were used as a vehicle with which to transfer equipment into the near patient area and provided a surface on which to work.

There was also an organisational assumption that only nursing staff undertook medicines work, exemplified by medical staff not having physical access to medicines storage areas. Nursing staff were so burdened with tasks and work that they had to prioritise and plan their shift activities. The importance of The Handover as an informal tool to support activity planning was demonstrated in all sites with careful mapping of available time and demands scheduled into that time. Within that available time, nursing staff also had to account for their personal needs – bathroom and meal breaks – which led to a close working relationship with other nursing staff on their shift. On one occasion an error in the preparation of the rota left one research site down a nurse on a busy morning and the result was a strong focus on "…just getting the job done…"

In order to cope with these demands, the medication system was observed to be spread between nurses and parents. While organisational policies all very clearly stated that nurses must administer medicines to the children in their care, this was often delegated to the parent to do, because children were more likely to accept medicines from a trusted adult during a short hospital stay. However, there was evidence that this was also delegated to families for efficiency purposes. On one occasion, a nurse was seen

checking doses of medicines for a child because the parent was refusing to administer what they asserted was "the wrong dose…" There was doubt as to the documentation in front of the nurse

"…but I could just give it to mum and let her draw it up and give it because I've no reason not to believe them but I can't do what she's asking me to do …." When probed about asking a prescriber to come and review "Oh if I do that I'll be waiting ages…" (Fieldnote observation, GH1)

This was also seen in situations where parents were administering medicines to their children and asked the nursing staff for doses. A parent who was self-medicating their child asked a nurse for a dose of omeprazole. The nurse dispensed it according to what was on the computer.

Mum "I'm sorry but that's not enough. He's usually on 40mg…"
Nurse "Oh is he? Well that's what the doctor's prescribed, and I can't give you any more until it gets changed…" (Fieldnote observation, CH1)

In one hospital site the ward pharmacist was also a qualified independent prescriber but that was not part of their role on the ward. In that hospital, no wards had pharmacist independent prescribers. However, they would often expand their role informally to support the workflow in the unit to provide a more efficient service;

"How long would you be waiting if you asked a doctor to review every ambiguous prescription…? If I do it, it gets done there and then…" (Interview 15, Pharmacist)

This reflected a need for pharmacy professionals to fill gaps in knowledge regarding medication, yet the pharmacy service was often unavailable. Questions about medicines that would be swiftly answered by a pharmacist or pharmacy technician would be discussed in their absence between those working in the area first and if someone had direct knowledge or experience that would be taken forward and acted upon. When explored with professionals during interviews and observations it was observed that it would take too long for "pharmacy" to give an answer, and where they could sort it out themselves then they had learned something.

"We had a pharmacist on the ward round when I did liver and renal and that was great… but in general paeds… I'm not sure what they would bring and they would slow us down. Our drugs here are simple. If I need them I can just call them, but mostly I can look up what I need…" (Interview 18, Junior Doctor)

The use of prescribers other than medical professionals was relatively rare in the study sites. Both children's hospitals employed a small team of APs who on qualifying acted in the medical pool, and were notionally equals to the medical staff, however there was a clear difference in experience base between the APs and the junior doctors in that APs had considerable organisational and professional experience in the area they were working in. Over the course of the study there was a very pronounced shift of senior nursing staff into these advanced roles. When exploring the motivations with one "…oh I was fed up of the management, and actually really like the clinical side of things, and this was really interesting…" However, there was concern at an organisational level about this shift of the top tier of nursing staff into more advanced clinical roles. Two nurses with medicines safety

roles graphically described the impact this was having on nursing capacity and competence.

"We're losing that huge band of experience from those with twenty years' experience – they're off to advanced roles in the community, or out to other care areas…" (Interview 11, Medicines Safety Officer)

"We're robbing Peter to pay Paul. We're using these fantastic experienced nurses to fill gaps in the medical rota, and we're stacking the wards with really junior inexperienced nurses." (Interview 14, Nurse)

There were also wider beliefs and perceptions that influenced medicine choices and decision making. One family preferred to administer pain relief to their child using suppositories "…because he doesn't like the taste of medicines… he just spits them out." Yet nursing and medical staff were dismissive of this preference.

"Ooh, I wouldn't do that with my children… we shan't be sending them home on that." (Fieldnote observation, CH1)

The parents agreed to attempt oral medicines prior to discharge which created great distress for the patient and a retreat to the rectal formulation of the medicine, and again nursing staff were dismissive of this choice.

"You can't let the parents get too soft. You've gotta pin 'em down…" (Fieldnote observation, CH1)

Perceptions around the urgency of medicines were often not rooted in the clinical need for the medicine but rather when the medicine was due. This was observed with the same family as above. After attempting to administer oral medicines without success, the parent said "Oh let's not bother, he's okay and feeling fine." Previously on the ward round it was observed that the

patient was bright and cheerful and ready for discharge. The trigger for the nursing staff to attempt medicines administration was the electronic prescribing system alerting them that paracetamol was due.

8.7 Chapter Conclusions

Communication among all participants in the medicines process in hospital was limited by the environmental conditions explored in Chapter 7. Nursing, medical and pharmacy staff and families functioned within discrete silos of practice and experience, and communication between the groups was transactional, seeking specific information for a specific purpose. Printed "Handovers" were the primary vehicle for information exchange among staff groups, but were not conducive to sharing information between groups.

Further these Handovers were centred on the immediate problem for each patient, and care was structured to resolve this problem. Additional information about medicines, or other medical problems was often truncated and only considered when it became a problem in its own right. This created some situations where the safety of a patient and their medicines were compromised because professionals looking after them were not fully appraised of their needs.

Communication between medical teams was a mixture of formal physical examinations and reviews, and informal conversations regarding a specific

issue. Where these plans were documented by the visiting speciality they were treated as firm plans, even where they conflicted with the general paediatric plan. Yet in informal discussions, it was seen that clinicians would contextualise their presentations and flexibly interpret the suggestions and recommendations they required to take account of service and family needs and expectations. This was seen to be undertaken more often in services that were remote from the speciality.

This distance from specialist services however meant that there was an absence of experience and knowledge for some of the more complex care that district hospitals were expected to provide. This led to situations where medical and nursing staff “muddled through” to resolve an issue until a time where more information could be obtained, and treatment decisions reviewed. This lack of experience and knowledge may also contribute to a steep hierarchy among healthcare staff looking after children and young people in hospital. That said, these hierarchies function in isolation and co-operate on a transactional basis only which affects the effectiveness and efficiency of the care provided. All hospital sites offered expertise to the wards in pharmacology and therapeutics in the form of pharmacy professionals, but these were often absent at the point of need, and only contributed to the post-hoc mitigation of DRPs. Further, where there is no frame of reference available against which adaptations in work can be compared, there was an observed tendency for individual practitioners to follow guidelines and recommendations to the letter.

There is also a clear suggestion that in an attempt to mitigate workload healthcare professionals forego some elements of tasks to save time. This is evidenced by a short-cutting of medication histories from doctors and nurses on admission because there was a clear assumption that the pharmacy team would pick up that workload later. This may, also be associated with a task-focussed “fire-fighting” mentality among overstretched NHS staff such that only immediate medical problems and treatments therein are considered. This was clear to the point that I had to intervene at one stage to ensure that appropriate awareness of substantial background medication were accounted for as part of onward care. However, as I have shown, it was unlikely that that any harm would have become that patient because of the involvement of their parent.

There is a great deal of practical support that parents offer within the paediatric acute care setting, but they have not been covered in this chapter in great depth because operationally and organisationally the medication work of parents is assumed by healthcare professionals. Their involvement is unofficial and informal, but they offer great resilience advantages and work hard to help keep their children safe. However, there are also risks associated with parents and caregivers getting involved in medication work therefore their role will be explored in more detail the following chapter.

9 Parental Involvement in Medication Safety

An important element of this study has been to observe and capture the important role that parents and families play in the safe care of their children while in hospital. Be it the provision of information, the administration of medicines, or to provide additional safeguards and protections against inadvertent and unintentional medication events, parents are in the main at the side of their child throughout their admission to hospital. This is in stark contrast to the experience of adults in hospital who, during the period of this study were constrained in who could attend hospital with them. Adults are assumed to have capacity and are able to advocate for themselves, whereas children are not and cannot. Children and young people require an adult with parental responsibility to make decisions on their behalf. Notwithstanding this simplistic statement of legal reality, it was observed that children in hospital care were wilful and able to express their dissatisfaction with an intervention (be it medication or a procedure). This necessitated a degree of parental involvement in the medication process which will be explored in more depth in this chapter.

All research sites endeavoured to be “patient-centred” and “child appropriate” care environments. This was evidenced by the continuation of parental visiting for children in hospital while visiting was prohibited for all other patients in hospital under coronavirus restrictions. The wards were decorated in a child friendly manner with wall decals and bright paint colours and play areas and toys were in evidence throughout the wards. However,

toys and play areas were off-limits due to social distancing regulations and control of touchpoints.

The purpose of this chapter is to explore the emerging aspects of families in the medicines processes for their children while in hospital. Unfortunately there were very few older children and adolescents admitted to hospital during the period of this study, and those who were admitted were largely under the care of mental health services, therefore this chapter may not hold in consideration of the care of adolescents and older children.

9.1 Parental Involvement in Medication Safety

There was a stated effort to provide care in a "patient-centred" manner, however it was observed that case that care and tasks were system-centric. Family routines at home were subsumed into ward schedules, and medicines tended to be prescribed for times related to their time of prescription on charts and EPRs rather than reflecting when those medicines would be administered at home.

"Every time we come in everything falls apart. I know that schedules and routines are different here, but if he doesn't get his nitrazepam on time he gets dystonic and it just makes everything worse…" (Fieldnote observation, CH1)

Further, attempts at providing "patient centred care" led to a perception of chaotic and "*ad hoc*" medicines processes which generated anxiety and concern for parents and nursing staff alike. Parents provided a vast amount of information about their child but how this was received, processed,

documented and considered varied depending on the nature of the medicine. Many processes within sites for managing this data were disconnected from other care processes, or were administered in a performative manner.

Consequently, parents were seen to support the wider service and team. It was quite clear from nursing staff and parents that without parental support medicines may not be given, or be given incorrectly. Handover of information and care planning was occasionally undertaken by some families to multiple teams across different institutions often with the tacit encouragement of the local care team. However, when parental involvement and engagement with care conflicted with closely held beliefs and practices, there was a propensity for teams to discount parental concerns or desires.

Parents were enlisted to support medicines administration processes, which was a clear policy violation. At an organisational level parents were expected to be passive observers of their child's care until their competency and capacity to be involved in medicines processes were assessed. This was a task that was undertaken by the ward the child was admitted to, but this did not realistically take into account the nature of the patient's journey through the hospital. Through conversation with parents, it was possible to identify that the patient journey in hospital started many hours prior to admission to the ward. All patients would come via ED or another assessment unit, where they would usually wait for between four and 12 hours. During this time, parents would continue to provide care to their

children – food, hygiene and medication. None of these interventions were captured or documented. One parent had a premature infant with breathing difficulties who talked me through their journey in CH1.

Mum: "So we've been here since about 6am, waiting in A&E for a nurse, then a doctor. I gave her a feed, changed her nappies… she's on vitamins and folic acid so I gave her all those as well… they're in the pram in her nappy bag. Never leave home without them…"

Me: "And have you seen a doctor here yet?"

Mum: "No and what time is it now… 12? Of course I'll tell them when they come to talk to me but no-one's asked about medicines or anything yet." (Fieldnote discussion, Parent, CH1)

Nursing ratios in all sites were maintained between 1:4 and 1:8 patients to account for the increased care requirements of children in hospital. Educational services and play services were also offered where available and appropriate. On admission to hospital family and household routines were disrupted with medicines work officially falling to healthcare staff (usually the nurses.) Consequently, there was a perception that some medicines processes were undertaken at times that suited the healthcare professional's schedule rather than the patient's needs.

This led to a medication process that was perceived as disjointed and chaotic. Medicines were prescribed at seemingly random times when viewed across multiple patients, however when considered separately, these were related to either a hospital's "standard timings" (e.g. co-amoxiclav given three times a day at 6am, 12pm and 8pm) or automated calculations based on the time of prescription (e.g. piperacillin-tazobactam prescribed every

eight hours, commencing from 1:30pm when the order was placed). These timings created challenges for nursing staff and families alike.

A pattern emerged in all sites with medicines administered in the morning, at around 8am. There were then surges in medicines activity between 12 and 2pm, and between 6pm and 8pm. Very little medicines activity occurred overnight, except in the sickest and least stable patients. It was observed that many of these schedules clashed with other ward processes – 8am was the same time as medical ward round and nursing handover; 12 and 2 clashed with nursing staff breaks, and 6pm coincided with both the winding down of other hospital services (like the pharmacy) so it was almost as if the bulk of labour intensive medicines administration processes happened at the time where those charged with medicines administration – nursing staff – were least capable of achieving them.

Medication work was time consuming because they were not co-ordinated across the ward or the clinical area, and professional routines differed. This often resulted in missed or omitted doses.

"…If I leave it to the nursing staff everything will be late – about 60% within an hour but the rest… oh my, the first time we were in hospital there was something that was missed and found in a syringe under a pillow four hours later." (Fieldnote discussion, Parent CH2)

Organisationally, there was some acknowledgement that this approach to medicines created inequity for parents and families with one matron observing that "…we almost cater to some families' needs over others, and as a result we miss things…" There were also episodes where care was

delegated to parents without first assessing their ability to support the process which led to problems. At GH1 a patient was admitted following a 4 day period of diarrhoea and vomiting. The parent was exhausted, and the decision was made to admit the patient for oral rehydration and monitoring, but also to give the parent some rest. The morning after admission during the handover ward round it was noted that the baby was hypoglycaemic on the morning bloods.

Doctor: "So we've given her a shot of glucose and we'll recheck the bloods on the ward round."

Consultant: "Do we know why she's had a hypo?"

Doctor: "The nurses told us that Mum was supposed to be doing to dioralyte two hourly overnight but she fell asleep and hasn't done it…"

Consultant: "Well of course she fell asleep, she hasn't slept in three days…" (Fleldnote observation, GH1

That being said the drive towards patient-centred care was complicated by every family having a different routine at home. It appeared that medicines were organised on an *ad hoc* basis and simple lifestyle considerations were lost in the chaos.

"And kind of it became frustrating at times because the nurses are very busy at certain times of the day so you were waiting. Which because he's on tacrolimus twice a day and you're fasting for an hour before and an hour after, so if they're late, then your breakfast is late." (Interview 17, Parent)

Numerous interventions had been implemented to support the management of these processes, but all were based on prompts and reminders to clinical staff that medicines were due. These included computer generated alerts and self-management with handwritten notes or reminders. Inevitably then it

became impossible to administer all the medicines to all the patients on time, especially at times where activity and patient acuity were raised.

"Oh yeah, you get one sick patient and they take up everything – drugs, cares, obs, reviews…. Everything else just has to wait." (Fieldnote discussuion, Nurse, CH1)

"…we're quite busy and so say the 8 o'clock morning drugs, they're all due at the same time, obs are due at the same time, feeds are due at the same time, there is a ward round too." (Interview 1, Nurse)

The strategy that emerged then was the informal involvement of parents in the administration of medicines to their children that was observed to be a critical aspect of medicines management in these patients. This ranged from support in holding and distracting their children during medication administration up to autonomous administration of medicines. It was seen to evolve based on the child's interaction with the administration process. Physical comfort and holding was required with children who were uncooperative, and in some situations the parent would be handed the medicine to give to their child "…because sometimes that's the only way they'll take it…" Other nurses took the view that delegating the administration of medicines to parents was "…the best way to show mum how to do it, and check their technique." In one case of a patient with an acute asthma attack, asking the parent to administer the inhaler allowed the nurse to identify deficiencies in inhaler technique and offer support to correct them.

In other circumstances, especially those where children with medical complexity were admitted to the ward, there was a preference to allow parents to continue administering medicines.

"They're the ones who know what they're doing and know best and it means its one thing less for me to do on my shift…" (Fieldnote observation , CH2)

9.2 Parents as Gatekeepers of Medical Information

Parents were the primary gatekeepers to the background and medical history of their child and were asked to provide this information to multiple healthcare professionals throughout the duration of their admission. This information was collected in different ways by different staff, and not always direct from the parents. This information was then stored in different places, used for different purposes and often only referred to by the staff group that have taken the information. This frustrated parents who felt that they were repeatedly asked the same questions, and implied that professionals looking after their children weren't working together.

"It's quite frustrating sometimes because you get the impression that no one knows what they're doing… I'm asked all these questions and I'm, like, I just told that doctor earlier…" (Interview 17, Parent)

Children's journeys through healthcare systems were long and characterised by several stops along the way – from the ED, to the assessment unit, to the ward and sometimes onto another specialist ward. This was particularly relevant considering those children with medical complexity who were often seen by multiple specialities and healthcare institutions. It was rare for

paediatric chronic disease to be managed in general practice as is the case for adults. Thus the documentation for paediatric medicines was often uncertain. Parents were the best placed people to describe what their children are taking, and when. Parents worked largely from long term memory when administering medicines to their children. Family routine played an important part in this memory with medicines often associated with other routine aspects of the child's care.

"…so he usually had his Movicol at teatime, with his tea. And when he went into hospital it was just left on his trolley at 8, 9 o'clock at night… it was really disorientating…" (Interview 15, Parent)

There was an assumption from healthcare professionals that parents would use the same reference sources to guide their child's medication such as clinic letters, and the labels on their child's medicines. This was not the case. During informal conversations with parents in hospital that their routines were important for setting when medicines were. They would map medication by mealtimes, or school times. Doses were often changed by clinicians over the phone, and medication labels or clinical records would never be updated in real-time. Labels were only changed electively to meet the needs of other carers of the child. Schools would demand medication be labelled with accurate medication dosing, and hospital staff relied on them as well for the medication history. Some parents were very clear that medication labels were often out of date or wrong "…because you get seen in clinic, or the consultant phones you and they tweak the dose slightly… the label from the chemist doesn't really change…"

However, at a policy level, these differences would be labelled as a "discrepancy" and would lead to doubt for the entire medication history. This led to a reluctance for medical professionals to rely on parental medication histories. Throughout the observations it was noted that healthcare professionals sought written information on medication histories sometimes without asking the family what the patient's regimen was. In one observation a family attended GH1 for routine blood tests for drug level monitoring. As part of the process the doctor was required to state the time of the last dose on the test request form, and instead of asking the parents at what time the last dose was administered, the doctor consulted the medical notes, guidelines and colleagues as to what time the monitoring was due.

"I know its four hours after the last dose, but I can't find what time that should have been…" (Fieldnote observation, GH1)

Notwithstanding this operational need for duplicate corroboration of medical histories, consultation with parents was a clearly described part of the formal medicines reconciliation process. However in practice, this conversation with parents only occurred *after* the production of an idealised medication history from "independent" sources – GP records, clinic letters, and medicines brought into hospital where available. This was reinforced by training and education that medicines histories needed to be "confirmed with [mum]" even where there were no signals or suggestions that a medication history was relevant (for example, in a previously fit and well child admitted to hospital with a fractured leg). There was an almost cultural distrust of any medication history that hadn't been validated independently by a pharmacy professional,

rather than reflecting on what parents and families reported as they were actually administering to their child. A pharmacist in GH1 who was covering the ward during annual leave of the regular pharmacist commented

""…because we can never be sure… I won't trust anything that's not written down because you never know…" (Fieldnote discussion, Pharmacist, GH1)

However, pharmacy teams did acknowledge that parents brought a lot of information with them, and that it aided their jobs greatly.

"…we get the long stay patient that you know really well or the frequent flyer who you know and, therefore, you know…as soon as you see their name, you know, you sort of remember what they're on. And those parents obviously are dead organised and [everything's] labelled well and the [history is] generally quite easy to do." (Interview 3, Pharmacist)

Additionally, parents offered a great deal of practical and intellectual support with medicines for their children, particularly where there were gaps in knowledge or understanding. In chapter 8 I introduced a patient on warfarin and explored the staff communication elements of that case. In this chapter I would like to explore the role of the parent in this case.

Though the child had been admitted the previous evening, no prescriptions for the patient's regular medication were written until the following morning. Exploring with the doctor the following day it was posited that the anticoagulant wasn't prescribed "…because there's a special chart in the rest of the hospital, but not for kids. So it didn't get written down." Overnight it transpired that the patient's carer administered the medicine anyway,

"…because that's what we always do. He doesn't come into hospital often anymore, but we just get on with it." (Fieldnote discussion, Parent, GH1))

No one had advised her to stop and she didn't want a dose to get missed. There was no specific anticoagulant procedure or chart for use in the children's service, and the child was managed at a hospital two hundred miles away. The parent intervened to offer support and guidance.

"When I come into hospital I let the surgical team know by WhatsApp and they tell me how much more often to do the monitoring if necessary. I then tell the hospital I'm in what the results are and tell them what the dosage should be. The surgical hospital keep in touch with me. This morning I think there was a conversation between them and they sent over the spreadsheet so they know what's what… I do a lot of the leg work when we're here because they just don't have that knowledge…" (Fieldnote discussion, Parent GH1)

While medical staff were happy to accept the support, nursing staff were less trusting of the medication management and dosing. A dose of enalapril was higher than the dose specified in dosing references and despite confirmation from the parent and clear documentation in the medical notes of the medication history, the nursing staff were reluctant to administer.

"The nursing staff raised, is this medication the right dose, and again, go and have a look and then double checked they were happy. And again, so that liaison with mum was really, really helpful because she's the parent and the expert, absolutely, I check with BNFc again just to check that they're within the range that normally would be prescribed for that type of condition and spoke to seniors" [Interview 9, Doctor]

9.3 Parental Agency and Autonomy

These conflicts between parental expectations and practices and the expectations of the hospital were not uncommon, and it was clear in other sites that expectations of parental roles in hospital were not made clear to

parents. In CH2 there were challenges with parents requesting anti-sickness medicines for diarrhoea and vomiting

Cons 1: "...because they stop puking and see it's worked, and then don't want to go home without it…"

Cons 2: "Yeah, but to be fair, are we managing those expectations properly and telling them what we're doing and why? We know there are guidelines and evidence base, but how are we telling parents about that? I don't think that's specific for your area but is for wider consideration…"

Lead Nurse: "No you're right, I don't think we're very clear with families at all about what their stay in hospital is going to be like… Like, here's what you'll be asked to do and here's things we don't want you to do…" (Fieldnote Observation, a Multi-Disciplinary Team meeting, CH2)

Despite this informal need for parent support in medication work, at an organisational level there was an assumption that parents should be passive observers of their child's care. The default position in all organisations was towards presumed incompetence for medicines administration among parents and carers, and parents felt that their role was actively removed on admission to hospital.

"It did kind of take the mum away from you. I felt like I was just a spare part that was just sat there and not being able to do much." (Interview 19, Parent)

"For me, you lose the control that you have at home… I'm giving all these meds at home and then I'm coming in and I'm having to ask for them…" (Interview 17, Parent)

Two sites had "Self-Administration" policies for parents, which consisted of a competency and capacity assessment. These policies were enacted at nursing discretion, and depended on nursing staff having time to ask the question, so occasionally it was overlooked or unattended to.

There were stark differences in the approach to parent assessment. One site involved a detailed psychological assessment and a practical competency assessment for medicines administration that was supposed to be conducted by nursing staff and verified by a medic and a pharmacist. It was largely unused because it embarrassed parents and families alike and the verification steps were often unavailable in a timely manner.

One of the nurses is asking about parent self-medication in another pod.

N4: "Yeah we've done the assessment and everything so they're fine."

Me: "How do you find those assessments?"

N4: "Really bloody patronising. There's very little in there about the medicines and the doses and stuff, and more about "are you suicidal today…" just feels really weird asking those questions of parents who are so on board with their kids medicines and stuff…" (Fieldnote discussions, nurses, CH1)

In another centre, the assessment approach was more pragmatic with nursing staff permitted to use their professional judgement as to whether or not parents were competent to administer medicines. In this setting, most parents were effectively asked to self-certify their competence. A form was given to parents on admission that was signed and then kept with the paper nursing records.

"…they asked me to sign like a waiver to say that I could give the medicines and it was my responsibility. Then it was just down to me to give the meds so it was just like being at home…" (Interview 17, Parent)

However these policies were not consistently employed. There was evidence that where a family were "known" to the ward or clinicians there was a different standard applied.

“On one of our stays in another ward I asked, well, you need to check the medicines and the nurse said we don't normally check the medicines. So it seemed like that ward had a different policy.” (Interview 17, Parent)

Within the body of these assessments, there was a clear derogation of certain medicines to the auspices of nursing staff – primarily controlled drugs and intravenous medicines. All other medicines were assumed to be administered by parents when they were on the ward, otherwise administration was undertaken by the nursing staff.

On the other hand, parents participating in their child’s care were often useful barriers to medication error. In the event of a prescribing error which would have resulted in an omitted dose of tacrolimus in a solid organ transplant, the child’s parent continued giving tacrolimus to their child.

“The medicine was three times a day orally and that day the level came and it was a bit high. I was asked to change it to twice a day. I did it, it was late in the day and I went home. The next day in the morning handover the nurse told us there was a drug error with tacrolimus. When I went back and looked into it, it kept that same day dose but the [electronic prescribing] system had started the medicine automatically from the next day, it didn’t start it for the same day. So if that wasn’t a self-administered medicine, a whole day of tacrolimus would have been missed.” [Interview 18, Junior Doctor]

Thus, while there is an operational reliance on parent medication to ensure that medicines are administered to children, there is an absence of processes within the care environment to ensure that parents are updated on changes in their child’s care.

In the example above the parent prevented a potentially harmful medication related problem through their being unaware of the dose change, and had

only nurses been responsible for administering medicines in this case, a dose of tacrolimus would likely have been missed. Yet when discussed with clinicians regarding how parent involvement in care processes is captured it's clear that everyone records things differently depending on how they document. Some nurses would document "Medicines administered by parent" in their shift documentation, others would document parent administration on the administration chart. However, even in those hospitals with appropriate policies there was no facility to clearly document parent-administered medicines. In electronic systems, a note or flag was added to an administration record, and in paper based systems a nurse would merely write "Mum" in the administration box.

This inadequate communication and recording process manifested into parental medication administration errors which were seen at an organisational level as a problem. It was clear that responsibility for medication incidents was sometimes shifted to parents.

"I think there's just that assumption that they're the parent so… I can see from some of the incident reports when family have self-medded and that breaks down. You do some fact-finding, [and] they've built a real rapport … but ultimately you're the registrant… you're responsible." (Interview 14, Nurse)

The challenge here is how this communication problem is managed alongside the need for nurses to utilise parents as a resource effectively. Currently organisations act to prohibit parental involvement because communication is so difficult, but the contribution of parents to patient care is so important to achieving the wider objectives of the system.

There is clear evidence that parents are powerful advocates for their children while in hospital, and want to exercise agency over their children's care. There were frequent observations of parents policing medicines administration and identifying when things might not be right. One parent insisted on checking all medicines with the nursing staff prior to administration "*…because they've got it wrong before and it's just to give me peace of mind…"*, while in another situation a parent insisted that the in-hospital prescribed dose of levetiracetam (an anti-epileptic) was wrong and specified another dose.

"Well, this parent is saying that the prescribed dose of levetiracetam is different to what they give at home, so they're refusing it. They say its 600mg but the prescription is for 500mg and I can't find anything to support the higher dose." (Fieldnote observation, Nurse, GH1)

In this situation, the nurse elected to ask the parent to administer the "correct" dose because the parent would accept that dose.

The views of parents and healthcare professionals were sometimes opposed which created conflict between teams and families. Parents are still autonomous, and have agency over their child even when in hospital and were occasionally observed to request specific interventions or voiced concerns about care and progress. In the majority of observed situations this was managed gracefully and collaboratively, but occasionally the preconceptions of the healthcare team would be presented during handovers and ward rounds where candid opinions were sought. Parents were sometimes described as "hard work" or "difficult" by the wider ward team, and this occasionally impacted clinical decision making.

A situation was observed where a patient with bronchiolitis was taking longer than expected to recover, and the patient's mother was asking about active treatment where a decision had been made to provide supportive care with oxygen only. The mother was an intensive care nurse so had some awareness of airway management, but not in bronchiolitis. During the evening handover round one of the medical registrars described the "…real problems we had last night, not with the patient but with the parents." Similarly though, where a parent is concerned about the safety and security of their child and they continue to escalate their concerns through the nursing and medical hierarchy, it is often only at the last possible moment that action is taken and concerns are acknowledged.

"…They are, like, you're just an over-reactive mum… no, she's normal, she's fine… and there we are an hour later in intensive care and I'm watching her nearly die…" (Interview 19, Parent)

This represents something of a negative feedback loop. Care is arranged without considering the needs of the autonomous and competent parent who will continue to exert their agency and autonomy over their child. This can occasionally conflict with the closely held beliefs of the team caring for the child. In an attempt to place the "best interests" of the child at the centre of their care, the beliefs and autonomy of the parent is overruled which further drives to parent to exert their agency in what they perceive as the best interests of the child. In rare situations this results in parents taking decisions or actions that the wider care team disapprove of which further entrenches positions of conflict.

Consequently parents exercise their agency and autonomy sometimes regardless of medication advice or instruction. There was an observed event where parents purchased their own medication to treat their child's troublesome cough after their doctor had advised that there was no medically viable treatment for it. This was on display in the patient's bed-space the following day but no one noticed it. The administration of medicines without the clinical team being aware was not uncommon, especially in the early stages of admission. The hospital journey of most patients began several hours before their physical admission to the ward and this would be the point at which medicines would be prescribed. During that in-between time, medicines would be administered as per the family's usual routine. Parents perceived that it was important that these routines be maintained as much as possible when in an unusual environment and remarked that "…they would just tell the nurse what I gave and what time I gave it at…" assuming that this would be documented.

However, there was a suggestion in the data that parents' interception of potential medication errors created animosity between caregivers and parents. Where a parent escalated concerns about an inappropriate dose of a medicine being given there were repeated descriptions of these being ignored by nursing staff, or nursing staff rechecking and proceeding to administer the incorrect dose anyway, to the point that one site had resorted

to implementing a specific campaign encouraging nurses to "…listen…" to parents.

"They're not the enemy you know…?" (Interview 11, Nurse)

Yet repeatedly the interventions to improve safety of medicines administration leaned harder towards removing parents and carers from the administration process, and doubling down on patient assessment and documentation. During observations during a nursing huddle there was an exhortation from a ward manager to "…make sure that self-med assessments were completed because there was a rise in the incidence of parent medication error." There was a sense in one site that these assessments were increasingly used as a way to cover the organisation for otherwise suboptimal communication and involvement of parents in the medicines process. During this study no parent-medication errors were observed, but parents intercepting potential errors were observed relatively frequently.

From medicines during admission to medicines on discharge the approach was very different. All sites had very clear discharge policies that outlined the minimum level of information to be given to parents about their medicines. At the very least, parents were expected to know what the medicines were for, what the dose was and how to administer them.

The handover of medicines was observed to be one of the last transactions of the inpatient stay and very little verbal information or counselling regarding medicines was observed, with medicines often being handed over to families in a bag just as they were leaving. This bag was then often stuffed in a pocket, or tucked into the parcel shelf under a pushchair. As we've demonstrated, the pragmatic and loose approach to parent self-administration meant that much information on acute medicines was provided at the point of care. For example, inhalers and spacer devices are often required every hour or two hours while in hospital and nursing staff would use this as an opportunity to "train up" parents in these procedures while they were in hospital. Technique could be checked and encouraged over a period of days and nursing staff could satisfy themselves over time that parents were competent; but on other medicines no other checks were carried out prior to discharge.

This led to occasional problems for families who were on regular medicines. Despite clear processes for the verification and checking of all patients' medicines on discharge, it was not uncommon for medicines that were NOT part of the acute care pathway to be accidentally kept in the hospital storage or misplaced altogether, resulting in parents becoming more protective of their medication.

"I recall an incident where the parents were adamant that they were not giving a medicine to the nurses, it was prescribed by a private paediatrician. It was expensive… there was just something about parents insistence on, this is an expensive medication, I'm not messing with it. I'm keeping it. I'll let you know when I'm giving it." (Interview 8, Consultant)

Some nurses posited that it was increasingly harder for them to manage discharge processes in shorter and shorter time frames, with more and more equipment being supplied from the ward. Discharge checks for medicines were only one small part of the checklist. Yet at a managerial level the issues encountered around ensuring that all medicines are returned to the patient was described as "…basic housekeeping…" with the onus laid onto individual nursing staff for ensuring these processes were adhered to.

It could be argued that there were systemic contributions to these events. There were stringent expectations on the safe and secure storage of medicines whether they were from the hospital or owned by the patient and family – medication that needed to be stored in a refrigerator were stored in one space (often not a designated space for patients' medicines), controlled drugs had to be stored and recorded in a specific cabinet, and then there was a mixed ecology of stock- and non-stock medicines that again were stored either in the wider ward storage facility, or in a "Patient's Own" storage solution – usually a white box near to the patient's bed space, or a lockable drawer in the patient's room.

Furthermore, the final act of discharge seldom occurred in a planned or controlled manner. Parents were often told during the ward round in the morning that "…they could go home today…" but often there were additional investigations and decisions attached to the final authorisation of the decision. As such in most hospitals families were waiting hours for the final

approval to leave the hospital, and the processes involved were often compacted into a relatively short period of time. Parents and families also had lives outside of the hospital, and it was not uncommon for families to decide to leave the hospital "…and we'll come back for the medicines later." While this relieved the immediate pressure of parental expectation it often transferred the issue of supply to a team of nursing staff who were unfamiliar with the patient or their care.

9.4 Chapter Conclusions

Parents and carers are sources of considerable operational resilience and a source of safety for their children in hospital. They provide accurate information regarding medical and medication history, and are often the only people who can reliably administer medicines to their children. To this end, it is understandable to see how healthcare services can describe themselves as "patient centred."

Parents and families have to adapt their routines to suit those of the hospital system, which often functions under considerable pressure to the detriment of their child's medication. Parents are not formally trusted to provide information about their child's medicines, to look after their child's own medicines or to administer those medicines without validation by another healthcare professional, thereby eroding parental agency and autonomy. Parents are expected to be almost passive consumers of their child's care and can feel powerless to intervene if they perceive things as not being as

they should. Thus parents continue to advocate for their child and exercise their agency and autonomy whenever they can which can occasionally lead to conflict and disagreement which if unchecked can become distressing for everyone in the system.

Organisationally, this is a challenge. There is a strong duty of care towards the children admitted to hospital, but it is difficult to square this with the need to acknowledge and encourage parental involvement in care which, it is assumed, requires assurance of competence and capacity before parents can be admitted to the system. Furthermore, it is clear that the diversity of healthcare teams cannot assure the organisation of appropriate and effective communication with parents and families therefore the default of organisations is to exclude parents from systems entirely rather than consider the systemic issues relating to communication between providers and patients.

10 Theoretical reflections on medicines safety

10.1 Chapter introduction

The systems studied in this thesis were very clearly complex. The unit of study has been the acute paediatric ward which sits within a wider system of wards and departments, all of which exerted an influence on our ward. I saw the ED send patients to the ward independently, and patients transferred to other wards to make space for more patients. Within this ward, there were multiple teams that worked within other systems. Nursing staff were employed by and largely based on the ward, pharmacy teams were accountable to “Pharmacy” and medical staff worked within teams that covered multiple spaces. We have also identified that parents and families are a part of this system and it could be argued that children themselves are an independent system. Consequently, we have demonstrated how the environment and the way teams are constructed impacts on how workers within the system approach their tasks and deal with their problems. There is warranted a deeper theoretical exploration, considering how these observations may contribute to or mitigate DRPs to therefore identify where future interventions could potentially be targeted.

The purpose of this chapter is to explore the rich data presented above to identify potential error provoking conditions using Reason’s model for accident causation and relate this to more fundamental cognitive theories relating to team work and decision making. Finally, there are insights within this data to illustrate how staff adapt and adjust their work in order to

accommodate unexpected events, or where capacity and demand are misaligned.

10.2 Latent failures and their potential to cause DRPs.

Reason posits that there are three levels of failure that can contribute to organisational accidents – organisational or managerial, workplace and person/team. The purpose of this thesis has been to explore the systems-related contributory factors of DRPs and it has identified some organisational factors that may directly contribute to these events. Organisational failures (or "latent" failures) are decisions at an organisational or managerial level that are always present within the system but do not reveal themselves until an event occurs. This study has presented some interesting suggestions of organisational failures which relate to team structure and interaction that in turn are related to skill mix and staffing levels, and availability of knowledge and expertise.

It was quite clear that there were not enough staff to perform the tasks that were required. There were medical rota gaps which led to sites conscripting "supernumerary" staff into active roles (such as using Foundation Year doctors) or shortening induction periods in order to have staff available to cover rotas quicker than may have been ideal. Some study sites were using remote inductions to be done outside of the work environment as a method to accelerate availability of "new" staff for core duties. This was mooted during an informal conversation with a GP trainee in GH1.

"Yeah so I was supposed to start on Wednesday, but they sent this enormous bundle of stuff over for me to do as "induction" that I was expected to do before I got here… then there was some confusion over the rotas because my start letter said "arrive at this time…" and then when I did arrive, I got told off because I was supposed to be on-call…" (Fieldnote discussion, Doctor, GH1)

Structures of the medical teams were all different in each of the sites. The larger independent children's hospital (CH1) had a complement of 17 full time consultants who were arranged into five teams. Each team was rostered onto a day of the week (Monday to Friday) with a separate roster for the weekends (Saturday and Sunday). On these days, one of the consultants in the team was "on-call" – responsible for all the patients admitted to that speciality during that 24hour period, and they would oversee those patients through their stay to discharge. This resulted in up to seven ward rounds occurring in the ward every day as patients were reviewed followed up. It was seen to be quite difficult for other team members to identify which team was responsible for which patient. I observed a pharmacist trying to contact a prescriber regarding a discharge order that was ambiguous and needed clarification.

"Hi, are you the doctor on for this patient…? No…? Okay do you know who they're being looked after? Oh that person? I've already asked them and they told me to contact you… okay, I'll try the hot bleep." (Fieldnote observation, CH1)

Multiple teams looking after multiple patients was one of the reasons why nursing and pharmacy staff didn't participate in the ward round.

"You've seen what it's like… we'd love to go on the ward rounds, but which one do we choose, and who does my work while I'm on it. Some of them can last an hour…" (Fieldnote discussion, Nurse, CH1)

This was important because in all sites, the ward round was the primary decision making and planning opportunity for patient care. During the ward round there was opportunity to make proactive plans for discharge or escalation, and to influence medication decisions. Consequently, all medication interventions by nursing or pharmacy professionals were, by definition, after-the-fact and required amendment of something already prescribed. There was no proactive work to ensure the prescription was "right first time."

In contrast, in the other study sites, the on-call consultant was available for three or four days. They had a second consultant who was back up "second on-call" who was available to support in periods of high acuity or emergencies. In CH2 there was a third consultant who worked remotely and fielded referrals so that the junior medical staff didn't have to make those judgements. It was seen that with these more stable team structures, nursing and medical staff worked more closely, and the team had more clarity as to the activity in the unit. However it was still rare for nursing staff to join the medical ward rounds because they had other tasks to attend to. Ward rounds would generally occur in the morning between 8:30 and 10am which also coincided with peak nursing activity.

Nursing staff in all sites were attached to the ward – they were employed as part of that ward's establishment and were grouped as part of that team. There was a single ward manager in each site who was co-located with the

ward and a visible leader. On occasion there were agency nurses and nurses from other wards brought in to support, particularly if specific skills were lacking. This was most apparent in CH2.

"So we've got a nurse coming down from [WARD] this afternoon to support IVs as we only have one IV trained nurse on the whole shift…" (Fieldnote observation, CH2)

10.3 Team Work and Mental Models

Teams were flexible and adaptive. While formally medical, nursing and pharmacy teams were structured in isolation and worked to separate goals and objectives, smaller short-lived multi-professional teams would form and disperse in order to solve specific problems. Salas et al. define a team as "…two or more people with specified roles interacting adaptively, interdependently, and dynamically toward a common and valued goal."[338] Teamwork is achieved through communication and coordination, whereby people come together and negotiate a common understanding of a situation, and work together to resolve it. According to Salas et al., this co-ordination is mediated through three mechanisms – shared mental models, closed-loop communication and mutual trust – that are enabled through five dimensions; team leadership, mutual monitoring of performance, backup behaviour, team orientation and adaptability.[338]

Medical staff focussed on diagnosis and prescribing, nursing staff on administration and pharmacy staff on verification and supply. Parents, meanwhile, wanted their children to be safe and healthy.

A nurse arrived at the door of the pharmacy office with a question.

Nurse: "This kid with Crohn's needs a methylprednisolone infusion and they've prescribed it at 2mg/kg but I don't think that's right. I'm sure we've done, like, 10mg/kg for these kids before. Can you check for me? There's nothing in the BNFc."

Pharm: "OK, let me check the guidelines…" the pharmacist pulls up a file on their computer and reads through it in silence. "Hmm, it just says "Methylprednisolone" but there's no dose." They pull up an internet page looking for more information. "Even the NICE guideline doesn't say." They open a messaging platform. "Let me ask the gastro pharmacist and I'll come and let you know."

Nurse: "OK, but the quicker the better, I've made up the methylpred already…" (Fieldnote observation, CH1)

Team leadership in paediatric medicines safety was difficult to ascertain. There were three hierarchies which suggested divided leadership; the consultant was the overall individual responsible for the management of the patient, but the responsibility for medicines was fragmented between the three staff groups. Nursing staff were primarily responsible for the administration of medicines, while pharmacists were responsible for ensuring medicines were available, and prescriptions were correct. Individual practitioners were held accountable for their own involvement in adverse events and there was a sense among the teams that medical and nursing teams were handled differently for their mistakes.

"So when a nurse makes a mistake, they're bollocked – reflection, interview with line manager, something on your personal file… but it feels like medical staff just get a talking to." (Interview 2, Nurse)

"So when I make a prescribing error, I feel awful and… I'll talk about it with my educational supervisor and I'll reflect…" (Interview 6, Junior Doctor)

"Medication errors are one of our biggest problems, but we do see that nursing staff get treated a bit different to medical staff. So what I try to do is get some time to talk to the medical staff with reported errors… it can be helpful for some context…" (Interview 12, Pharmacist)

However, there is a suggestion in these data that leadership in medicines management comes from nursing staff. They are the only formal staff group that deal with medicines throughout the cycle from prescribing to administration and monitoring. They held themselves in high regard as being the "last line of defence" against DRPs and were often the practitioners that identified potential DRPs. However, nurses were not empowered as leaders in this dimension. Organisational policies and procedures placed the prescriber at the top of the hierarchy. However, the prescriber often lacked the contextual or practical awareness of how problems may emerge and would be seen to make the required changes without question.

"All ambiguous or incorrect prescriptions should be referred to the prescriber" (Medicines Policy, GH1)

Pharmacist: "Hey, you know that methylphenidate you prescribed… we don't keep the 50mg strength. Can you represcribe it for me please?"
Junior Dr: "Yeah sure, what do you want? 10s and 20s?" (Fieldnote observation, CH2)

This referral to prescribers could be described as an act of monitoring within the system. I observed a clinical nurse educator coaching a new member of the nursing team in medicines safety which involved rote teaching of policies

and guidelines, but made clear expectations that when things were not as expected, they should be clarified and referred back to prescribers.

"Yeah, so when you see this… that's right, that dose isn't what's in the guideline, so you'll need to get the doctor to change it." (Fieldnote observation, CH2)

There were also examples of how teams supported each other in unexpected or high-stress events. I observed many situations where nursing staff predicted medical action before it had occurred. In CH1 a parent called for help when their child was having a seizure, and instead of heading to the room, the nurse in charge pulled a set of keys from her pocket.

"You go see what's happening, I'll go get some buccal midazolam…" (Fieldnote observation, CH1)

When the emergency was over, I was able to observe the nurse explain to some students around her what had happened.

"So he's been with us for a couple of days, and during the huddle this morning I had reiterated the seizure plan. At the time, I had the keys and I knew that there was already a nurse nearby and a doctor on hand so my priority was to get the seizure medication out of the CD cupboard." (Fieldnote discussion, Nurse, CH1)

On occasion such preordained action provided quick and efficient treatment, but on other occasions, these predictive actions sometimes went wrong. In CH2 a medical team had decided to start magnesium therapy in a deteriorating patient. Nursing staff decided to prepare it before the prescription was written to minimise delays in therapy, and referred to a local guideline where doses were "banded" to reduce the need for complex calculations. Once the medicine was prepared, the nurse checked the prescription on the electronic prescribing system. .

"Bugger… she's done mg/kg and I've made up the dose-banded dose. The order is 1120mg and I've made up 1100mg…" The doctor came into the clean utility to ask if the magnesium was right. "Erm, no, the guideline says it should be dose banded… can you change it?"

"No… I want to give the higher dose…" (Fieldnote observation, CH2)

At an organisational level, a decision had been made to trade-off dosing accuracy for reduction in error and time to prepare doses, but occasionally these decisions were not acknowledged or accepted by prescribers which created a space in which practitioners were in conflict. "Norms" of practice were overridden, which nursing staff felt required to challenge. Mechanisms of performance monitoring and backup which were demonstrated in these situations were interpreted as challenge and undermined mutual trust. Where pharmacists sought to clarify or amend prescriptions, it was initially difficult to track down the prescriber to take responsibility for the change, and then would occasionally have to review their decision in the light of new information offered by the prescriber. In the same vein, nursing staff were often perceived as "passing the buck" to medical staff to make decisions. Yet nursing staff lacked the authority to make those decisions. On a ward round there was discussion between medics and nurses regarding stepping down doses of inhalers in readiness for going home.

Dr: "So let's come down to six puffs four hourly. Can we do that now?"
Nurse: "Yeah sure. Can you re-prescribe it?"
Dr: "Do I have to? Can you not just do it?"
Nurse: "Well, no… it needs to be prescribed…" (Fieldnote observation CH1)

It was seen that there was considerable back-up offered within defined teams – nursing, medical and pharmacy – and there were examples of this at the boundaries of the teams as well.

"I'll always back up my team with others. We have an issue with the surgeons – they're not paeds trained and they often make prescribing errors. One of my nurses did their job and told them it was wrong, and they were really rude to them. I basically said "leave it with me" and… well, you kick one of us you kick us all…" (Fieldnote observation, GH1, ward manager)

"Look, I know that this patient shouldn't be here, and I completely have your back. What do you want me to say to that team when they come back…?" (Fieldnote observation CH1,)

This backup could also be seen as "reaching in." It was not unusual to see some people doing what would usually be described as the job of another person. Pharmacists would prescribe or adjust prescriptions of medicines in order to ensure they were administered at the right time or dose. Many policies did not permit this action.

"Ah but y'know, it's just editing and if we asked for every prescription to be rewritten… nothing would ever get done." (Interview 13, Pharmacist)

"I would usually just clarify what the medicine name was if it was written badly in the box…" (Interview 3, Pharmacist)

This support with technical tasks was not restricted to staff members, and I observed family members intervene with nursing staff to support decision making and action.

"While we were waiting in A&E he had to have a dose of this antibiotic and it was horrible, but he loves ice cream so they managed to find an ice pop in the freezer so he was happy with that afterward." (Fieldnote discussion, Parent, CH1)

The teams within the system were defined by their professional designation, but there was little definition to the ward team. The people who formed this changed frequently. Pharmacy services were constrained by their hospital-wide commitments thus there was on occasion a different pharmacist in each ward every day. Medical staff were also constrained by their shift patterns, such that trainees in each site would change frequently. Thus, the teams observed undertaking medicines safety work in these spaces are unstable and often short-lived. This also creates issues with understanding of what individual roles and commitments actually are, and there were frequent conflicts between the priorities and goals of workers within the team.

Thus there is evidence here of deficient mental models between teams, when it comes to medicines safety. Johnson-Laird posited that people carry with them mental representations of their work which they use to evaluate their progress and outputs.[339] These mental models support teams in complex systems having a shared situational understanding of the plan and the roles and tasks of each person in the team.[340] This means that members within the team can identify changes in the system, and adapt strategies together. It has been suggested that this happens almost imperceptibly, with unwritten rules and relationships becoming embedded into the structure of the system.

Organisationally, the medicines management system had become a system of silos – medical, nursing, pharmacy and parents working separately.

Under “normal” conditions, orders were written by doctors, dispensed by pharmacists, and administered by nurses and parents. When these “normal” states were unable to proceed, there was evidence of informal team work between nurses and parents, nurses and pharmacists, nurses and doctors. The exchange of information between these workers was largely transactional.

Nurse:“So this isn’t quite right according to the BNFc but they’ve had it before…”

Pharmacist: “Hmm, I see… but hang on.” The pharmacist consults their medication history notes. “Ah yeah, here. He’s been on that dose for a while, and I think there’s a clinic letter with it on as well. It’s fine.”

Nurse:“Great, thanks.” (Fieldnote observation, CH1)

There was no proactive discussion about medicines among the team unless they were directly pertinent to the immediate problem facing the patient which contributed to some of the situations seen where background medication were not accounted for during the patient’s stay.

There is further evidence to these unaligned mental models in the reliance on printed Handovers (described in Chapter 8). These documents were used by participants to quickly summarise important clinical information and were representations of the mental models used by each clinical group, populated with different information and levels of detail. Nemeth described such artefacts as “boundary artefacts” or “cognitive artefacts” as they provide insights into the cognitive work of the people that use them.[341] The Handover offered team members a field of expression in which to plan their

activity, evaluate their performance of pre-defined tasks, and to co-ordinate the transfer of information between other members of staff.

These mental models were also used to guide interaction between other teams, and it was common to see nursing and medical staff referring to their Handovers when discussing patients together. The Nurse in Charge would also refer to The Handover as a way of identifying patients ready for discharge or patients who could be repatriated elsewhere (another ward, another hospital) in order to free up capacity for other patients. Further supporting the finding that mental models were dysfunctional, there were efforts being made in CH1 to standardise and formalise this Handover into a single defined dataset that was virtual, and accessible to everyone, synthesised the same information, and ensured that tasks were allocable. Yet there were suspicions that the motivation for this were to enforce some kind of organisational control and personal accountability in terms of tasks and roles.

"Yeah so they want us to use this because they think it'll mean fewer bleeps for the doctors and more timely response to some of your jobs and requests… but also, you know that the Handovers aren't saved anywhere and when there's a problem they can't audit them… it's just another way for them to keep an eye on us…" (Fieldnote observation CH1)

These suspicions created an atmosphere where some people were afraid to break or bend the rules when they needed to, preventing adaptation. We have already presented the case of the nursing staff refusing to administer an unusual dose of a medication despite there being a clear case and

experience shared from other parts of the team. There was an underlying sense of a fear of operational retribution for “errors” that could be described as adaptations that have gone wrong. People “not following the guidelines” was often because the guidelines were not accessible at the time, or were ambiguous. On one occasion I observed a clinician writing a discharge letter using an electronic system, and they wanted some hydrocortisone cream for a skin complaint. They opened up a drop-down menu for hydrocortisone and was presented with an array of different selections. They sat there staring trying to make sense of what was in front of them. They then consulted the BNFc on their mobile phone and still struggled to find what they were expecting.

“Do you know what…? I’ll just choose that and if it’s not the right one someone will tell me.” (Fieldnote observation, CH1)

Sure enough an hour later, the ward pharmacist was processing the discharge letter and picked up that the selected hydrocortisone was not appropriate.

“You see, they want it for the face, but they’ve ordered 1% and that’s not right. I’ll have to phone them…” (Fieldnote observation, CH1)

Decisions in this context were not made rationally using predictive generalised rules, but based on experience and underlying knowledge. When that knowledge was exhausted, then advice and suggestion would be sought from the wider pool of experience. There was a great deal of subconscious deferral to other services when decisions were not

immediately actioned – in this case, just left for the pharmacy service to pick up.

10.4 Sense-making and Requisite Imagination

In order to analyse situations and make decisions, workers undertook considerable "sense making" efforts to manage and plan their work. Weick defines sense making as the process of creating understanding from words into a "springboard for action."[342] These words could be a spoken instruction from a clinician, or the written guidelines and policies that workers were expected to follow. It was clear that where organisational recommendations or rules were insufficient to support a particular course of action, staff would come together to explore options. For example, magnesium sulfate is given as an infusion to treat acute severe asthma. Local guidelines in CH1 were framed in the context of a single dose. In the case of a patient with worsening symptoms, the clinical staff wanted to give a second dose, but they were unclear as to when would be an appropriate time after the initial dose.

Cons: *"Can we give a second dose?"*
Doctor: *"I'm not sure… the guideline only refers to a single dose."*
Cons: *"Right, well can we find out…?" (Fieldnote observation, CH1)*

The junior doctor then turns to the nurse who was looking after this patient and asks the same question.

Nurse: *"I don't know… have you asked pharmacy…?"*

The doctor and the nurse then went to the pharmacist in their office and repeated the discussion cited above. The pharmacist downloaded the same guideline as they were referring to from the intranet and together they looked at it.

Pharmacist: "Well here it just says single dose but I'm sure I've seen magnesium given more than just as single doses…"

Nurse: "Yeah, down on PICU they'll give it every eight hours I think if they need to…"

Pharmacist: "Is that for asthma or corrections?"

Nurse: "Oooh, I'm not sure… corrections probably."

Doctor: "Well, the magnesium on the last bloods was fine… 0.8 I think"

Pharmacist: "Okay, well I think it should be okay… let me check with a senior though…" (Fieldnote observation, CH1)

The pharmacist then sent an "instant message" through their computer to a senior pharmacist who was providing backup. After a few moments they replied "Yeah should be fine as long as magnesium levels aren't raised." With reassurance, the medical and nursing team left the office and executed the plan to repeat the magnesium dose.

In this example there are several examples of the cognitive work involved in resolving healthcare problems. Sense making has been described as part of the theory of distributed cognition (DCog), whereby the shared experiences of a group of people are greater than the sum of the knowledge of the individuals.[343] DCog considers that people and systems interact spontaneously based on a functional relationship. Within the sphere of medicines safety, this was related to "how to" prescribe, administer and

monitor medicines safely and appropriately, however there was a mismatch in the system in that it assumed that medicines were referred to in linear and isolated processes which as we presented in Chapter 7 is not the case. Further, DCog involves more than just sharing memories of actual acts, but as can be seen in the suggestion of the nurse, a further identification and representation of practice that may not have been directly experienced, but nevertheless is potentially useful to the resolution of the problem.

On the other hand, there is also evidence of organisational sense making as a way of coping with unexpected and unpleasant events. Weick describes how organisations use stories to make sense of the complex constantly changing system that they create. The concept of "errors" could be considered an example of a hegemonic story to rationalise and understand the concept of failure in healthcare systems. Dekker's description of "folk models" aligns with Hutchins concept of a dominant story. Folk models seek to reduce complex events into over-simplified yet easy-to-comprehend event associations that make easy sense of complex problems and support assumptions about causation of events without decomposing the event into its more complex (and less measurable) component parts. Similarly, Weick's dominant stories join together diverse operational observations into a single narrative that clarifies and supports action. In this study "errors" were used as the subject of stories of previous wrong-doing and examples of consequence of "not following the rules" which were used both to illustrate why certain interventions or processes were implemented, but also to manipulate staff into following the rules.

The implementation of BCMA presented in Chapter 7 is a clear example of how these dominant stories support a folk model of medication error. Nursing staff were perceived to be prone to errors associated with not adequately checking medicines, and there was an opportunity to reduce their involvement by introducing a technology that will "check" features of the medicine. Yet as demonstrated, this folk model did not take into account the messy reality of work and thus did not function as expected, which ultimately contributed to the intervention's failure.

Further, these dominant stories persist within the system in spite of worker's real experience. When discussing medicines safety informally, nurses, doctors and parents spoke of their own experience of "errors."

"Y'know, it was busy, I was supervising two new starter nurses and one of them was experienced and knew how to operate the infusion pump so I prioritised the newly qualified nurse who needed some extra help, y'know… and then before I knew it she'd programmed the infusion pump wrong and given the whole vancomycin dose in six minutes instead of an hour… I should have paid more attention…" (Interview 2, Nurse)

"Oh I remember this as if it was yesterday, was asked to do a septic screen on this neonate. Now, in this unit we did septic screens on little yellow cards, and one was started with each screen. You were meant to check through the notes to see when the last one was done, but y'know… notes were never filed, the cards were buried under other things… so I cracked on and started the screen and gave the dose of gentamicin as per the guideline and it was only later when the nurses were doing the bloods for a dose of gentamicin given previously that another card was found and the infant had already had a dose of gentamicin about 18 hours earlier…" (Interview 6, Junior Doctor)

All these stories spoke clearly to the complex contextual factors that influenced the events that had occurred, yet none of the individuals

acknowledged them as a core feature that should be addressed. At the end of the day individuals accepted the blame and burden of the events that they disclosed. "I should have paid more attention…" "I should have checked…" "I should have taken more care…"

As part of Westrum's theory of organisational cultures, there lies a feature of highly performing cultures around collaboration and creativity. We've demonstrated in this study that where activity and resources were unaligned, staff would improvise and adapt their practice to cope. In CH1 this was represented through a nursing policy that permitted deviation from the formulation of prescribed medicines in order to administer medicines unnecessarily. In CH2 I observed a nurse manipulating a 65ml dose of an intravenous medicine into a syringe to administer through a syringe pump because no volumetric pumps were available.

"It should go into a bag, but we don't have any of those pumps and this is already an hour late, so I'll have to make do. You can get 65ml into these syringes easy… just have to be careful not to knock the plunger that's all." (FIeldnote observation, CH2)

Manipulation of medicines is a normal part of paediatric practice because medicines are not usually developed with children's needs in mind. A pharmacist described it as "blue-petering" in the context of trying to identify suitable formulations for children when requested to continue a medication on behalf of another centre.

"…so you've got to play around with it, see if it dissolves, do the tablets split…" (Interview 3, Pharmacist)

But while this is something that the pharmacist spoke of in the context of an organisational governance process, it was not uncommon to see nursing staff and pharmacists in the ward “blue-petering” with medicines in order to administer them. Only one site had specific guidelines, which were transposed into the electronic prescribing system. In the other two study sites, it was normal to see nursing staff with package inserts from medicines, the BNFc or guidance available on the internet in order to “figure out” how they were going to administer the medicines. Children themselves were unpredictable and in some ways uncontrollable. They were wilful and exerted their own autonomy against many medical procedures, thus it could be seen that the use of parents in this process was also an adaptation to unpredictable events.

These actions are examples of “requisite imagination.” Established processes and rules cannot cover all conceivable events and conditions that a worker may be required to act in. Requisite imagination holds that training, team organisation and procedural manuals provide sufficient supporting information that workers can make reasoned and informed judgements under circumstances of “surprise” – when situations are not proceeding as expected. In this study, there was considerable use of requisite imagination between workers which could be seen with nursing and medical staff considering a problem and then agreeing a course of action, but similarly there were limits to this which were not shared, and on occasion led to the administration of a sub-optimal treatment, or no treatment at all.

For example in the case of the dexamethasone for croup, it was clear that when faced with the problem – the child vomiting the prednisolone – the doctors plan was to use a similar medicine that in their experience worked better and would be better for the patient. The nursing staff however did not share this experience, and their frame of reference was the BNFc which had a much lower dose. Nursing staff were reluctant to execute the plan because they lacked the practical knowledge and experience to see how it fit into the plan. Thus their instinct was to refuse the order and refer to the standard-of-care. This was also exemplified by nursing attitudes to guidelines and policies which was of rigid adherence, demonstrated in their insistence on prescriptions for ceftriaxone of 49.9mg/kg.

This form of “naturalistic decision making” (NDM) has been of great interest in healthcare systems since the late 1970s.[344] In NDM, operators use their experience and the patterns that they are used to seeing to inform their decisions. Klein defines this as the “Recognition-Primed Decision Model” (RPD),[345] with operators presented with a situation comparing it against an internal list of cues and expectancies. Where these are all within normal expectations, the usual action is implemented. However, where these are violated, the operator has to create another course of action and seeks additional information with which they build a mental simulation of success or failure.

Another aspect of NDM is that it allows decision making rapidly in dynamic and changing conditions where there is uncertainty. One of the core mechanisms of this is something described as transactional memory – the pooling of task-critical knowledge between individuals. Bachrach posits that in dynamic complex systems, these individuals rely on one another to accomplish their tasks because they cannot reasonably or feasibly hold the requisite knowledge and experience to complete all their tasks themselves.[346] These systems rely on credibility, co-ordination and specialisation to function, and yet in acute paediatric practice these aspects of transactive memory may be missing. Increasingly junior staff were being utilised to support overstretched teams, increasing the burden on more senior members of staff who had to support these staff members while also having their own workloads to deal with.

"I'm just sending this question to one of the seniors on Teams but… oh, she may have already gone home. Let me check with the on-call…" (Fieldnote observation CH1)

"Oh, I wouldn't guess at anything… if I was stuck and really didn't know I'd always seek help from a colleague. Not that I need to do that much anymore because I've been here a bit longer now and know my way around…" (Interview 9, Pharmacist)

However, these aspects of supervision are an important part of the flexible management of information in complex systems. Within this study, these examples represent a form of distributed supervision. Woods and Shattuck posit that the authors of guidelines and procedures also fulfil this role as they are involved in providing information for multiple actors, with these authors and distant supervisors having a better grasp of the wider organisational and

operational picture with local actors having more granular understanding of activity “on the ground.”[347]

Yet these guidelines and those remote supervisors are often inadequately prepared to deal with operational surprise – where situations evolve in unexpected ways or there are unanticipated responses to problems. One parent relayed a story about the administration of a medicine to his child for which the guideline that was being referred to was intended for a younger cohort.

“So he’s on this enoxaparin at home, and the dose is really fiddly… y’know. And we tried to do it the way the guidelines told us to but it was fiddly and we weren’t sure the dose was accurate… His levels were all over the place, and in the end one of the nurses on the ward who usually worked somewhere else said “Right, this isn’t the way we would normally do this, but try it because it’s better for these bigger doses…”” (Interview 17, Parent)

Further, there is clear evidence that this distributed supervisory control is missing from smaller less specialised children’s services. The examples above should demonstrate that those services that are part of a larger children’s hospital being more able to adapt. In part this was because there was a larger pool of experience and memory to call on for support for adaptation, and for understanding.

10.5 “Violations” as necessary adaptations to work

Thus there was a suggestion in this study that there were insufficient resources for staff members to carry out all the mandated safety work. The primary example would be that of omitted or truncated second checking processes described in Chapter 7. Without adequate resource to undertake those checks, nursing staff would make considerations to the value of the second check in preventing potential errors against the cost of the check in delaying administration of medicines. Thus the “primed check” described in Chapter 7 emerged. This was a performative check – demonstrating superficial compliance with a procedure while also ensuring that operational goals are met. It could also be argued that the “independent second check” was an organisational safety artefact. Hutchinson et al. explored these in the context of risk assessments that encourage organisations to believe that risks were managed, without giving attention to the work or resource required to deliver those risk mitigations.[348] The documented “independent second check process” could be considered an enabling device - a symbolic artefact that assures the organisation that “something has been done.” In two organisations it was seen that “independent second checks” were taken-for-granted that all medicines would be administered with this check done, therefore when there were errors and the checks hadn’t been completed, it was because of this failure that the event occurred.

These trade-offs, however, were not universally held. Some nurses expressed faith in the independent check process as being an important barrier to medication error. Yet there were stark differences in attitudes to

checking between paediatric services and adult services which emerged through the study of the mixed tertiary paediatric/large adult organisation.

"There's not a law in the land that requires a second check on anything, and we know that they don't do it properly… we've asked them if they want to make everything single check except controlled drugs and IVs, and they've said "no… it's not safe…"" (Interview 14, Nurse)

In at least one organisation in this study it was suggested that the use of independent second checks may not contribute to safety, and in fact may predispose to less safe practice, exemplifying Hutchinson's conclusion that safety artefacts "…can broaden the gap between work as imagined and work as done and increase the level of risk."[348]

However, other organisations reinforced mandated double checking, and in the case of one study site appeared to be using technological interventions to impose these second checking processes on nursing staff as a method of making efficiency-thoroughness trade-offs (ETTO) harder, when in actuality, those trade-offs were probably important in managing workload and ensuring medicines were given on time. It could be implied then that organisations viewed violations as a failure to follow procedure as a single isolated "cause" of error, whereas theoretically this may not be a valid position.

Reason et al. posit various types of violation that emerge based on organisational and environmental factors.[349] Within my study there are examples of situational and intentional (optimizing and routine) violations, which I will now explore.

Situational violations emerge when the organisational and environmental factors in the system make it very difficult to adhere to policies and procedures and still get the job done. In my study, this is exemplified by the prevalence of ETTO outlined in previous chapters. Many of the mandated medicines safety processes were difficult to deliver because of the lack of human resource and time to administer all medicines under these constraints. These situational violations were observed throughout the system, be it omission of second checks, failure to scan medication barcodes, or the deliberate prescription of the wrong thing to trigger an intervention from another member of staff further down the line to suggest the right course of action.

Intentional violations occur when a process or rule is perceived as valueless or obstructive. Reason describes two potential intentional violations – optimizing violations where violation of the rule or process produces some kind of psychological reward, and routine violations where the action is neither rewarding nor necessary but has become a workplace norm.[349]

An example of an optimizing violation would be the use of parents and families as adjuncts in medication administration. There were clearly perceived benefits for staff to utilise parents in these processes. They provided uninterrupted observation of their child and have no divided attention with other tasks. There was also a need to ensure that they could

continue the medication once they were home, yet there was no scope within organisational policy and procedure to support that. On the reverse, routine violations can be identified in the way that medicines were manipulated unnecessarily in order to achieve ambiguous “on time” administration requirements. In one hospital, there had been an attempt to formalise these routine violations to support nurse-decision making, yet this procedure then contradicted many aspects of good practice, and the new policy became a “bad rule” in some circumstances.

Yet when a DRP emerged they were classified as “errors.” Throughout conversations with pharmacists and medicines safety officers (leadership figures with operational responsibility for medicines safety) there was a clear implication that “…if people followed the rules then nothing bad would happen…” and yet it was clearly impossible for these rules to be followed because there were so many of them, there was conflict and contradiction, and as demonstrated through earlier chapters many of them were untested in the real world.

10.6 Safety Culture

Organisational perceptions and ideals of medicines safety were apparent throughout the study, and was identified through the documentary analysis and the discussions with practitioners in the field. In CH1 there had been a large push on enforcing administration checks with the use of technology, however there was evidence that this technology (the BCMA system) was

being used more as a managerial tool to measure and monitor adherence to second checking policies.

"BCMA should be really important… y'know we've had errors in the past where the wrong drug has been given or two doses of paracetamol have been given too close together and… this should y'know prevent those from happening. But they don't use it and I don't know why…" (Interview 10, Nurse)

This introduction based on previous errors suggests that this organisation used a Safety-I lens to make things safer – learning from errors. While BCMA was unique to CH1 there is considerable evidence of a largely Safety-I perspective on medicines safety from other sites as well. Interventions to mitigate distractions and interruptions were based on their perceived involvement in medication errors obtained through incident reports where "distractions" was laid forth as the cause of the error. There was no demonstrable Safety-II approach in any of these settings to explore what caused the distractions. Controls were proposed to help people manage the distraction rather than manage the source of them, and these controls were based on the findings from retrospective and unsolicited incident reports, with no suggestion that prospective empirical data collection was used to inform practice.

While nursing staff engaged in incident reporting processes they often complained of little or no feedback on their contributions.

Me: "So when there's a drug error and you report it, what happens?"
Nurse:"So I have to write a statement, or a reflective account and then give that to my line manager…"

Me: "And what then…"

Nurse: "Sometimes they'll have a chat with me, but largely nothing."

Me: "What about feedback or follow up…"

Nurse: "Nothing. The reflection just goes on my personnel file I think…" (Interview 2, Nurse)

There is an implication that nursing staff particularly are blamed when care doesn't go according to plan. Nurses complained about being blamed for not completing tasks or delivering plans that they were unaware of, while medical staff reported frustrations with pharmacists questioning management plans which had been developed during ward rounds. Staff also doubted the veracity of parental lived experience because it clashed with their own practice and habits. There were also some comments from ward managers about maintaining surveillance on the performance of their nurses.

"We need to be assured that our nursing staff are okay, and incident reporting means we can identify nursing staff early who might need some additional support…" (Fieldnote discussion, Nurse manager, GH1)

Returning to the BCMA case study, there were inconsistencies in the justification of implementation of BCMA, which suggest an attitude to medicines safety that is not shared through the organisation from top to bottom. Through informal conversation with service leads and MSOs the intention of the BCMA intervention was to "…introduce a closed-loop system for medicines administration." These systems remove elements of human interaction within systems that are expected to be sources of error. Ergo, the reconciling of the "right" medicine to the "right patient" at the "right time" would be achieved using the barcode associated with the medicinal product

and the barcode associated with that patient's unique identification. On paper, this intervention carried significant promise.

However, in practice, the application of the system was very different. It emerged through observation that there were multiple identification systems for patients based on where they had presented to the hospital. The ED had a separate patient identification system to the rest of the hospital, and given the large number of patients admitted to this ward through ED, barcode identifiers for those patients needed to be changed once on the ward. Consequently it was not uncommon for this to be forgotten or overlooked.

Medicines supplied by the pharmacy department did not have accessible or reliable barcodes. Because of a reliance on oral liquid medicines it was not uncommon for labels on medicines to become contaminated with residue and thus become unreadable. The hospital encouraged parents to bring medication in from home that the hospital could then use, but the barcodes associated with these did not concur with the barcodes for hospital procured products and again were unreadable to the system. This all added up to a substantial number of medications that BCMA would have been inapplicable to. Yet there were still drives to "improve adherence" with stated targets of "95% compliance" within a system where the likely compliance with barcodes had not been studied.

Thus there is a suggestion that when it comes to medicines safety for children and young people Safety-I was still the dominant paradigm in these sites. It could be described that the safety culture in these sites was relatively undeveloped and assurance focussed. Audits around safety and secure storage of medicines and adherence to guidelines and policies were described throughout the systems but over the 18 months of observation in these sites, there were no observed changes in process to account for the findings of these audits.

Organisational norms, values and activities shape employee behaviour and represent the overall culture of an organisation.[350] Safety culture reflects employee attitudes to organisational safety, perceptions of risk and how to respond and control these risks.[351,352] It can be measured qualitatively and quantitatively and it is accepted that measures of "safety culture" correlate with improved safety performance.[353,354] The two primary qualitative safety culture scales are based in healthcare and aviation,[355–357] and qualitative constructs of safety culture have been defined by Reason – informed, reporting, justice, flexible and learning.[358]

Westrum suggest three models of organisational culture – pathological, bureaucratic and generative.[359] Organisations are structured around their attitudes to people, their approach to information flow, and the importance of their "mission." Westrum's model of organisational culture was further extended into a continuum of five stages of safety culture through interviews

with oil and gas safety professionals to incorporate elements of Reason's constructs.[356]

As well as the three cultural states described by Westrum, Parker broke down the bureaucratic state into three progressively more enlightened states – reactive, calculative and proactive. The trajectory through these included changes in the way the organisation used data, from measurement to explanation; formal data collection and audit becoming a central aspect of organisational performance, the use of trained investigators and wide sharing of event information, and incident reporting becomes second nature, with incomplete forms being welcomed and completed later (the speed of reporting is more important than the accuracy.) This spectrum has subsequently been adapted and operationalised in health services to become the Manchester Patient Safety Assessment Framework (MaPSaF).[360] This study has enabled some insights into the extent of safety culture observed in the participating sites, and I posit that these study sites are in a bureaucratic model of patient safety.

Bureaucratic models focus on rules, positions and departments. The MaPSaF defines this as "We have systems in place to manage patient safety."[360] There was a lot of focus on "quality dashboards" and "RAG ratings" and compliance with interventions, yet there was no clear evidence of how these interventions had been developed with reference to people's everyday work.

"Ah, y'know, they just come in one day and say "this is what we're going to do… it's safer… we want you to do it…"" (FIeldnote observation, CH1)

The focus on rules and procedures was manifest in the diversity and complexity of the available information to support these tasks, however when they were changed it was not uncommon for these changes to be identified incidentally either through informal transfer of information from one practitioner to another, or following some untoward event. For example, in CH1 there was a change to the asthma guidelines that meant that patients could go home earlier once established on inhalers. During the ward round one morning, this had not occurred.

Cons: "Why are they still here? They could have gone home yesterday…"
Nurse:"Oh really?"
Cons: "Yeah, we change the guidelines so they can go home once they're on 10puffs four hourly and you're happy that parents know what they're doing…"
Nurse:"Oh, well we didn't know…" (Fieldnote observation, CH1)

Organisations relied on established communication pathways to advice practitioners of changes in process.

Me: "So how do you find out about new guidelines and stuff?"
Nurse:"Usually they'll send it by e-mail but who has the time to read that? Most of time someone who knows will tell me when I need to know." (Fieldnote observation CH1)

"Yeah so usually, e-mail and stuff but we're talking five thousand people who all work different shifts and in different places... it's not the best. So I'm working on developing a sharepoint thing it'll tell people when things are updated…" (Interview 10, Nurse)

So while these rules were seen as the primary mode of maintaining patient safety, they changed relatively frequently and it was difficult to advise

practitioners that the rules had changed. Further, communication from top to bottom relied heavily on conventional messaging – e-mail and word-of-mouth. Thus it was observed to be difficult if not impossible for operators to follow the rules at all times, because it was impossible for them to know the rules.

However, CH2 demonstrated some features of a “generative” safety culture. There were markers of increased participation with staff members in the development of safety interventions, and a shared teaching base that drew in nurses, pharmacists and doctors into a shared forum to discuss events and different perspectives. The COVID-19 pandemic had facilitated this through the increased use of computer conferencing platforms, thus many more participants were able to join. Ward-based teams were also more stable because of the longer period of consultant on-call and the location of two junior doctors in the ward, to complement a relatively stable nursing team. The use of a nurse-led “huddle” prior to the medical ward round supported an open and questioning culture between medical and nursing staff, and on numerous occasions pharmacists would join this huddle and offer their input into patient care. It must be noted that CH2 was part of the NHS early implementation and evaluation of the Patient Safety Incident Response Framework (PSIRF) so it is possible that this intervention had stimulated cultural shifts within the organisation but that was not one of the questions in this study.

10.7 Graphical Representation of the System

As described in section 4.6.8 a graphical representation of the system was developed, to support understanding of how each element in the system interacts. The starting model is presented in Figure 10.1.

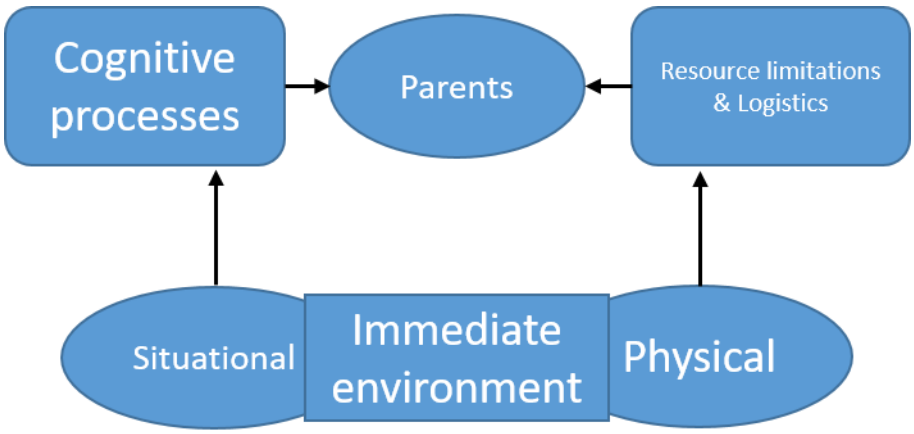

Figure 10.1 - Initial system representation

The immediate environment represents the physical, fixed spaces in which people work alone or together (offices, workstations, storage rooms.) The situational space represents the psychological space which people occupy and work within and includes knowledge, experience, professional status and emotional state. It is sensitive to cognitive limitations around experience and understanding, and the way information is shared and communicated. The physical space represents the teams and the environment in which we work, and the equipment that we have to interact with, and is susceptible to resource limitations – the availability of personnel, equipment and knowledge. Finally, the way people interact with these components of the system is important – deficiencies in any component of the system, results in

a tangible change in how those people work in order to get the task done thus providing a clear representation of the sociotechnical system.

However during co-production this “othering” of parents within the system represented and supported some of the findings related to epistemic injustice and there was a recommendation to widen this component of the system to include all people. This would then encompass the interactions with all people in the system. Further, while the demarcation of cognitive processes and resource limitations was understood and clear, they were considered an intrinsic aspect of the way safety was manifested within the system, and thus it was proposed that these aspects would be better presented together. Subsequently, the final model of the system for medicines safety is presented in Figure 10.2.

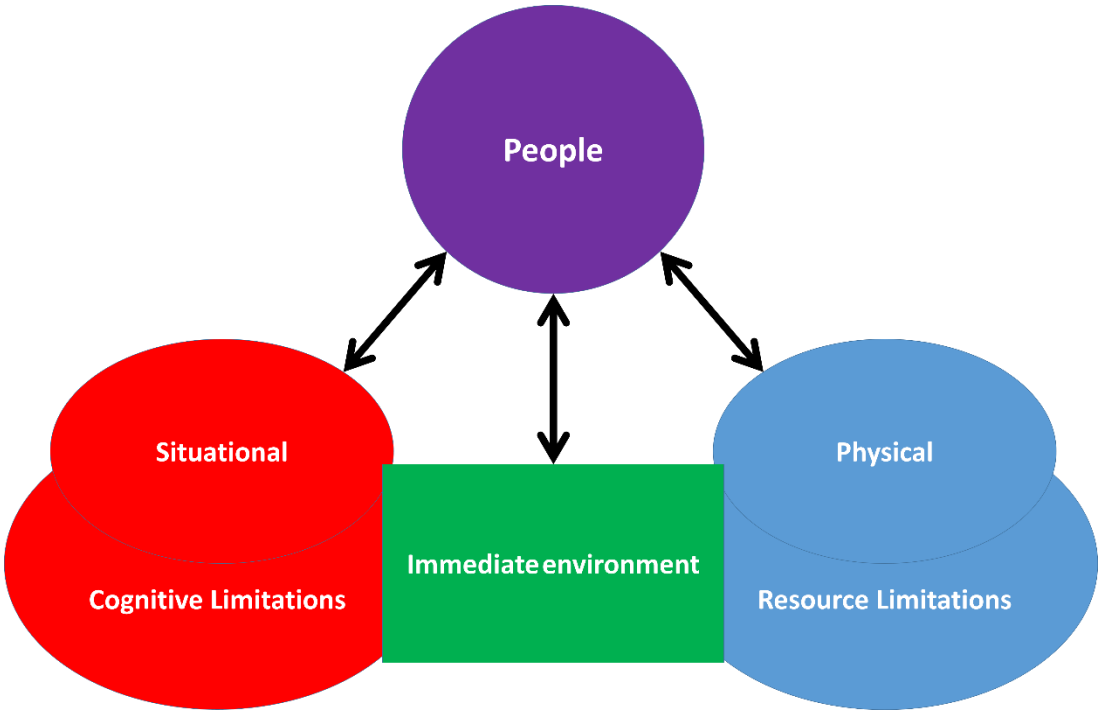

Figure 10.2 - Final theoretical model of medicines safety showing interactions between people, resources and the environment.

While this graphical representation offers some understanding of the complexities and interactions within the system, it could be argued to represent only the limitations that are identified in the system. There is no scope with this model to represent the resilience features of the system though the bi-directional arrows between people and the environment may suggest that. Resilience in systems is difficult to capture graphically. This study has not been designed specifically to identify resilience, but to explore the reality of medication safety work.

It is unsurprising then that suggestions of internal resilience have emerged through the course of the study but in order to truly identify and characterise these features requires specific approaches. Anderson et al.[361] have proposed the Concepts for Applying Resilience Engineering (CARE) model that identifies mismatches in resources and capacity with demand, reflecting Hollnagel's tradeoffs theory. Similarly, Hollnagel's Functional Resonance Analysis Method is able to describe the variation in processes within a complex system and identify the impacts that this variation has elsewhere in the system.[362] Resilience and Resilient Healthcare (RHC) are still relatively young concepts,[363] and at the time of inception of this programme of work none of these approaches were embedded in wider research. Therefore there are now better methods available to study RHC which could be considered as onward work from this thesis.

10.8 Chapter Conclusions

There were easily identified latent failures relating to staff numbers and relative knowledge and experience. Consequently, the medicines management field in acute paediatrics is exerted a large cognitive burden on operators within the system, partially because of the dynamic and unpredictable nature of clinical work, but also because of a relative lack of shared knowledge and experience manifested as a shared mental model within the work environment. Teams were isolated and worked together only at the boundaries of their day to day roles, and there was no coherent “ward team” for any role, not just for medicines. Priorities and tasks are not aligned, and there is clear evidence that clinical staff work separately, prioritise tasks independently, which creates confusion and conflict.

Most adaptations to medicines safety work can be described as situational violations – necessary in order to get the job done, and yet there was insufficient human resource and time to undertake many of the required medicine safety processes. Furthermore, some of these processes widen the gap between work as imagined and work as done, and further erode safety. Organisations use their policies and procedures as enabling artefacts to reassure themselves that risks are managed, and thus when those processes are not followed or are violated as described above, these acts are viewed as the root cause of many medication errors.

In order to support the cognitive load of providing care to children and young people in hospital, cognitive artefacts have evolved in the form of “The

Handover" to support the synthesis and exchange of information within teams, and to support resource planning in the ward. However, The Handover was not universal for the ward, held in multiplicity between the different teams in the ward, providing different information. Medicines were not seen as a central aspect of these Handovers, and thus not considered as part of the routine handover. This was perhaps exacerbated by the lack of a consistent and credible pharmacy team within the ward space. When pharmacy professionals were present they were essential parts of the ward team and had much to offer, but many medicines optimisation queries and issues arose when they weren't present.

Safety cultures in CH1 and GH1 could be described as bureaucratic, with a strong reliance on adherence to rules and hierarchy. Potential DRPs were "escalated" through the hierarchy, yet nursing staff were informally the leads for medication safety in the study sites as their roles touched every part of the medication process. However, the rigid hierarchy and interpretation of regulations held them back from exercising their considerable knowledge and experience in medicines management and expected the least experienced practitioners to resolve DRPs. As a result there was a suggestion that nursing staff were reticent to adapt or exert creativity in resolution of these DRPs, instead interpreting guidance literally and insisting others adhere. Psychological safety was degraded in these centres but for different reasons. In GH1 this was likely because there were no other paediatric spaces within the organisation against which to compare practice, so they were largely alone in their decision, while in CH1 there was a strong

hierarchy of expectation and “best practice” which had never been compared with the messy reality of work.

Meanwhile in CH2, there were clearly demonstrable signs of a mature and generative safety culture. Managers and leaders were easily identifiable, did the same work as everyone else and carried credibility, while discussions about DRPs and other incidents were conducted largely in the open and different perspectives were sought. There was also clear evidence that adaptations were acknowledged for what they were – adjustments in working in order to get the job done, and teams were happy to reach in across boundaries to support and assist where necessary to ensure the safe running of the ward.

11 Using Experienced Based Co-Design to Make Sense of mixed-methods data and Prioritise Interventions.

11.1 Chapter Introduction

Throughout HF/E methodology there is a strong philosophy of participation from all stakeholders be they service users, end-users of devices or the management of the services that are being considered. In this final empirical chapter of my thesis, I will set out the aims of using established participatory methods to involve parents, healthcare workers and researchers in the production of this research, the participant validation of the findings, and in developing potential interventions and priorities for them.

11.2 Background

Co-design is a method of service development and evaluation that includes and centres the process around service users.[364] It also encourages those service users to participate in the process of service development. Participation is part of the ethos HF/E engineering paradigm,[365,366] and co-design is acknowledged as an important aspect of intervention development by the Medical Research Council (MRC).[193]

There are multiple iterations of co-design (or co-production – the terms are used synonymously).[367,368] Boyle defines it as:

"…delivering public services in an equal and reciprocal relationship between professionals, service users, their families and their neighbours. In this way

both services and neighbourhoods become far more effective agents of change." [369]

Vincent and Coulter advocated for stakeholder participation in patient safety in 2002.[370] The NHS has recently operationalised this through the Patient Safety Incident Response Framework (PSIRF) but only in *post-hoc* investigation and reporting.[371] That being said, there has been considerable interest in using collaborative development processes for patient safety for several years, drawing on the unique perspectives and experience of service users.[372] Further, it is suggested that meeting patients and their families "…on their turf and their terms…" may support engagement and involvement of vulnerable and underserved patient groups and improve the generalisability of our work.

However, there is little clarity as to the "best" framework or approach to delivery of co-production involving healthcare service users.[373] Clarke *et al.* conducted a systematic review and identified 11 studies that reported co-design processes, but they were unable to identify the process of co-production in several of the studies. There was also a lack of any outcomes related to the effectiveness of the co-designed interventions.[374] Concerns were also raised about the potential for excessive cost implications of using co-production methods because of a lack of economic analysis. Similar concerns have been raised by other health services researchers [375] which is grounded in a perceived lack of methodological rigour, standardisation and

outcome evaluation. However, meaningful co-design is hard. Ocloo et al. [376] have identified barriers to good co-production around power gradients, inclusion of diverse perspectives and experiences and the presence of a clear framework for the process. On the other hand, the same review identifies that meaningful co-production needs to come at a system-wide level i.e. it needs to be considered as part of the research or service development process, to ensure democratic and meaningful participation.[377]

What makes for "good" co-production? In a meta-synthesis of research engagement studies in 2018 Fransman described public engagement with research as "…an institutional and administrative set of activities, rather than rooted in theory and practice."[378] Consequently, a number of frameworks and theoretical constructs have emerged. Common in healthcare related study is the Experience Based Co-Design (EBCD) model developed by the Point of Care Foundation.[379] This has been used in more than 20 UK healthcare studies with varying levels of fidelity.[380] EBCD has eight stages, including ethnographic observation, interviews with service users and service providers, separate feedback stages for providers and users, and concluding with joint provider/service user workshops.

Raynor et al. adapted the Point of Care Foundations' EBCD toolkit to incorporate application in multiple sites, and to incorporate theoretical analytical approaches.[381] These were operationalised and their feasibility

demonstrated to develop complex interventions in a transitional care model of elderly patients with frailty.[382] The first six stages of this approach were adopted to produce a shortlist of potential interventions for further co-design and evaluation as part of the future work from this thesis.

11.3 Methods

The correlation between the Raynor model of EBCD and this study is presented in .

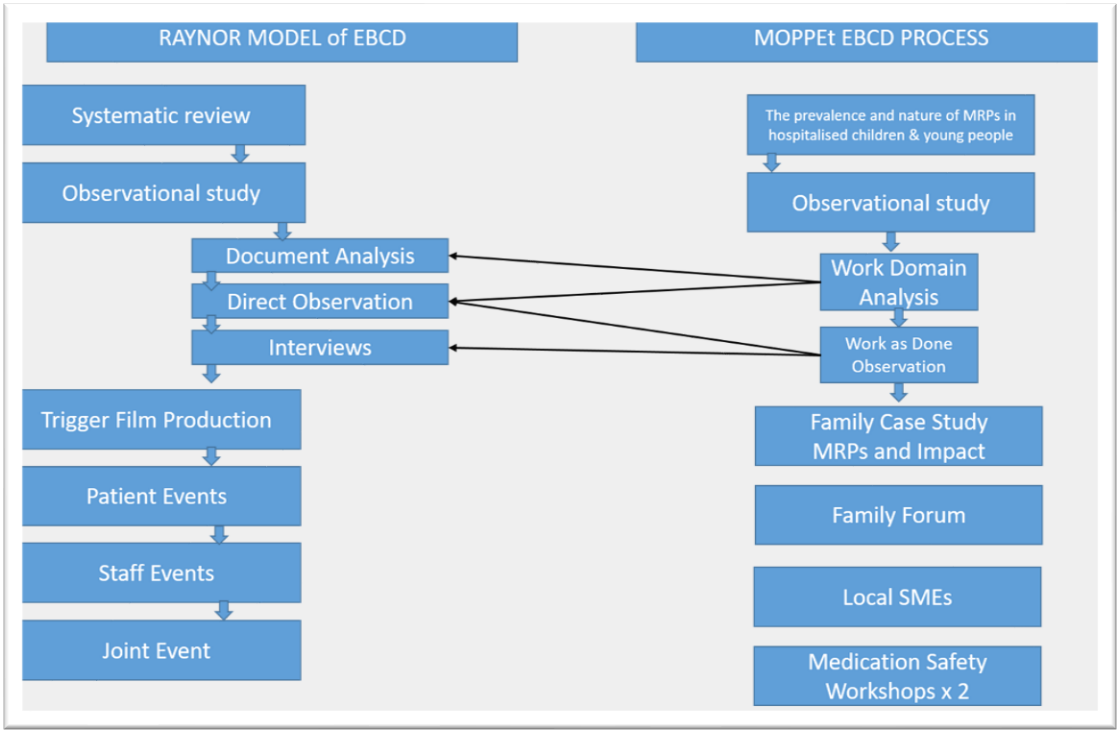

Figure 11.1 - Comparison of MOPPEt co-production process with Raynor's model.

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The systematic review has been presented in Chapter 2 of this thesis, and the results of the observational studies in Chapters 5, 7, 8 and 9.

The trigger video was produced in collaboration with a parent interview participant. They were approached by the lead researcher and asked if they would mind retelling a story from their interview to act as a stimulus for discussion and to set the purpose of the workshops on DRPs and their impact on patients and families. The method for trigger videos described by the Point of Care Foundation involves the editing and clipping together the experiences of a number of service users.[379] However the use of a single story in this setting was justified on the basis of harmful DRPs being rare, a relatively small number of parents participating in the study, and a lack of resources for expert filming and editing. The parent in this case provided written consented to sharing of images and videos for specific PPI/E purposes with both the video and the soundtrack destroyed immediately after the workshops concluded.

Parent workshop participants were identified through the fieldwork and through local networks who had lived experience of the services being studied. The inclusion and exclusion criteria were the same as those described in section 4.6.6 Members of the Family Forum were also invited to attend. As the focus of the workshops was to explore the results of the study and to look at onward prioritisation of future work, there was no creation of new data involved. This was considered patient and public involvement in research and formal ethical approval was not required. At the beginning of each workshop, participants were asked if they objected to images being

taken for the purposes of sharing on social media and celebrating the work that was being done. Parent participants were also reimbursed reasonable travel and accommodation costs where necessary to facilitate their participation.

Two EBCD workshops were organised at venues in the base cities of the two children's hospitals. One workshop was in Liverpool in March 2023 and another in Leeds in April. The aims and objectives of the workshops were to:

- Discuss the implications of the findings on practice
- Suggest priorities for onward research and development work

Sampling and size of groups for the workshops was determined using the same purposeful strategy as described in 4.6.6

At each session, following viewing of the trigger video, a short summary of the findings was presented to all attendees, focussing on the sociotechnical nature of the system and its interactions. Participants were then placed into two groups that were weighted for diversity of experience, to encourage medical, nursing and pharmacy representatives to work with parents. Each group at a minimum would comprise of a doctor, a pharmacist, a nurse, a parent and a facilitator. Determinations of group size and composition were made at the beginning of the session once all attendees were in place (Table 11.2).

Each group was facilitated by a member of the research team, and groups were presented with a case vignette drawn from the study data, and asked to discuss the factors present within each case with reference to their own experience. Groups were then asked to feed back their questions and comments on the findings and propose potential interventions. These interventions were then ranked and prioritised by participants to produce a shortlist. Records from the workshops consisted of contemporaneous notes that were taken by each facilitator which were then written up into formalised reports and summaries of discussion. There were also wall charts and doodle-pads that were also summarised into these reports. Furthermore, a professional illustrator was contracted to provide a visual record of the workshops which could be later summarised into a plain English and accessible abstract of the study for onward dissemination. The analysis of the sessions was conducted using the written reports as the primary data source, and these were analysed inductively to identify and group interventions into themes. Analysis was conducted by myself in conjunction with the facilitators. Prioritisation of potential interventions was decided using an adaptation of the Nominal Group Technique.[383] The workshops were planned around this method, to incorporate three of DelBecq's four stages – the round robin, clarification and voting.[384] This was considered a suitable approach to stimulate broader discussion among the participants, and reduce potential power gradients among the participants by empowering everyone to offer their opinion of perspective. Participants were asked to express their preferences for three interventions in order to indentify early

priorities, and were then asked to select just one of those priorities as their preferred interventions.

Participation at the workshops was also evaluated to provide data on the acceptability and feasibility of the method for future study. At the end of each session participants were asked to complete an evaluation form consisting of three sections:

1) Six questions relating to their enjoyment, inclusion, contribution, expectations, organisation and facilitation of the event. These were scored on a five point Likert-type scale, ranging from “Strongly agree” to “Strongly disagree”.
2) They were then asked to provide three words to describe their experience of the day
3) Finally they were asked to reflect on how their practice or interaction with healthcare services may change as a result of their participation.

The contemporaneous notes of the two workshops were typed up into a formal record of the sessions and were analysed descriptively alongside other records of the workshops (diagrams and flipcharts) to produce the potential areas for interventions.

11.4 Results

Participants were representative of the actors within the medicines systems (Table 11.1) While both workshops were designed with the same aims and objectives in mind, an organic drift in the first workshop meant that no prioritisation work was undertaken. It was in this workshop that Figure 10.2 emerged and most of the session focussed on the production of that as it's outcome. Following the analysis of the reports from Workshop 1 the researcher and facilitator decided to change the focus of workshop 2 to specifically work on the prioritisation of future work.

	Workshop 1	**Workshop 2**
Parent/Carer	2	5
Child/Young person	0	2
Nurse	3	0
Medical staff	1	1
Pharmacy professional	3	2

Table 11.1 – Composition of co-production workshops

Workshop 1, Group 1	1 x Nurse	**Workshop 1, Group 2**	2 x Nurse
	2 x Parent		1 x Medical
	1 x Medical		1 x Pharmacist
	1 x Pharmacist		
Workshop 2, Group 1	2 x Parent	**Workshop 2, Group 2**	3 x Parent
	1 x Medical		1 x Medical
	1 x Pharmacist		1 x Pharmacist
			1 x Researcher

Table 11.2 – Distribution of workshop attendees in groups

11.4.1 Potential Areas for Intervention

The groups identified four fields in which intervention should be based.

These were:

- **Trust & respect**

  It was apparent that health services were constructed around service provision and available resources, with policies and procedures put in place that disempowered individual staff members and excluded parents and families. A parent participant remarked that the service "…worked to serve itself…", and safety emerged as a secondary outcome of service delivery. It was felt that there was an organisational distrust of healthcare provider autonomy and families were excluded from the system entirely. Information provided by families was always validated against secondary sources which were often inaccurate, and there was a concern that this validation placed value on medical history over the history reported by the parent, who were those who had the lived experience and were solely responsible of administration of those medicines.

  Furthermore, some of the systems embedded in the name of patient safety – second checking of medicines, security of all medicines – were felt to create barriers to safe practice. It was agreed that the lack of staffing availability and perceived redundancy of the checking process led to widespread efficiency-thoroughness trade-offs to undertaken medication work. There was also a question about whether or not medicines in the possession of parents were safe, with experiences described of medicines retained by the hospital going missing, being destroyed through inaccurate storage, or doses being missed or administered incorrectly.

- **Power & control**

  It was clear that there was conflict within paediatric healthcare systems that were likely not present in other healthcare settings. Health services were constructed with the view that the medical and nursing teams held the power and autonomy over treatment of the children in their care. This was the case in adult settings where sick adults would often yield their autonomy to their healthcare professionals. Children were accompanied by essentially fit, healthy adults who held capacity and wished to exercise authority over their treatment. However, the assumption made in paediatric services was that children had no autonomy, and parents were often overlooked in that evaluation.

  And yet, it was almost universally observed that parents were part of the process of administering medicines to their children which was outside of the governance and professional arrangements within the system. In line with the Trust pillar above, there is no way of administering medicines to children in hospital on time, and appropriately without involving the parent or carer in some way, but there were questions around how organisations can ensure parents are safe and competent to do so without making assumptions, while also maintaining parental autonomy to step back from caring for their child should they need to.

- **Heuristics & Problem solving**

  Many processes in healthcare systems were so rigid that they precluded any flexibility and adaptive capacity. Guidelines were written in a linear fixed process format, with little or no information to support problem solving. There was also a suggestion that heuristics were unacknowledged at an organisational level, with frequent exhortations to healthcare staff to "…be aware of and follow available policies and procedures." There was almost a blind faith from organisations that if the rules are followed nothing bad will happen. And yet, it was impossible for nursing and medical staff to follow all these rules because there were so many of them, they often contradicted each other. As reported there were a multitude of policies and procedures to follow for medicines use, but these had to be balanced alongside other tasks and duties (e.g. safeguarding responsibilities, care planning.)

  This made efficiency-thoroughness trade-offs the norm, rather than the exception. At times where a clinical situation did not fit with the expectations of the providers, there was a natural drive to reach out to colleagues and other information sources to seek information with which to make a reasoned judgement and decision. It was not uncommon for these events to be subsequently categorised as "errors" after the fact, which created sensations of guilt and incompetence.

Thus heuristics need to be acknowledged and studied as an essential aspect of modern healthcare, and guidelines and procedures developed with these in mind to foster resilience and provide a framework for safe adaptation.

- **Communication**

Throughout the results of the study it is clear that communication is suboptimal between all actors within the system. Transfer of information between people is transactional, based on a need for specific information or knowledge. Because of the rigidity of routine processes for asking patients about their medicines, it is susceptible to assumption or values-driven assessments of the care circumstances of children and young people which results in omission of some information because these assessments are not holistic, or patient-driven. Indeed, parents continually observed that at each interaction with a “new” service provider, they had to tell their story again. It was perceived that there was no centralised information repository about their child, or the people looking after their child were not fully aware of the patient’s history.

There was also a suggestion that people in the system are unclear of the roles and responsibilities of other actors. It was clear in the data and from participants that it was not uncommon for medication histories to be left to pharmacy professionals to be completed

because “…that was their job…” which led to delayed assessment of medicines and occasional identification of significant medicines related problems. Part of this could be attributed to service design with pharmacy services being centred in office hours during the week, but there was also a relative absence of pharmacy services from the ward environment within those office hours as well.

Aligned with the transactional nature of information exchange, there was also evidence of siloing within the services with people working on defined and discrete tasks. Objectives and outcomes were often considered in isolation of overall objectives and nursing objectives were not the same as medical or pharmacy objectives. The objectives of parents (e.g. getting home to maintain childcare for siblings) were often not considered by other actors in the system. This resulted in a disjointed and inefficient process of information exchange where again, some vital information was missed because it was not specifically sought (Figure 11.2). In short, when it comes to medicines, people do not know what they do not know.

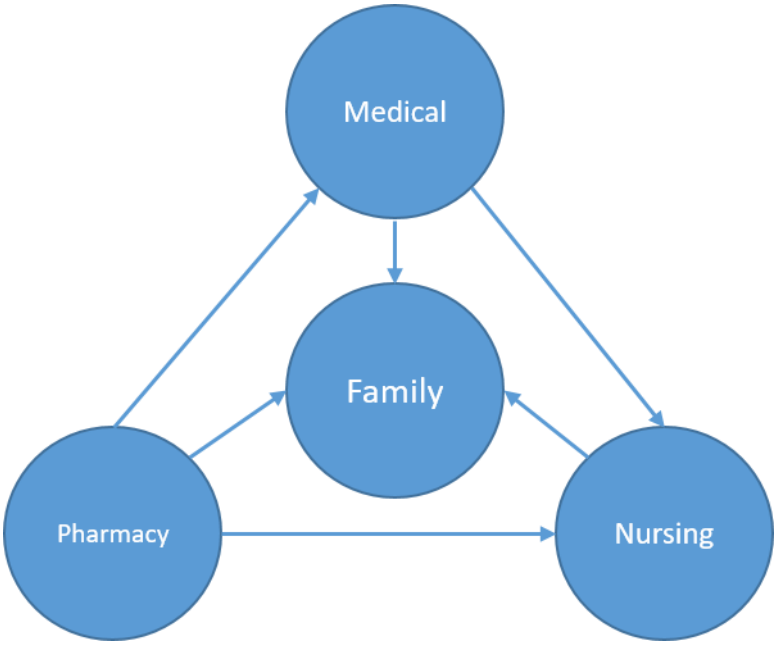

Figure 11.2 Communication pathways for medication safety for CYP in hospital

Which brings in the consideration of skill-mix as a safety construct. It was very clear that there were some professional groups (mainly nurses) on which all the work of medicines safety was laid, while other groups were perceived to only have responsibility for a single aspect of the process. For example, medical professionals were only operationally acknowledged from their role in prescribing, yet it was nursing staff that were commonly held accountable for administering medicines according to a wrong prescription. And yet, nursing staff had no power over prescriptions or insight into decisions that were made because of a lack of contextual information around them. Furthermore, pharmacy professionals were responsible for medicines only in the context of completing medicines reconciliation at admission and discharge, and supplying medicines throughout the patients stay. As such they "bookended" in-patient episodes, being present at the

beginning and the end, and interactions during the inpatient episode were reactive, related to problem prescriptions identified when ordering medicines.

Primary decision-making stages with regards medicines were medical ward rounds which were medic only and were organised differently in each site, dependent on medical service needs. This impeded the transfer of information and provision of decision support from other relevant professionals and introduced opportunities for the emergence of medication related problems, therefore should be explored in more depth.

11.4.2 Potential Interventions

Interventions were considered and suggested in the second workshop. Nine participants were involved in the NGT process. Communication was considered the single most important area for intervention, followed by trust and respect. It was considered that other aspects would flow from these. Thirteen potential interventions were proposed, grouped into each area and presented in Table 11.3.

Participants were asked to then vote on their preferred interventions in two rounds. In the first round, they were asked to vote for three interventions, and in the second for one single intervention that represented their preferred choice. Vote tallies in the first round are presented and ranked in preference order in Table 11.4.

1.Communication	2.Trust & Respect	3.Power & Control	4.Problem solving
A.Individual health passport with a defined standard data set for medicines history derived from routine NHS data	A.Training in non-verbal communication for service providers incorporated as part of continuing professional development.	A.Shared access to medical notes and electronic medicines administration records (MAR) for parents and providers to support safe engagement with medicines administration for parents.	A.An app-based clinical summary of the child's care and progress that enables two way control and rapid feedback on data issues and errors.
B.Open forum discussions between parents and care teams to discuss problems away from the clinical environment	B.Support parents to share their experience and skills as part of provider training programmes and to promote respect for parental skills and attributes.	B.Incorporating family feedback into key performance indicators for pharmacy services	B.Ensure that ward teams have an appropriate skill mix for the routine daily activity including a dedicated pharmacist, medical staff and other therapists as necessary and that all are part of the patient's journey.
C.Including parents in medication change decisions and communicating these clearly	C.Provide systems to support parents routinely administering medicines to their children in hospital because children trust them implicitly. and ensure that these are encompassed in clear expectations of parents while in hospital	C.Parents validating medicines reconciliation rather than providing information that is validated by professionals repeatedly on each encounter with healthcare systems.	
D.Foster a collaborative working environment involving all stakeholders with multidisciplinary ward rounds and parental involvement with clear delegation of responsibility.		D.Medicines administration procedures and equipment need to be standardised across the healthcare system, rather than localised to each site.	

Table 11.3 – Co-produced potential interventions

1A	5
1D	5
3D	5
4B	5
4A	4
2B	3
3A	2
2A	1
3C	1
1B	
1C	
2C	
3B	

Table 11.4 – Vote tallies on first round, multiple transferrable voting

Subsequent single choice votes are presented in preference order in Table 11.5.

1A	2
2B	2
4B	2
1D	1
2A	1
1B	
1C	
2C	
3A	
3B	
3C	
3D	
4A	

Table 11.5 – Vote tallies on second round, single-vote

Thus our co-design group identified the following as their priorities for future intervention:

1A: Individual health passport with a defined standard data set for medicines history derived from routine NHS data.

2B: Support parents to share their experience and skills as part of provider training programmes and to promote respect for parental skills and attributes.

4B: Ensure that ward teams have an appropriate skill mix for the routine daily activity including a dedicated pharmacist, medical staff and other therapists as necessary and that all are part of the patient's journey.

However, it must be noted that there were a number of potential interventions that also attracted a great deal of interest from participants:

1D: Foster a collaborative working environment involving all stakeholders with multidisciplinary ward rounds and parental involvement with clear delegation of responsibility.

2A: Parents and families often experience difficulty in communicating with healthcare professionals because non-verbal cues and responses may discourage them from advocating for their child's care and best interests. Therefore it was considered of some importance that healthcare professionals receive some training in non-verbal communication to support their empowerment of families.

11.5 Evaluation of Co-Production

14 of 19 participants returned evaluation proformas. This proforma is available in Appendix 11, and a summary of the quantitative results are presented in Table 11.6.

Question	Responses
1. I enjoyed the event	Agree or Strongly agree: 14/19
2. I felt included in the event	Agree or Strongly agree: 14/19
3. I felt able to contribute	Agree or Strongly agree: 14/19
4. I knew what was expected of me	Agree or Strongly agree: 14/19
5. The workshop was well organised	Agree or Strongly agree: 14/19
6. The workshop was facilitated well.	Agree or Strongly agree: 14/19

Table 11.6 - Quantitative summary of workshop evaluation responses.

All participants agreed or strongly agreed that the sessions were enjoyable, inclusive and well organised and facilitated. Analysis of the qualitative responses identified that all participants found the sessions immersive, engaging, and thought-provoking. The single most common free text response was around clarity and openness in communication Some respondents mentioned challenging assumptions and exploring other perspectives, suggesting that a safe environment was created for participants. Participants also provided reflexive comments regarding changes in perspectives and practice including giving more time to listening to family stories and lived experience. A limitation of this evaluation is that an analysis of response by participant designation is not possible. In view of the small numbers of participants in each session, a decision was made to aggregate all responses to provide an assurance of anonymity to respondents. .

11.6 Chapter Conclusions

The EBCD process that we have used has continued to bring healthcare professionals and parents and carers together in this research. The co-production approach has helped to bring the voice of families to healthcare professionals in a safe and constructive space. Our approach to co-production has potentially changed the perspectives of participants and empowered parents in the design services for children and young people. However, an appreciation of impacts of this approach on parents and healthcare professionals would provide a better evaluation of the achievement of the overall goals of the workshops around empowering participants, and should be considered in future iterations. However, the interventions that service providers and users have proposed in this study would bring parents and families into the working space and offer them some assurance and agency over their child's care while offering support and assistance to overstretched healthcare services.

We would propose that the first intervention that should be developed from this study be a personalised medication passport, derived from a standardised medicines reconciliation dataset for every child and young person in the country that is automatically populated from the routinely collected data already held on NHS patients across primary, secondary and specialist care. Instead of medical, nursing and pharmacy staff validating this data repetitively and independently on each admission, this dataset would enable parent validation on admission which would offer an efficiency

on current practice, and empower parents to proactively identify medication discrepancies and potentially mitigate error on admission or discharge.

The second potential intervention is to involve and engage families in the training and development of healthcare professionals in medicines management and administration. Parents have a wealth of practical knowledge and experience, and much of the conflict observed between nursing staff and families particularly was around disagreements on medication administration timing and techniques. An understanding from all service providers and users about the adaptations that parents make to care for their children would be beneficial in building mutual trust and respect.

Finally, the co-production process advocated skill-mix interventions to improve access to medicines and medicines information. In reflection of the wider findings of the study, this could be described as an intervention around service structure and provision in hospital. It has been identified throughout this study that the only members of the ward team who are responsible for medication processes are nursing staff. Medical and pharmacy staff are associated with different service structures, which removes them from the point of care and results in a largely reactive service provision with respect to medicines. Furthermore, pharmacy teams are not part of ward rounds or the wider clinical infrastructure for in-patients, and this removes them from the decision-making setting. This absence from the clinical environment drives

clinical staff to make decisions “on the hoof” rather than seek proactive advice from the pharmacist, which in turn creates medicines related problems. Therefore we would propose a programme of study examining the impact of an embedded paediatric clinical pharmacist with ward based teams including presence on ward rounds as a method of reducing harmful medication related problems, improving communication with parents, patients and the wider clinical team, and improving efficiency in medication supply.

While these proposed interventions are robust in that they are proposed by a broad representation of service providers and users, they are by no means assured of being deliverable. The interventions proposed could be argued to be quite complex, and outside of the control of the participants in the room, thus require considerable onward development before they can be considered suitable for feasibility testing or piloting. Furthermore, some of the interventions may challenge closely held beliefs of the wider healthcare practitioner community, and thus studies of barriers and opportunities to these interventions are required as part of that feasibility testing.

A final limitation of the EBCD process is its necessity for in-person meetings. These are difficult to co-ordinate and expensive (for this study alone, the organisation and facilitation of the co-production events cost in excess of £5000) which may not be accessible to other studies. Careful consideration and balancing of the potential benefits of co-production against their costs

needs to be taken into account when designing such events.[385] That being said, the Covid-19 pandemic has facilitated great advances in the delivery of co-production events in virtual settings, which could have been considered in this PhD were resources more constrained.[386]

12 Discussion

This PhD set out to explore the systemic factors that potentially contribute to Drug Related Problems in hospitalised children and young people using methods rooted in sociotechnical theory. As well as identifying potential contributory factors to these events, I have also identified considerable resilience within the system, captured in the way teams form and disperse rapidly when faced with problems, and through the involvement of parents and carers directly in the care of the children. This research has also identified how the system works against patient safety by creating artificial boundaries and barriers to safe care, through the use of safety artefacts. I can also challenge some of the historical assumptions around children's medicines themselves being a source of this risk. At no point during the observations or through the interviews did I identify medicines formulation or manipulation expressed as a problem. DRPs emerged through a lack of knowledge and understanding of the clinical pharmacology of medication in children, a focus on episodic-care rather than person centred care, and a lack of real team work between all the participants in children's medicines management.

Medication safety systems for hospitalised CYP are still set within a Safety-I paradigm with a focus on reactive response to events as a model of intervention development. Further, there is evidence that some of the key targets for intervention in each site – management of distraction and interruption, and interventions to mitigate medication administration errors –

do not take into account the natural limitations of human capacity and capability, and consequently may be futile targets for intervention or require additional future study.

This research was also designed to utilise co-production methods to include and acknowledge the perspectives and experiences of all stakeholders in the medication safety system. This included parents and carers which, to our knowledge, is the first such study to present this perspective. I have identified important insights into the role of parents and carers in hospital systems which has not been described before, and I have identified how these roles bring resilience to the system and help keep CYP safe while they are in hospital. I have also been able to describe how the system works to suppress this involvement in the interests of patient safety, but which may work against that goal in real life.

This PhD represents a systematic application of HF/E methods in the pursuit of understanding of patient safety and healthcare related work and potentially presents a model of how HF/E based healthcare projects should be conducted in the future. It is important to note that this study has been designed to ensure fidelity with the early sections of the Medical Research Council's framework for the development of complex interventions.[193] I have also successfully applied a robust co-production approach to this research to ensure meaningful involvement of all stakeholders in the study, from participant validation of the findings to production of potential

interventions ensuring a theoretical anchor to these findings throughout. This final discussion chapter will bring together the study as a whole, reflect critically on the work in relation to the wider literature, and consider the strengths and limitations of the work.

12.1 Description and definition of complex systems

At a theoretical level, complex systems defy representation because they change and adapt constantly. Leveson argues that these perspectives are subjective and rooted in the experience and contextual understanding of the analysts and thus defy description.[15] Complex systems change and evolve in response to imperceptible changes in the surrounding environment. Cilliers suggests that such systems are not in equilibrium, and the multiple components they are composed of interact endlessly, resulting in almost constant change and evolution.[387] Consequently, representations of these systems can only really be viewed as instantiations, created through the subjective interpretation of the observers.[388,389] Thus methods that attempt the decomposition and representation of complex systems such as WDA can be argued to be reductive, and overlook the complexity and ever-changing nature of these systems. Read and Shorrock posit that "…systems only fail through the perspective of human stakeholders…"[232]

Notwithstanding these theoretical challenges, there is merit in decomposing complex systems to their component parts and their interactions, if only as a method to understand the tasks, their complexity and to prioritise targets for

further study. Previous HF/E studies in medicines safety have explored medication safety work using normative analytical techniques.[42,390–392] They have sought to represent and decompose the task in the way it *should* be done and describe a single, best way of approaching the task. These have been described as reductionist in their approach as they use a linear analytical model and as such do not capture the complexity and context of these processes leading to misleading results.[202]

Graphical representations of complex systems have been criticised as reductive summaries of instantiations of system configuration, and their complexity can be lost in the "simplified" graphical representation.[393] Yet I balance this critique of visual methods such as WDA against its intended use as part of a larger systems-design approach (CWA).[394] WDA is designed to identify the constraints and organisation of the cognitive elements of human work without events or people, which can then be re-modelled and designed using other methods. However, this study reflects blurring of boundaries between subject and obkect. Thus people can also be viewed as objects within the system, and are used as such. An example of this has been our ability to identify the role of parents within the system, through the means-ends links in the model.

There is a strong tradition of cognitive work analysis in patient safety, which this study now adds to. However, the tools of CWA have been used relatively rarely in the study of medicines and medicines safety.[306] Lim

and colleagues used WDA as a systems-based tool to retrospectively explore medication errors in residential homes in England in order to identify potential contributory factors.[395] In comparison our WDA has been used to prospectively identify these contributory factors and also the resilience factors in the system. There are similarities between Lim's findings and those in this thesis. Lim identified that residents were passive receivers of care during medication rounds, and there is a similar expectation of parents in this thesis. However, Lim's study was not designed to capture the voice of residents in the homes, whereas my PhD thesis has taken steps to seek the views of parents in this system and it is very clear that this expectation from healthcare providers is at odds with parental wishes. Indeed, this expectation towards passivity may contribute to DRPs as family routines are disrupted and care is assumed by people without experience of that child's needs. The concerns of parents in hospital have recently been identified in a meta-ethnography of 15 parent experience studies in PICU, where relational and temporal aspects of parental involvement – technical expertise, responsibility, and lived experience – contributed to the co-construction of patient safety in this environment and represented risks to patient safety if these were not acknowledged.[294]

This PhD is not the first study to use WDA in the care of children and young people. Abebe and colleagues used WDA to study paediatric medicines safety processes, and were also the first to use the parental perspective on these.[326] Observing and interviewing 12 parents and families through an outpatient centre for children with medical complexity, they revealed the

adaptive mechanisms that parents used to provide care to these children in the home. A large part of this work was the formulation of medication management goals and organising systems of care around them. These parents also developed their own monitoring mechanisms to evaluate the provision of care and the achievement of their medication goals suggesting that parents are not naïve amateurs, but laden with the practical experience of living with these children and learning and adapting to their care. We can complement these findings with additional insights around the expectations of the system of these parents, which does not acknowledge their experience and expertise. We strengthen these findings by also being focussed on acute, in hospital care and demonstrate that these family adaptations are cast aside on admission which creates vulnerability for these patients.

This is one of the many strengths of using a theoretically informed system-representation tool to explore the context of a complex system. We have proactively identified a number of environmental and contextual factors of the system that may pre-dispose the system to failure but also have identified how the system adapts in these situations to maintain safety. This contrasts with Lim's approach whereby WDA was used as a retrospective analytical tool to provide contextual information to support medication error investigation and offer theoretically informed interventions based on these reports of failure.

12.2 Medication safety systems in the wild

The studies in this thesis have demonstrated that medicines safety work is social and adaptable. However, how these processes were intended to be undertaken – the "Work as Imagined" – reflected a linear, independent process reliant on written rules and procedures. The reality was that these guidelines and procedures, developed using a normative perspective on tasks and work, clearly didn't work. This in itself is not new. Phipps et al. identified that a variety of factors affected how anaesthetic practitioners followed guidelines and rules including their credibility and perceived outcomes.[396,397] Building on this, Sutherland et al. in their study of the causes of prescribing errors in paediatric critical care identified that guidelines and policies often didn't meet the needs of practitioners in the space. My study provides a generalizable validation of these findings and has allowed identification of the mechanisms that are in place in paediatric centres to manage these gaps in support.

The environment in which work is expected to be conducted exerted an impact on medicines safety. This physical space was designed in a way that separated different actors in the system. Medical staff had offices, or had no physical base and were peripatetic team members congregating to discuss their work at fixed points in the day. Pharmacy teams were present for a relatively brief period of time, during pharmacy opening hours only, and parents were usually isolated alone with their children in side rooms alone. The only group of actors who were based on and affiliated with the field of study (the ward) were the nursing staff, who occupied their own domain – the

nurses' station. These boundaries of work were reinforced by having separate cognitive artefacts (clinical handovers and ward rounds) which resulted in little information sharing between the actors. The impacts of handovers and ward rounds on quality of care are well known. Manias and Street published a critical ethnography of communication about medicines between nurses and medical staff in Australian critical care units and identified that much medication-related information was transferred in writing between clinicians.[398] Jennings in two ethnographic studies of American medication practices also identified that ward nurses spent much of their working time chasing medical practitioners to enquire about and clarify medication orders.[266,399] These studies suggest that the ward nurse is at the centre of all medication-related activity which I have also identified in this PhD thesis. This poses challenges in terms of medical hierarchy and legal responsibility. However, this responsibility was played out and shared through the telling of stories and sharing coping mechanisms.

Allen used workplace interactions to describe boundaries and "Boundary-Work" in nursing and medicine by using "atrocity stories" – stories told between different professional groups to reinforce social and professional roles.[400] Dingwall defines atrocity stories as "…asserting and defending the rational character of an occupation and its members against illegitimate claims to its work or to social superiority." I found many of these stories in this research, relating how some nurses were treated by managers and families when things had gone wrong, and it was clear that nurses felt the weight of responsibility and accountability because they were the primary

staff group facing patients and families. Similarly parents also told stories of delays in medication supply and administration, or of times when their input into the care of their children was ignored or contradicted; while medical teams talked about how problems and questions were escalated to them by other health professionals ("Doctor informed...") and pharmacy teams talked about how they were always blamed for delayed discharges "…when half the time the medicines are done and ready to go on the ward, and there's actually a load of other stuff to do…"

Fournier posits that professional boundaries are important to individuals as a way of demarcating their roles and responsibilities in what is becoming an increasingly distributed system.[401]

> *"The knowledge and expertise of the professions act as a "centre of translation" – translating a disorderly world of complex relationships and heterogeneous materials into homogeneous and ordered patterns"* (p.71)

Rarely were decision making processes (ward rounds and handovers) seen to be multi-professional. Decisions that were made in these circumstances were often subject to post-hoc challenge from nursing or pharmacy staff, and on occasion were only challenged after medication had been administered. However, when considering the wider literature, there is very clear evidence that pharmacist interventions to prevent medication problems are most effective if offered during the prescribing phase.[402] Kaushal undertook a small single centre study comparing a full time pharmacist in the intensive

care unit and acute medical unit with a part time pharmacist in the acute surgical ward and identified that only a full time pharmacist generated significant reductions in ADE rates.[403] This was argued to be related to the fact that surgical ward rounds were frequent and commenced before the contracted start time of the clinical pharmacist, and also that the part time pharmacist could not provide the “on-demand” interventions and teaching that a full time pharmacist could do.

Similar correlations between pharmacy service organisation (ward-based or department-based) and duration of service (full-time or part-time) have been identified in other controlled studies.[404,405] Five categories of pharmaceutical activity have been identified – knowledge application, medicines reconciliation, improvement in communication, direct patient care and “other activities” (including dispensing, logistics and education). In our study, pharmacists were only observed undertaking medicines reconciliation and dispensing. Indeed, it would appear that the pharmacy service’s role begins only when a medicine is prescribed and ordered. Only rare interactions with ward rounds were observed, and usually reactive associated with a prescription that was ambiguous or inappropriate. These observations also reflect the findings in two Health Services Safety Investigation Body reports where the presence of a pharmacist could have intercepted and mitigated serious patient safety events.[406,407] Both these reports identified variation in definitions and expectations of pharmacy services across organisations, and in the context of paediatric hospitals, found that communication pathways were informal, unstandardized and

pharmacy services were dispensary based, especially at weekends. Thus there is a major structural issue around access to appropriate medicines related expertise at the times when it is needed most.

Thus we reach the point where we can identify the nurse as the final arbiter of medication administration, which corresponds with Manias and Street's findings that nurses in the ICU have more experience and medication knowledge than junior doctors so will advocate for the "right" medication, thus exemplifying Allen's suggestion that boundaries in medical work are negotiated and flexible.[408] Folkmann and Rankin in their critical discourse on nurse's medication work described nursing work as socially organised with assumptions made at legal, managerial and professional levels that medication work is a linear and predictable task.[409] In an integrative review, Manias identified communication through "guidelines, protocols and communication logs" in which multi-disciplinary working to create standardised procedures and document medical notes as an important mediator of medication safety.[87]

An Australian study in intensive care units suggested that nurses and pharmacists to "take instruction" from medical practitioners.[243] However in this study this is not the case, with nursing staff taking their responsibilities in relation to medication administration seriously, and questioning and challenging unexpected dosing or treatment choices. A substantial

contributor to these knowledge gaps is a deficiency in documentation regarding medication choices and justification.

This is a common problem in wider health practice with Feather and colleagues reviewing “indication based prescribing” interventions to improve markers of medication safety.[410] The benefits of stating indications against medication orders include improved antimicrobial stewardship, enhanced communication with patients and carers and reducing prescribing errors. Our study has demonstrated that the current structure of services leads to decisions being made on independent and separate ward rounds, and prescriptions are often not captured in the documentation of those ward round assessments.

The pharmacy team was also present and visible during this study, with variable service structures. Pharmacists are reported throughout the literature as being a central part of the medication system in hospitals.[333,404,411,412] However, there were long periods in this study where there was no pharmacy team available at ward level. This has been recognised as a potential service level problem. The Health Safety Investigation Board identified highly variable ward based pharmacy services as being part of a fatal adverse drug event.[406] Among its findings was that ward based pharmacy services were not in evidence for patients after admission but before discharge. The findings from this PhD would reflect this, with pharmacy services “bookending” patient hospital care episodes and

only being consulted on care issues when a problem has been recognised or when they identify a problem themselves.

Why then are pharmacy services so patchy and piecemeal? There is uncertainty around the clinical and economic benefits of clinical pharmacy services. Historical interventional studies have shown benefit in reduction of medication error rates and costs associated with medicines. However, it appears to only be in the context of a full-time pharmacy presence in clinical areas. Furthermore, the interaction of pharmacy services with other teams may also contribute to this uncertainty. In Kaushal's prospective study of clinical pharmacists in paediatric wards they attributed the failure of the intervention in surgical wards to the likelihood that surgeons were in theatre for the majority of the day and therefore not available to benefit from pharmacy input.[413] This is supported by a study in adults using a full time pharmacist, serious medication errors were reduced by 79.5% (from 26.5/1000 patient days to 5.7/1000) and 98% of pharmacist recommendations were accepted.[414] While descriptions of the pharmacists role in medication safety are common in the literature [333,404,411,412] a great deal of the evaluation of their work is through retrospective interventions. Part time sessional services create a retrospective nature of pharmacist review in the systems studied, because often prescriptions had been administered by the time the pharmacist identified the problem.

And yet pharmacists have so much more to offer than just checking of prescriptions and validation of medication histories. The qualitative role of the pharmacist is described as central to complex medication decision making.[89] In this ethnographic study, the description of this involvement was on demand, or on discovery of a medication related problem. This retrospective service delivery is also found in this PhD programme with pharmacy teams not engaged as part of the fabric of the ward environment, and therefore exercise a reactive role in problem identification and management.

Cognitive resilience including mental models and transactive memory systems (TMS) appeared to be a common mechanism for coping with these problems. However, in practice these are not well defined or well supported. Burtscher and Manser have demonstrated that mental models and TMS are critical to successful team performance.[415] In a meta-analysis of 1390 teams across 31 studies, Schmutz et al. posited that teamwork potentially contributed to a 30% improvement in clinical team performance, thus suggesting that considerable avoidable harm was associated with poor teamwork.[416] However, TMS are complex social frameworks and take time to embed within a system.[338] This is reflected by much of the research of TMS in healthcare settings focussing on stable teams in operating theatres, emergency departments and intensive care units which raise questions about their importance in less well defined teams. This is an important consideration in view of this study given the largely rotational nature of both medical and pharmacy teams within the acute paediatric

setting. The nursing staff however are largely static, and within this frame of mental models support is offered to our suggestion that nursing actually lead the medicines safety work, despite not being empowered as such at a policy or regulatory level.

The importance of good teamwork has been clearly shown in this study. The constraints within the system however were not conducive to supporting problem solving. Policies and guidelines were a mode of communication between the organisation and the workforce, but they were limited in their application and occasionally could not be translated into practice. Where these guidelines were unable to resolve ambiguity or uncertainty, clinical staff would then reach out to colleagues around them – medics and nurses and sometimes parents – and ask "what should we do." This is an example of transactive memory.[417] Bachrach et al. describe this as "…members know who knows what, and is best at what."[346] Teams that operate with good transactive memory are thus able to distribute work and seek advice from the most appropriate people at the time that is needed. Lavelle et al. identified that healthcare teams with good transactive memory systems had higher performance.[418] Using established psychological scales to measure the correlation between the three domains of TMS (credibility, co-ordination and specialisation) and indicators of safety and conflict and identified that both TMS credibility (the trust members of the team have in the abilities of each other) and psychological safety had the greatest impact on team performance. What job the respondent did, how long they had worked in the research site, and how many years of experience they had in their

roles was less important than their integration into the team. Ergo, it can be concluded that skill-mix and interpersonal relationships (defined in this study as belief in the reliability of other team members knowledge) between those teams would be an important safety feature for future teams.

TMS theory stems from Rasmussen's "Mental Models" which are part of the taxonomy of cognitive work analysis and describe the strategies and resources available to actors in the system to determine a course of action or decision.[419,420] Shared mental models have importance in the way actors make decisions in rule-based environments and situations.[223,397] Mental models are not unique to healthcare and arise in a variety of other industries, and have been attributed to accidents in nuclear power plants and aviation.[421] Stout identified common mental models in the US navy as being important for safe functioning of warships [422] while Langan-Fox identified that team mental models were a pre-requisite for good team functioning, and define them as a network of associations between domain concepts - equipment, task, team or interaction.[423] Further, these mental models appear to explain how psychological safety emerges, and in turn describes how adaptations are made in practice. What this PhD adds to the wider literature on medicines safety is that while medication management can be and is viewed as a single system at organisational levels, there are actually four discrete medication management systems – medical, nursing, pharmaceutical and family. All have different objectives and priorities, the only connection is through the medication order, and there appears to be

little way for the systems to communicate with each other. I posit that this represents a defective or absent mental model.

Tasks relating to medication – prescribing, dispensing and administration were interdependent, and thus team members needed to have a shared understanding of the goals, objectives and responsibilities of all members of the team in order to achieve this safely. However, I have shown that each member of the team had their own interpretation of what their role was, and a poor understanding of the role of others. This reflects the findings of Andersons study of nursing team work in elderly care contexts, which identified that while nursing staff co-ordinated a multidisciplinary team, their adaptation to changes in the system was hampered by a poor understanding of other roles in the team with "staff levels, skill mix and doctor rotations also affecting how teams work together".[424] While this study focussed only on nursing teamwork, and did not include the perspectives of medical staff, there is relevance of this work to this PhD. Teamwork and shared mental models in Anderson's study were built on "getting to know" team members, and shared goals and objectives. Within this ethnographic study the rotational nature of the medical and pharmacy staff groups in acute paediatric care was seen to impact on nursing and medical activity. For nursing staff, there was less trust and credibility in the abilities and experience of junior doctors, and pharmacy services were viewed as having a supply and logistics role rather than a clinical role. While from a leadership perspective consultant paediatricians had to undertake more of the work and offer more supervision than may be seen in other care settings.

This difficult team-working terrain has also been explored in the USA, through a large-scale ethnographic study of nursing work in the context of patient safety. This study presented the non-linear nature of medication management processes in acute medical wards,[266] and has described the turbulence of nursing work as they struggle to adapt their behaviours to constantly changing demands and needs.[399] Communication and workload were major sources of this turbulence, as were the environmental and resource constraints. Jennings considered this turbulence specifically with regards to medication administration and identified that "…medication…is not simply the giving of drugs, nor does it have clearly defined temporal boundaries."[266] Similarities can be drawn in our data in the way that medication processes were impossible to separate from other tasks, and it was not uncommon to see medication explicitly scheduled around other care tasks to make best use of time – what Strauss described as "articulation."[425]

Mesman has discussed articulation as a key feature of collective work, with allocation of responsibilities and description of the work provided.[426] She posits that protocols and guidelines are one of the resources required to support this articulation as "…a point of reference to which staff members can refer, orientate themselves and find instruction on what to do next…" and serve to support and co-ordinate decision making. However, in our study we have demonstrated that these protocols and guidelines are often physically

and intellectually inaccessible, and contrary to Mesman they did not form an anticipative resource – they provided only information on how to prescribe, prepare and administer medicines in specific situations or circumstances.

It is known that these sorts of decision making processes under situations of uncertainty and cognitive demand are prone to error and adverse outcomes.[427,428] Pragmatically it is impossible for protocols or guidelines to cover every conceivable situation, however it is argued that they should provide sufficient information and knowledge to permit a suitably qualified or experienced agent to arrive at a suitable and appropriate adaptation. In this study some participants have exhorted that "…clinicians should follow the guidelines…", and this resonates with other research that has described how clinicians "pay lip service" to clinical guidelines,[429] which may be an unfair summary of why clinicians fail to follow them. Gabbay and le May studied the social construction of knowledge exchange among medical practitioners and found that the predominant manner that changes in practice or guidance were communicated to practitioners was through formal communication or conferences, whereas the most effective way that clinicians picked up changes in practice was through social discourse and the use of "mindlines" – "collectively reinforced, internalised, tacit guidelines." This would appear to be the case in paediatric care in this study where new information was obtained either through transfer between those "in the know" or with reference to what was already known. In contrast to Gabbay's study we did see clinicians explicitly seek and refer to guidelines, but only in the context of

situations where they were not experienced thus exemplifying Mesman's assertion that guidelines are sources of orientation and inspiration.

While guidelines have been argued to be the gold standard to support evidence-based-medicine, much work around guideline development has focussed on the synthesis and translation of clinical trial evidence into wider practice.[430] Within paediatrics there was less robust clinical trial evidence to support medication decision making, yet guidelines and procedures were everywhere and sought to provide a standardised approach to medication choices. However the extent of adaptation and adjustment to working practices in real life implies that these "rules of the road" may not be effective. Jones et al. used human reliability analysis methods to explore the how paediatric guidelines for intravenous medication may be misinterpreted and demonstrated that the guidelines under test, which were routinely used throughout healthcare systems at the time, were prone to multiple error types, including access the wrong information, and 25% of the observed discrepancies could have led to a clinically significant error.[431] Subsequently, the same research group developed standards for information retrieval developed through user testing and redesigned these guidelines.[432] Finally in a randomised in-situ simulation study, these redesigned guidelines were tested in a single-blind controlled setting. While major medication errors were not reduced, there were more manipulations made "perfectly" and less time was taken accessing information leading to faster infusion preparation.[433]

While the above studies demonstrate that guidelines and protocols in healthcare may be poorly designed, there are also questions about their application in situations of surprise and unexpected events. Standardisation of processes and procedures is advocated as an important reliability step in supporting workers to make the right choice at the right time. However, there is a very real risk that by centralising and standardising processes, the resilience within complex systems is lost.[240] The law of requisite variety was described in chapter 9, where the operator of a system must have a wider variety of potential behaviours than the system being operated means that it is necessary for operators to be creative and use their own knowledge and experience (or that of others around them) to make decisions to maintain the safe function of the system.[434] Guidelines and procedures also forego two other properties of complex systems – the principle of equifinality (there are many equally good paths to the same outcome) and the principle of multifinality (from the same initial conditions multiple outcomes are possible.)[435] Thus we come to a point where healthcare workers have to adapt and work around guidelines and protocols when faced with situations or conditions where they cannot be adhered to.

The prominent example in this PhD is around independent second checking of medicines. These have been implemented across all sites as a safety control, the logic being that a second independent review of the process increases the likelihood of intercepting errors. However, in practice this has

been disputed. Alsulami et al. conducted a systematic review of the effectiveness of medication double checking and reduction of medication errors, and identified three studies, with only one RCT reporting a statistically significant reduction in errors.[436] This review was updated in 2020 and identified three RCTs from Australia and the USA but the results were equivocal and reductions in error or severity could not be reliably associated with the double checking process.[437]

The qualitative findings in our ethnographic study would reflect the findings of Armitage 15 years ago – all nursing staff agreed that double checking was important, yet there were issues with the time it takes, the deference to authority in the hierarchical nursing structure, and the primed nature of the checking process.[438] Using our observational methods, we have been able to provide insight into how nursing staff cope with these challenges in a busy clinical environment. The use of “primed checks” has become the norm. Primed checks were developed and implemented based on bedside checklists yet in our study sites, checks were based on the five rights of medicines administration – the right drug, at the right dose, via the right route, at the right time, for the right patient.[439–441] These “rites” are central to the nursing practice of safe medicines management, and yet themselves have shown the limitations of checklists in their evolution over the last twenty years with the addition for four more “rites” to account for medication errors.[442]

The Institute of Safe Medication Practice (ISMP) in North America advocates for judicious and targeted use of second checking to high-risk medicines.[443] This has been recommended for high risk medicines, and high risk spaces. Children have historically been grouped into this "high risk" domain, because of their perceived vulnerability to medication error, but over the course of this thesis we have demonstrated that children are perhaps no more vulnerable to medication error than adults. It is just the systemic drivers and contributory factors that differ. All study sites had made attempts to relax double checking expectations, but in inconsistent and unpredictable ways. However, there is evidence to support expanding this and allowing nursing staff more agency in their management of medication checks. Nurses have been shown in controlled studies of nurse-driven checks compared with mandated checks that they will still seek an independent second check where they are uncertain or concerned, and this is associated with a significant reduction in harmful medication errors.[330] I argue that nursing staff already do this with their performative primed checking, trading off thoroughness in the second checking process in order to get the job done, and identifying and requesting more in thorough checks where they are unsure or require support.

I also observed a great deal of priority given to making sure medicines were given "on time" as part of the "five rights" but there were also strong systemic drives to get medicines given "on time." Delayed and omitted doses have been associated with medicines associated harm. Between 2006 and 2009, the National Patient Safety Agency (NPSA) identified 27 deaths and 68

severe harms associated with omitted or delayed medicines.[444] A qualitative analysis identified complex systemic reasons for delayed and omitted doses including nursing schedules, patient acuity and logistical delays in ordering and delivery.[445] A more recent review of National Reporting and Learning Service (NRLS) data identified that 31.4% of deaths associated with medication administration errors were related to the failure to administer a medicine.[53]

These statistics have driven organisations to prioritise missed and omitted doses for intervention. This resulted in considerable nursing workload in ensuring that medicines were administered on time. Nursing medication work is wrapped into complex environmental and social contexts which exert a considerable burden on their performance.[266] In a wide ranging study of US paediatric hospitals, 7.7% of nurses surveyed reported that they missed medication related activities in a previous shift.[446] Workload is also associated with qualitative deficits on nursing experience (job satisfaction and burnout) and medication error likelihood.[447]

Throughout the study there were examples of the introduction of technology in order to support workers in their tasks. Electronic prescribing in two sites and an automated dispensing cabinet (ADC) and barcode medication administration (BCMA) in one site. The use of ADCs is standard practice in the United States, but has not yet been realised fully in the UK.[448–450] ADCs alone are unlikely to offer any benefit to carers but do improve

adherence to governance and policy requirements for storage of controlled drugs.[451] Conversely, they increase the time taken to administer medicines. This was described in Sandelowski's "Medication Day" study, which described queues at ADCs waiting for access to medicines.[266] In some studies of ADCs, delays were also likely associated with enforcing adherence to second checking processes.[452] In the site with BCMA and ADCs it was noted that the ADC was not linked to the electronic prescribing system, thus may have obviated any benefit in assuring correct medicines were obtained. Certainly when explored with the pharmacists in that site, the ADC was described as more a stock management intervention. Furthermore, there have been few (if any) studies of ADC and BCMA in paediatric care. Morriss et al. studied BCMA in a neonatal unit over 50 weeks and observed an almost 50% reduction in the risk of MAEs in this cohort, but this was a single centre study without other medicines safety interventions (e.g. CPOE, ADC) so other sources of error were excluded.[453]

Pruitt identified that while improvements in measures of safety and satisfaction improved with BCMA, measures of efficiency did not and recommended future research focus on this element of implementation.[454] Kahn and Abramson also identified that workarounds were common with BCMA.[187] Many of the workarounds identified in the studies and reviews above are related to efficiency-thoroughness trade-offs – engaging with the "new" processes takes more time than the "old" way of working, and no account was made for that in the implementation. We see this in our

observations – we have identified a centralised approach to medication storage and security, which created delays by requiring negotiated access between carers, families and the pharmacy service. The multiple keys and digital codes which had to be shared and reverified periodically. From a HF/E perspective this introduced physical demands on workers in the field with travelling to the dedicated storage areas, which led to the introduction of near-patient storage solutions.

BCMA processes in this research were not implemented with reference to nursing workflows. It was clearly described as being launched without sufficient equipment or understanding of the impact on existing workflows. Further, many medicines in the centralised dispensing model used in these hospitals didn't carry accessible or valid barcodes to allow BCMA to function. Nursing staff bypassed BCMA the majority of the time because they could not physically use it without some form of adaptation. However, this was not acknowledged or considered by local managers, and nursing staff felt pressurised to use it.

12.3 Parents as part of the system

One of these adaptations was the use of parents and carers in the administrations of medicines. There is only one study that has detected the activity of parents around medication administration and that is Alsulami's study in an English children's hospital which identified parental administration as the most common administration error occurring in 31% of observed

MAEs (64/191).[455] Our study now provides some context to this finding, and rather than labelling it as an administration error, we posit that this is a natural situational adaptation by nursing staff, utilising a resource that is available to them, and that is respecting of the agency and autonomy of parents.

Family and patient involvement in patient safety is not new or novel. Vincent and Coulter advocated for the involvement of patients in healthcare safety more than 20 years ago with five suggested roles including the monitoring and verification of treatment.[370] How this has been operationalised in modern healthcare system is often as “knee-jerk reactions to adverse events.”[456] Further, Wong also advocated for the involvement of parents in paediatric medication safety, but only in the context of them voicing concerns about medication dosing. This PhD has provided generalizable insight into the roles and activities of parents in this context.

We have demonstrated that there is a great deal of undocumented work that families undertake to support their loved ones and keep them safe. O’Hara et al. described this role as “scaffolding” around our systems,[457] with parents having a place simultaneously outside, inside and across the boundaries of care such that they provide a space in which healthcare related problems can be intercepted and mitigated.[458] Parents act as knowledge brokers with medical and teams.[459] Of importance is the contextual information that knowledge brokering provides, which in clinical

systems is often lacking or limited. It was seen that parents were available and willing to support medical and nursing staff in solving problems associated with their child's medicines. Similarly, where medical and nursing knowledge and experience did not encompass a child's care, there was a tacit acknowledgement that parents can and do fill that gap.

On the other hand, there is a tension between organisational expectations and service needs on the ground. At an organisational level there is concern about parental knowledge, competency and ability. This study observed the validation of parent medication histories against multiple additional sources. It is well understood that medication histories for children and young people are often inaccurate or incomplete however it has been demonstrated in several well designed studies that parental medication histories are often more accurate than those documented in the medical notes.[146,460,461] Thirty years ago Pless and Pless posited that parental recollections were as accurate as medical notes, and in some circumstances more reliable.[462] Thus there is a confusion between what is actually being administered to the child (based on the parental report and recollection) and the data that is recorded in health records. Health record data are acknowledged to be often out of date and incorrect yet parental medication histories are considered to be of equal fallibility. However there is a consideration to be made that is not broached in the literature that is rooted in parental autonomy and agency – if the medication history reported by a parent differs from those officially held sources, is the medication history from the parent the best possible medication history anyway?

There were also suggestions about concerns regarding parental medication "error." This is a phenomenon that has received limited study. Walsh et al. studied medication errors in the home of patients with chronic diseases and identified a high prevalence of parental medication error (61/280, 95%CI 46-123).[127] They attributed these to delays in collecting prescriptions, and failure to change doses due to "problems with communication." On the other hand, in a recent systematic review of medication errors by parents or carers, Lopez-Pineda et al. identified a prevalence of parental medication error of between 30 and 80%.[129] Most common errors were wrong dose and wrong time errors, with parental age, health literacy and socio-economic indicators being associated with higher risks of medication error at home. There were many anecdotal stories uncovered through this research of parent wrong-doing, but none of these events were identified through observation and through conversation with parents it seemed as if in-hospital parental medication error was mediated by the system itself.

It is possible to compare the statistics relating to parental medication error with medication error rates among nurses and doctors. Estimates for healthcare professional medication error vary around 29% in paediatric and neonatal intensive care units [131], 19% in British paediatric care [132,163] and across all general care areas in paper-based medical systems being around 27% (18.8-37.2).[130] However, where "wrong time" medication errors are included, the rates of these may increase up to three fold.[60,69]

This is comparable to the 30-80% statistic for parents in the home quoted above, with many of the identified parental errors being related to delayed or omitted doses. Further, while errors in healthcare can be studied using direct observation, in studies of home-based medication error parental disclosure is a common method for identification. Despite these limitations however, Lopez-Pineda offers some insight into how we might resolve those issues around parental competency and safety, and it would largely appear to be related to culturally appropriate and engaging care with parents and provision of adequate training and education about medicines.

Notwithstanding the parental role as a resilience mechanism in this system, the exploration of parental medication error among professional staff revealed the potential for episodes of epistemic injustice. While no child was observed to be harmed as a result of this, there are signals of this phenomenon as a feature of paediatric practice with high-profile stories in the national press of associated negative outcomes.[463] Epistemic injustice is defined as a failure by professionals to believe the people they work with because of structural prejudices related to the power structures intrinsic in healthcare systems.[464] Fricker describes this as a "…potent yet silent dimension of discrimination…" in healthcare. Patients are disregarded for reasons relating to emotional instability or cognitive unreliability (testimonial injustice) but also because they struggle to make their lived experience relatable and relevant to healthcare professionals (hermeneutical injustice).[465] Because of this, the opinions and needs of patients and families are rejected by the staff around them.[464] It is possible that the

approach to parental participation in medication histories and medication work is negatively influenced in this way with the weight placed on validation of parental records by healthcare professionals.

In summary, this study has demonstrated that parents offer considerable resilience to a complex and busy system by bringing their knowledge and experience to the care environment. Parents are able to bridge between complex services and translate abstract clinical descriptions of problems and solutions into relatable practical experience. Yet it is clear that the system is not constructed with these experiences and contributions in mind, with parents expected to be passive observers of their child's care. However, parents are powerful advocates for their children's safety and care and will intervene. This creates a tension in some cases between healthcare providers who are expected to work within the constraints set by the system, yet parents will intervene where these constraints prevent the delivery of what they perceive as safe care.

12.4 Reflexivity

It is impossible to isolate and decontaminate ethnographic studies from the influence of the researcher.[466] The researcher is the main tool of data collection, and the way this is presented through ethnographic writing offers an element of reflexivity in the way the reality and structures that have been observed are presented.[285] I have attempted through this thesis to present a balanced representation of the medication systems, with

identification of the common elements and differences.[467,468] However, it is necessary to reflect on how my position as a pharmacist, as a researcher and as a non-parent may have impacted on both data collection and interpretation. I will also consider how these potential sources of bias were managed through the research.

I identified and approached the research sites myself through my insider knowledge and connections as a paediatric pharmacist in a children's hospital, and with their support gained entrée into the field. While I reserved my professional role within each site, it was inevitable that this would emerge through natural conversation and discourse. "And what do you do…?" were a frequent aspect of the relationship building conversations through the fieldwork. An initial concern was that my presence as a "pharmacist" would lead to self-censoring of the workers in the field as they would consider me to be judging or evaluating my role. However the reality was somewhat different. On revealing my professional background as a pharmacist barriers were removed as nursing and medical staff assumed a degree of shared experience and understanding. Through these conversations I always made it clear that I wasn't an employee of the organisation, which facilitated relatively swift engagement and trust among the participants. There was a strong sense of freedom and openness from participants who saw the objectives of the research as giving an opportunity to air their opinions safely and authentically. This is exemplified through the presentation of real stories about satisfaction and involvement in ADEs from participants in the thesis.

To honour this openness and trust I have presented these stories verbatim, using their words and expressions in my descriptions of these stories.

Reflections on being a pharmacist ethnographer have been offered by Faisal who explored the separation of her role as a pharmacist and as a researcher when undertaking research procedures.[469] This was the same position taken in this study – I did not do the work of a pharmacist, nor did I offer advice as a pharmacist. Where such questions arose I was careful to signpost to appropriate services. That being said, there were occasional challenges to this position. During fieldwork I was once asked about formulary choices in my own place of work, while in another site I was asked about experiences relating to a specific situation and how it was dealt with in other research sites. In both episodes I had to weigh up the potential for influencing the progress of the study and compromising my field relations. In the former situation the question was relating to a specific patient care question and would have been a question I would have fielded through my normal work, so I offered the information. The latter situation represented a clear opportunity to compromise the wider integrity of the study and I offered no information but did provide contact details of gatekeepers at the other sites.

During the study, only one situation emerged where concerns were raised by gatekeepers and service managers about the potential for the work to "…cast the service in a bad light…" This has been observed in other

qualitative studies in healthcare and educational settings.[470,471] My observations and associated questions about work were perceived as judgemental and there was an underlying nervousness regarding comparison with other hospitals. This supported some of my reflections in the results around the perception that some children's units may be seen as less capable than others.

Another difficulty that I identified through this study was in the way I could relate to parents and families as a person without children. When interacting with parents and carers, there was an initial suspicion when I presented in clinical attire and participated in ward rounds that I was "one of them" but once introductions were complete and it was made clear that I was an observer and interested in the process parents were more accepting of my presence. Parents were happy to discuss their experiences during observations and when they asked me "…do you have kids…" they were also happy to provide more emotional descriptions of their experiences in hospitals which I was able to hold objectively. I had no experience, therefore had no preconceived sense of how these events made people feel. However, through analysis of these conversations and interviews, there was always something at the back of my mind that doubted the veracity of these stories. It was clear that this was influenced by my experience as a healthcare professional in tertiary paediatric care, and in the observations and opinions of the healthcare professionals I had observed.

The potential for this contamination was identified early in the conception of this research and the Family Forum was established to support the analysis and interpretation of these data and to provide balance and perspective to the analysis and challenge my own assumptions and biases. The forum met three times during the analytical phase of the research to specifically explore and discuss the parent interviews and the parent interactions from the field notes. I was careful not to provide any interpretation of the data provided, and served to facilitate discussion among the families to arrive at their interpretation and understanding of the meaning in those stories, which I then incorporated into the results. It was these analytical approaches that led to our findings around epistemic injustice and an acknowledgement that parents are an important element of resilience in hospital medicines safety systems.

One must also reflect on the above together. An important aspect of ethnographic research of this type is immersion which it is argued underpin reflexivity in organisational ethnography. As a methodology, ethnography is quite sensitive to unexpected changes in the research field, and is able to adapt and capture those unexpected events. However, most ethnographies of this type have been reported in single sites (for example McDonald, Waring and Harrison in a single hospital operating department;[429] Sanford et al. in a central London acute hospital;[472] and Jennings and Sandelowski in a US medical and surgical care unit.[266]) where the researcher becomes

a part of the place as part of their research. Dumont however considers immersion in the context of space rather than place, which has utility in clarifying the positionality of multi-centre ethnography.[269]

I have been careful to present medicines safety as a spatial construct and abstracted localised practise where possible to support generalizable conclusions. In terms of study duration, the duration of this study is comparable to other ethnographies of patient safety using system-focussed methods. Sanford studied five hospital wards for 88hours over six months which is similar to my 230hours over 3 hospitals. Other elements of Dumont's immersive framework however were harder to operationalise due to resource and governance constraints – it was not possible for me to participate actively in the work of multiple sites within the funding and time envelope of this study.

13 Conclusions

13.1 Strengths and limitations

This study is one of the first multi-centre qualitative explorations of medicines safety for hospitalised children and young people, and has also served to accomplish the first three elements of Brown's "Pre-Implementation Evaluation" of intervention development.[473–475] I have undertaken both a qualitative and quantitative exploration of the prevalence and nature of medication related problems in hospitalised children and young people. Furthermore, I have studied clinical practice through the lens of "Work as Imagined" and "Work as Done" using both WDA and ethnographic observations to provide insights into how these medication related problems might emerge, and how workers adapt day to day to meet these challenges. This model is a valid theoretical model based in sociotechnical theory and provides rich and deep information on the system as a whole and how the individual components interact within it.

I have also been able to suggest how complex interventions that are already in place may not work as planned. I have demonstrated how technological interventions such as BCMA are implemented without consideration of the clinical workflow and habits (the "work as done") of the practitioners who are meant to use them. Additionally, the views and experiences of end users of these systems (including patients and families) have not been sought or incorporated. A fundamental principle of HF/E design and implementation is

to use end users and stakeholders in their design and implementation.[219,220,476] Participation in these processes is a cornerstone of ergonomic practice, and is advocated in the NHS as part of the patient safety investigation process utilising families and patients in patient safety investigations.[371] Thus this is the first study that has explicitly involved patients and families in the development of potential interventions to improve medicines safety. The interventions that are proposed are also congruent with the findings of the study.

This involvement of parents and families in the data analysis and interpretation presents novel findings which can contribute to a holistic understanding of how medication related problems emerge in practice, and acknowledges the presence of parents within the system of study. The experience from this study will promote ongoing engagement and incorporation of parent and carer experiences of medicines safety in future research and practice intervention.

However, as with all research there are limitations that must be acknowledged. The data was collected by a single data collector which will reduce some of the perspectives that could have brought additional strength and weight to the observations. While additional data collectors may have been desirable, there is a strong pragmatic component in all ethnographic research around balancing the economic costs of the data gathering with the inferences that can be gained from the analysis. In this consideration we

identified that an analytical team of methodological and practice domain experts, including parents and carers would provide these additional perspectives and they were empowered to make suggestions regarding future observation directions, and were invited to participate in post-analytical procedures including co-production events.

A further limitation of this study is that no adverse drug events were observed through the course of the observations. Many were discussed in formal and ethnographic interviews, but it was not possible for this study to observe the emergence of safety events to their logical conclusion. In one event where there was the sign of emergence, the potential outcomes for the patient in those circumstances required me to intervene to prevent any harm. This reflects the difficult position of observational safety research – serious events, or patient harm especially in children appears to be relatively rare, therefore in order to robustly study adverse drug events observers have to be “in the right place, at the right time.” Conversely, it would be ethically and professionally difficult for observers to justify allowing the event to play out.

This rarity of events has been accounted for in other studies. In separate studies Barber, Lewis, Ryan and Keers used retrospective reflections on reported adverse drug events using the Critical Incident Technique among medical and nursing staff.[74,75,224,477] To support these data collection procedures, these studies have either been based in a single centre, or a single professional group. Additionally the design of this study has not

included quantitative data collection or analysis on events and their potential causative or contributory factors, thus currently this study can only be considered exploratory, and causation of events cannot be inferred. However, we have considered the future of medication safety research, and intentionally developed this study to provide important context indicators for future realist evaluation of interventions.

Finally, it must be considered that the impact of the 2020 COVID-19 viral pandemic may have influenced some of the observed findings, particularly around service provision and accessibility to some professional services, and the way families were nursed and occupied in the ward environment. Notwithstanding these unavoidable changes, it was fortunate that this study was not part of the complete cessation of non-essential COVID research instituted by the NHS after the first UK national lockdown of March to June 2020. While as at May 2023 (when this thesis was written), all pandemic restrictions have been removed it is still the case that most patients in children's services are nursed in isolation where practicable, social distancing of patients is still in operation and restrictions on ward round sizes and access to patient spaces continue to be in place. Healthcare will never be the same after the pandemic, and this study brings the strength of having been there during the adaptation phase to this global health catastrophe, and has been able to study it's recovery and reformation.

13.2 Overall conclusions

The objective of this PhD was to explore the systems in place for medicines safety for hospitalised children and young people using a robust theoretical lens, and to consider the systemic contributory factors to DRPs that may emerge through this deep exploration. This is something that is largely absent in previous literature and many of the interventions proposed to make medicines for children safer are based on observed events, and supposition as to the causative factors of those events, with little exploration of the complex systems-related factors that may also contribute to those events. Secondly, I wanted to propose potential interventions to deal with those systemic factors informed by all stakeholders including parents and patients. In this chapter I will summarise the findings of this thesis and present the implications of these findings on policy and practice and propose and prioritise potential interventions for future development and study.

13.3 Medicines safety is a complex social endeavour

Medicines safety processes are enacted in a social environment through the co-operation and co-ordination of four discrete groups of people – medical, nursing and pharmacy staff and the patients and their parents or carers. The working environment isolates these groups, leading to fragmented transactional communication. All actors in the system have divergent objectives and priorities. Notwithstanding these systemic barriers there are signs that professionals and families co-ordinate between themselves to achieve their objectives, but this is inefficient and important information is often lost. Organisations have adapted to mitigate some of this information

loss through the use of cognitive artefacts (“The Handover”) though these are imperfect.

Parents and families are not advised of the expectations of them while their child is in hospital, nor are they advised of what to expect from healthcare workers. They are expected instead to be passive observers of their child’s care, even when that care is delivered incorrectly. Ward rounds and medication processes are on the surface chaotic and unpredictable, and the healthcare system does not explicitly take account of family responsibilities and needs outside of the hospital system which results in decisions and actions being taken without parental involvement. Yet parents offer additional information and insight into their child’s condition and medications which is not explicitly sought. However, there is an organisational distrust of parents and carers as parts of the care system.

Parent and carer adaptations to medication related tasks are based on lived experience and practical reality but are often ignored on admission and replaced by hospital-based “best practice” which similarly contributes to parental anxiety and distrust. Parents will watch healthcare workers follow established practice and hospital policy and fail to administer medicines properly, but are not empowered to intervene in support of their children or the healthcare staff looking after them. There is also a clear suggestion that communication between teams and parents is suboptimal.

Thus we conclude that epistemic injustice plays a part in treating parents and carers as outsiders and regarding their lived experience with suspicion or disbelief. Yet medication records are often inaccurate or out of date, and medication is prescribed incorrectly as a result and sometimes in spite of parental protest. It is too easy for healthcare workers to assign responsibility to parents for medication-related problems, without reflecting on the systemic problems that contribute to these because these may be difficult to resolve, particularly around communication.

Medicines were supposed to be locked away securely, in centralised holding spaces which resulted in delay in gaining access to those medicines and considerable physical work from nursing staff. This in turn contributes to potential delayed doses. Corresponding adaptations were observed to prevent delays including allowing parents to keep hold of their own medicines. Nursing staff would also manipulate formulations of medicines not specified in the orders in order to give a medicine. This sometimes resulted in adverse drug events from excipient interactions or route-incompatibilities.

Medication work was not a linear, isolated task. Instead, nursing staff articulated their medicines work alongside other care activities to make best use of their time, and reduce intrusion on parents and patients. However, nursing and medication workload often interfered with provision of timely

care and created personal and professional anxiety about how well people are doing their jobs and looking after their children.

Parents and carers clearly wanted a role in providing mutual support to nursing and medical practitioners around the realities of medication administration in the home, including the adaptations that were required to ensure medicines are given on time and safely, but this would often be declined, or resisted as being “wrong.” However, looking forward, this work could help provide practical solutions to technical problems that “evidence based practice” does not capture.

It was interesting to note that there was an absence of HF/E informed terminology and discussion in written policies and guidelines, and no participating site had a HF/E Design policy therefore there is a clear space for HF/E expertise in the design and implementation of all interventions intended to improve the efficiency and safety of care.

This thesis has also support challenge of existing assumptions about the contributory factors of DRPs. While many historical studies have suggested that the use of unlicensed medicines and adult formulations are a contributory factor to DRPs, this has not emerged in my PhD. The medicines that were observed were merely tools within the sociotechnical system, and in the main practitioners adapted their practice around them. This in and of itself was not perceived or seen to be potentially harmful. Where potential

harm emerged, it was linked to the lack of space (physical and cognitive) to formulate an adequate plan, or to seek advice from an appropriate person.

13.4 Priorities for future study

13.4.1 Redesigning services to promote appropriate skill mix for medicines safety

Consideration needs to be given to skill mix in acute paediatric wards particularly around the extended role of pharmacy professionals away from traditional dispensing and verification duties towards inclusion in medication decision making, patient education and counselling, with outcomes related to medication safety and process efficiency.[402] There should be a view to building on the findings of King et al. and Maffre et al. who identified that while there is a great deal of evidence to support pharmacy involvement in routine ward rounds, this is lacking in paediatrics and should be studied in the context of resource availability and time taken to perform those rounds.[333,404] However, there is a focus in every study site in this PhD where distractions and interruptions are a strong focus for intervention. I suggest that distractions and interruptions are endemic and in the main impossible to mitigate for. This has been supported by a HF/E design study of a state-of-the-art children's hospital at Stanford, California where despite intervention distractions and interruptions persisted.[478] Focus should thus be on what workers need in order to mitigate and manage distractions themselves.

13.4.2 Ergonomic redesign of medicines storage and administration processes

Current medication storage and administration standards create ergonomic and care-delivery problems by centralising storage of medicines away from the point of care. Medicines storage is defined by Department of Health standards that are highly prescriptive, which are treated as obligations, yet have not been supported through ergonomic design principles.[479] Within study sites, there were variable approaches to meeting these regulations, with different storage solutions secured with keys, digital locks or automated dispensing cabinets. All had their limitations, and created workload and cognitive issues through day to day activity. It was observed that medicines were sometimes not locked away or secured per these policies because they were required often. It was also observed that parents would refuse to hand over medicines when asked because of previous experience with loss and delays. Near-patient storage was often inadequate for the needs of patients, which resulted in mixed-ecology storage.

Consideration should be given to an ergonomically sound medication storage system that incorporates and supports parent and patient access, reasonable adjustments to meet individual staff and patient needs and maintains patient safety.

13.4.3 Empowering parents as parts of the medication safety system

This study has shown the parents are an essential part of the medication management systems in English hospitals, and there is thus an opportunity here to reimagine and formalise the role of parents in the care of their children in hospital. They come with experience and knowledge that may not be available to nursing staff, and can support nursing staff in making safe adaptations for medication administration. Parents themselves through co-production have expressed a desire to be participants in all aspects of their child's care thus there is evidence in this thesis that such an approach is feasible. However, there are also suggestions in my data that healthcare staff may struggle to accept parental participation because it would introduce ambiguity in accountability in the workplace, thus work should be undertaken to explore the risks and barriers to parental involvement in patient care, as well as the opportunities and benefits.

13.4.4 Develop a centralised paediatric medication passport that can support efficient transfer of information

Vast human resource is expended in reconciling medicines for children and young people to account for the weaknesses in the system as it currently stands. Parent-reported medication histories are treated as less reliable than other recorded data sources, which is at odds with patient-centred care and does not acknowledge the fallibility of clinical records in comparison with patient lived experience. There is a clear argument from this study that regardless of the formal medical record, what the parent reports as being administered *is* the best possible medication history.

It is also the case that these records are available in data repositories, and yet there has been no effort to bring these together into a single medication history which parents and carers can then validate. This would potentially empower parents and support their role as primary caregiver, and also provide a single dataset that can be amended and adjusted on each healthcare encounter using parent reported reality. A recent report by Elliott et al. has estimated that improving the interoperability of medication records to new digital information standards would almost halve the number of harmful medication errors at transition, and save the NHS in excess of £6m.[480]

13.5 Implications for policy and practice

13.5.1 Embedding HF/E principles in day to day improvement practice

Where technological interventions were introduced to support medicines safety, it was clear that little or no consideration of the sociotechnical implications of such technology was taken when planning the implementation of the technology. It must be noted that the evidence base for these medicines safety technologies are based in American and Canadian studies of effectiveness and safety which may not be generalizable to the UK context,[454] therefore there is a requirement for additional study and development of things like BCMA and automated dispensing cabinets. There is a need to upskill and provide HF/E expertise and skills to all stakeholders in NHS organisations so that they can consider these aspects

of intervention implementation. It is noted that HF/E has been proposed as a part of the new NHS PSIRF but this remains a retrospective framework, and is only intended for use in patient safety events. HF/E needs to be expanded to encompass routine practice problems and improvements.

13.5.2 Promote stakeholder participation in service development and improvement

As part of this study, it was noted that staff on the ground were not involved in improvement or safety interventions. There was still a top-down approach to implementation of new interventions with little or no communication regarding motivation and proposed improvements to the staff using the intervention. Communication methods were inadequate and relied on e-mail communication or use of posters on walls. There were occasional “huddles” to share information but these were brief and lacking detail. Clinical staff were busy and often did not have time to engage with detailed documents or emails. This is likely a contributory factor to some interventions not being used as intended. Hignett and Burgess-Limerick have demonstrated that participatory ergonomic programmes for service improvement and development contribute to increased productivity, better staff communication and team working and reduction in adverse events.[220,254] Therefore we advocate on the basis of this study that consideration be given to implementing stakeholder driven medicines safety groups to develop or evaluate new interventions in the future, that can be tailored to local needs.

13.5.3 Exploration of theory-informed methods to investigate medication safety.

While there is a focus in the NHS on understanding how all the features of the complex sociotechnical system of healthcare using Carayon's SEIPS model, we have also demonstrated that there is a need to study team dynamics within complex sociotechnical systems. There has been much critique of "situational awareness" as a method of applying accountability for events to individuals who "should have known what was happening…" but I have demonstrated that there are four discrete groups of practitioners in paediatric healthcare who work in the same environment towards similar outcomes but who do not work together adequately. Stanton proposed a model of "distributed situational awareness" (DSA) where agents within a system have their own situational awareness which is different to but compatible with other agents in the system in a dynamic and collaborative process.[481] Salmon has proposed taking this further and incorporating the advanced technologies the healthcare systems are increasingly reliant on.[482] In the age of machine learning and complex advanced medication systems (infusion systems and BCMA) we propose further study of medication safety using a DSA framework to shine a light on how these systems will co-function and identify potential risks.

Further, I have demonstrated that there is little or no sociotechnical theory applied in the development of work routines at an operational level. I have already described the limitations of WDA in its utility in organic and physiological systems, and other theoretical methods are available. During

the conduct of this PhD Hollnagel's Functional Resonance Analysis Method (FRAM) gained considerable interest in the study and redesign of healthcare processes, by providing insight into sources and consequences of variation within processes.[389,483,484] FRAM has clear roots in Safety-II and sociotechnical theory, and therefore future studies of medication systems may provide more detailed targets for intervention.

13.6 Final comments

Through this study we have demonstrated that despite the weaknesses in the organisational understanding of how medication-related problems emerge and affect patients, the care that we provide to children and young people is largely safe and effective. I have for the first time demonstrated using robust theoretical methods how some of these medication-related problems emerge in a complex dynamic system like paediatric healthcare. We have also identified that medication systems in hospital are not a single self-contained process, but are highly social processes that are effected by multiple systems working together. However at an organisational level, these systems are not acknowledged, nor are they expected to work together. This division and isolation of systems leads to poor communication, a lack of co-ordination of roles and tasks, and may contribute to DRPs. It is likely that current interventions are ineffective because many of these DRPs have their antecedents in deep systemic issues such as access to and interpretation of information.

That being said, I have described considerable adaptation and adjustment in the clinical areas to keep children and young people safe. These adaptations include the articulation of medication-associated work, and delegation of responsibility to parents and carers who otherwise are expected to be passive observers of their child's care. I have also begun to shed light on how conflict between parents and healthcare professionals can emerge, by exposing the organisational isolation of these two groups, and the resulting lack of communication between them.

Furthermore, I have used established co-production methods to bring stakeholders including parents and carers together to share their experiences of medication related problems in hospital and explore together how we might reduce the impacts of those events. Consequently I have proposed four theoretically bound potential interventions that can now go forward into robust co-development to operationalise and explore their feasibility. I have also shown that co-production is well received and a positive part of improving medicines safety and thus recommend that all future studies involved in intervention development and the study of medicines safety ensure that all stakeholders participate in these studies.

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Appendix 1 - Ethical Approval

Mr Adam Sutherland

Division of Pharmacy and Optometry

Email: hra.approval@nhs.net

HCRW.approvals@wales.nhs.uk

Room 1.131 Stopford Building

University of Manchester

M13 9PL

20 February 2020

Dear Mr Sutherland

HRA and Health and Care

Study title:	**Medicines Optimisation in Paediatric In-patients - a qualitative multi-centre human factors study.**
IRAS project ID:	**266243**
Protocol number:	**N/A**
REC reference:	**19/YH/0430**
Sponsor	**University of Manchester**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **266243**. Please quote this on all correspondence.

Yours sincerely,
Alex Thorpe

Approvals Manager

Email: hra.approval@nhs.net

Copy to: *Ms Lynne Macrae, Sponsor's Representative* **List of Documents**

Appendix 2 - List of Documents included in the Documentary Analysis

Site	Document Title
CH1	Clinical Checking Procedure
	Controlled Drugs Policy
	Discharge Medicines Policy
	Drug & Therapeutics Committee Terms of Reference
	Endorsement of Prescriptions Policy
	Incident Reporting Policy
	Intravenous Medicines Policy
	Medicines Management Committees Policy
	Medicines Management Policy
	Medicines Prescribing Policy
	Medicines Safety Committee Terms of Reference
	Medicines Management Committee Terms of Reference
	Ordering and Supply of Medicines Policy
	Pharmacy On-Call Policy
	Preparation of Medicines Policy
CH2	Clinical Pharmacy Standards
	Discharge Policy
	Drug & Therapeutics Committee Terms of Reference
	Medicines Policy
	Medicines Reconciliation Policy
	Medication Error Reflection Document
	Medicines Safety Group Terms of Reference
	Clinical Pharmacy Handover
	Prescription Charts
	Incident Policy
GH1	Medicines Policy – Prescribing
	Medicines Policy – Dispensing
	Medicines Policy – Administration
	Incident Reporting Policy
	Endorsement of Prescriptions Policy
	Prescription Charts
	Diabetic Care Pathway
	Handover
	Discharge Packs from Ward Procedure
	Outpatient Prescription Form
	Manual Discharge Policy
	Drug & Therapeutics Committee Terms of Reference
	Medicines Reconciliation Policy
	Status Epilepticus Guidelines
	Pain Guidelines
	Antimicrobial Guidelines
	Diabetes Guidelines
	Sedation Guidelines

Appendix 3 - Systematic Review Search Strategy

Concept	Search term	Limiters
Concept 1 - Population	P*ediatric* (as key word)	TI, AB
	Neonate (Pre term)	
	Neonate (term)	
	Infant	
	Child	
	Adolescent	
Concept 2 - Setting	In-patients	
	Ward	
	Unit	
	Ambulatory Care Unit	
	Hospital discharge	
	Hospital admission	
Concept 3 – Drug-related problems	Drug Related Problem* (as key word)	
	Adverse Drug Event	
	Adverse Drug Reaction OR Drug Reaction OR Medication reaction	
	Medication error OR Drug error OR Prescribing error OR Administration error OR Dispensing error OR Monitoring error	
	Omitted doses OR missed doses OR delayed doses	
	Medicines reconciliation OR medication history OR drug history	

Appendix 4 - Interview Consent Form (Healthcare Professionals)

Medicines Optimisation in Paediatric In-Patients: A Qualitative Human Factors Study

(MOPPEt)

Consent Form for Adult Participants

If you are happy to participate please complete and sign the consent form below

	Activities	Initials
1	I confirm that I have read the attached information sheet (**Version 3.2; 12/04/2021**) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set. I agree to take part on this basis.	
3	** OPTIONAL FOR ZOOM INTERVIEWS** I agree to the interviews being audio recorded using audio conferencing software. I also understand that there may be possible processing of my personal data outside of the European Economic Area.	
4	I agree that any data collected may be published in anonymous form in academic books, reports or journals.	
5	I understand that data collected during the study may be looked at by individuals from The University of Manchester, XXXX Trust or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
6	I agree that any anonymised data collected may be shared with researchers/researchers at other institutions.	
7	(Optional) I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study or invite me to future events relating to this research	
8	I understand that there may be instances where during the course of the interview information is revealed which means that the researchers will be obliged to break confidentiality and this has been explained in more detail in the information sheet.	

9	I agree to take part in this study.	

Data Protection

The personal information we collect and use to conduct this research will be processed in accordance with data protection law as explained in the Participant Information Sheet and the Privacy Notice for Research Participants (http://documents.manchester.ac.uk/display.aspx?DocID=37095).

_____ _____

Name of Participant Signature Date

_____ _____

Name of the person taking consent Signature
Date

1 copy for the participant, 1 copy for the research team (original)

Appendix 5 - Interview Consent Form (Parents)

MANCHESTER 1824
The University of Manchester

Medicines Optimisation in Paediatric In-Patients: A Qualitative Human Factors Study

(MOPPEt)

Consent Form for Adult Participants

If you are happy to participate please complete and sign the consent form below

	Activities	Initials
1	I confirm that I have read the attached information sheet (**Version 4.2, 10/02/2022**) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set. I agree to take part on this basis.	
3	I agree to the interviews being audio recorded.	
4	I agree that any data collected may be published in anonymous form in academic books, reports or journals.	
5	I understand that data collected during the study may be looked at by individuals from The University of Manchester or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
6	I agree that any anonymised data collected may be shared with researchers/researchers at other institutions.	
7	(Optional) I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study and to invite me to future events relating to this research.	
8	I understand that there may be instances where during the course of the interview information is revealed which means that the researchers will be obliged to break confidentiality and this has been explained in more detail in the information sheet.	

9	I agree to take part in this study.	

Data Protection

The personal information we collect and use to conduct this research will be processed in accordance with data protection law as explained in the Participant Information Sheet and the Privacy Notice for Research Participants (http://documents.manchester.ac.uk/display.aspx?DocID=37095).

_____ _____

Name of Participant Signature Date

_____ _____

Name of the person taking consent Signature
Date

1 copy for the participant, 1 copy for the research team (original)

Appendix 6 - Interview Schedule (Healthcare Professionals)

Medicines Optimisation in Paediatric In-patients (MOPPEt)

Professionals interview schedule

Aims & Objectives

- Develop deep understanding of medication systems
- Explore medication practices from the perspective of the operator

Introduction

1. Introduce myself
2. Explain the nature of the research
3. Stress confidentiality
4. Explain how the data generated will be used – transcription, reporting and anonymization
5. Introduce the recorder
6. Offer the participant opportunity to ask questions

QUESTIONS

1. Tell me about your experience of medication systems in your work.

2. What do you perceive the objectives of the medication systems in your work are?
    a. *How do you know whether they're being met*
    b. *What do you need to do to meet those objectives*
    c. *How is the work done?*
    d. *Who and what is involved?*

3. Now I want to talk about Drug Related Problems – these can be adverse drug reactions, medication errors or adverse drug events
    a. *What sort of DRPs have you encountered and how do you identify them?*
    b. *How do you resolve them?*
    c. *What information do you give to parents and carers*

4. Now think of a situation where you've been involved with a DRP:
    a. *What was happening around you*
    b. *What were you expecting to happen*
    c. *What were your options*
    d. *What did you choose to do*
    e. *Why?*
    f. *What happened?*
    g. *What happened to you?*

Appendix 7 - Interview Schedules (Parents & Families)

Medicines Optimisation in Paediatric In-patients (MOPPEt)

Parent/Carer interview schedule

Aims & Objectives

- Develop deep understanding of medication systems
- Explore medication practices from the perspective of the parent

Introduction

7. Introduce myself
8. Explain the nature of the research (including what medication systems are)
9. Stress confidentiality
10. Explain how the data generated will be used – transcription, reporting and anonymization
11. Introduce the recorder
12. Offer the participant opportunity to ask questions

QUESTIONS

5. Tell me about your experience of medication systems when your child is in hospital.
    a. *How are you involved in decisions about your child's medication?*
    b. *What information about medicines are you given by the professionals around you?*

6. What do you perceive the objectives of the medication systems in hospital are?
    a. *Who tells you about them?*
    b. *Do they meet your expectations*
    c. *How do professionals work with medication around you?*
    d. *Who and what is involved?*

7. Now I want to talk about Medication Related Problems – these can be adverse drug reactions, medication errors or adverse drug events
    a. *What sort of DRPs have you and your child encountered and how did you identify them?*
    b. *How were they resolved?*
    c. *What information were you given?*

8. Now think of a situation where your child has experienced a DRP. Tell us about what happened?
    a. *How did you know that something was wrong?*
    b. *What was happening around you?*
    c. *How were you told about the problem?*
    d. *What happened to the professional?*

Appendix 8 - Parent Invitation to Participate (E-mail)

IRAS 266243

E-mail invitation to families

TO: e-mail address

FROM: adam.sutherland@postgrad.manchester.ac.uk

Subject: Medicines Optimisation in Paediatric In-patients

Dear Parent/guardian;

I hope this e-mail finds you well. I am a researcher from the University of Manchester studying medication related problems that occur in children in hospital. I have been doing my research at a hospital that you visit frequently and that you and your child have recently been admitted to.

The voice of parents and patients has not really been included in this type of research before, and so I would like to speak to you about your experiences of medicines while in hospital, and any medication related problems that your child might have experienced. This could be a late or missed dose of medicine, a medication error, or a side effect of a medicine. I have attached an information sheet to this message outlining how the interview will work.

If you'd like to speak to me, just reply to this message and we can set up a conversation at a date and time that's convenient for you.

I look forward to hearing from you,

With best wishes

Adam Sutherland

PhD Student, University of Manchester

Appendix 9 - Invitation to Hospitals to Participate in Study

The University of Manchester

ADAM SUTHERLAND MPharm, MClinRes, FFRPS, MRPharmS
NIHR Clinical Doctoral Research Fellow
Division of Pharmacy & Optometry
Faculty of Biology, Medicine & Health
Room 1.131
Stopford Building
The University of Manchester
Oxford Road
MANCHESTER M13 9PL

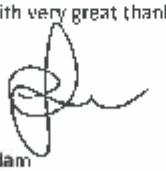
To whom it may concern

I am seeking your help in an exciting and important research project. Medicines Optimisation in Paediatric In-patients (MOPPEt) is a National Institute for Health and Research (NIHR) funded project exploring systems around medicines use in hospitalised children and young people. The study will take place in paediatric in-patient units in the North of England.

I plan to use observational techniques to develop understanding of the systems involved in medication use and use this to develop new interventions to improve safety. My research involves analysing trust guidelines and policies, observing the healthcare team during medication processes including ward rounds and medication administration and comparing the two. The research includes interviews of individual practitioners, patients, parents and carers about what I've observed. Together, this will help understand where problems may arise and help develop processes and systems, rooted in a real understanding of activity, which may be more effective.

In order to do this, I would like to visit your hospital four times during a two year period from Summer 2020 to Summer 2022. I would visit for a week at a time and there would be at least three months between visits. I require someone who can introduce me to the clinical team and direct me to your research department. I know that you are busy, so be assured that I am not asking you to lead or manage any of the research processes. This is NOT a pharmacy research project, and I alone will be responsible for the delivery and management of the research process. Any support that you can provide will be acknowledged in all research outputs.

With very great thanks



Adam

Funded by
NIHR | National Institute for Health Research

Appendix 10 – SRQR Checklist

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Title page
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	11-13
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Chapter 1, Chapter 4, pp 84-103
Purpose or research question - Purpose of the study and specific objectives or questions	Chapter 3
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	Chapter 4, pp94-104
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Chapter 4.6.2 p.108 Chapter 12.4, p349-354
Context - Setting/site and salient contextual factors; rationale**	Chapter 4.6.1, p105-108
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	Chapter 4.6.1, p106 Chapter 4.6.6, p113-117
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Chapter 4.6.8, p125 - 130

Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	Chapter 4.6, p104 Chapter 4.6.4 – 4.6.6 p110-117
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Chapter 4.6.4 – 4.6.6 p110-117
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Chapter 6.2, p160-161
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Chapter 4.6.7.2 – p122
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Chapter 4.6.7 p 117-122 Chapter 5.2.3, p137
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Chapter 4.6.7 p120-127

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Chapter 11 Chapter 12
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Chapter 7-10

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Chapter 10, Chapter 12
Limitations - Trustworthiness and limitations of findings	Chapter 13.1, p354-357

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Chapter 12.4, p 349-353
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	N/A

Appendix 11 - Co-Production Evaluation Proforma

MOPPET MEDICINES SAFETY WORKSHOP

EVALUATION FORM

Thanks for joining us on this workshop exploring the findings and meaning of this important research. We'd be grateful if you could complete this evaluation form which will only take a few minutes.

Please rate each of the following statements below:

1	I enjoyed the event				
	Strongly agree	Agree	Don't know	Disagree	Strongly disagree

2	I felt included in the event				
	Strongly agree	Agree	Don't know	Disagree	Strongly disagree

3	I felt able to contribute				
	Strongly agree	Agree	Don't know	Disagree	Strongly disagree

4	I knew what was expected of me				
	Strongly agree	Agree	Don't know	Disagree	Strongly disagree

5	The workshop was well organised				
	Strongly agree	Agree	Don't know	Disagree	Strongly disagree

6	The workshop was facilitated well				
	Strongly agree	Agree	Don't know	Disagree	Strongly disagree

7	What three words would you use to describe your experience today?

8	How will your participation in today's workshop change your practice (if at all?)