Paediatric safety in primary care: A cross-sectional mixed methods study of national incident report data

Philippa Claire Rees

This thesis is being submitted in partial fulfilment of the requirements for the degree of
Master of Philosophy

School of Medicine, Cardiff University 2015

Word Count: 44,026 (including citations)

Declarations

This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award.

Signed  (candidate) Date 05/10/15

STATEMENT 1

This thesis is being submitted in partial fulfilment of the requirements for the degree of MPhil.

Signed  (candidate) Date 05/10/15

STATEMENT 2

This thesis is the result of my own independent work/investigation, except where otherwise stated.
Other sources are acknowledged by explicit references. The views expressed are my own.

Signed  (candidate) Date 05/10/15

STATEMENT 3

I hereby give consent for my thesis, if accepted, to be available online in the University's Open Access repository and for inter-library loan, and for the title and summary to be made available to outside organisations.

Signed  (candidate) Date 05/10/15

STATEMENT 4: PREVIOUSLY APPROVED BAR ON ACCESS

I hereby give consent for my thesis, if accepted, to be available online in the University's Open Access repository and for inter-library loans after expiry of a bar on access previously approved by the Academic Standards & Quality Committee.

N/A

Acknowledgements

Firstly, I am extremely grateful to my supervisors – Professor Adrian Edwards, Dr Colin Powell, and Professor Andrew Carson-Stevens – for introducing me to academic research during my intercalated BSc; and for providing me with the opportunity, data, and funding, to pursue this further by undertaking an MPhil. Professor Carson-Stevens has given countless hours of his time to reviewing my conference abstracts and manuscript drafts, without which I would not have had the privilege of publishing or presenting my work internationally. My supervisors' encouragement and prompt feedback over the last two years has been invaluable.

I would also like to acknowledge Dr Sabine Maguire, my academic mentor to whom I am indebted for instigating my interest in academic paediatrics. Dr Maguire has introduced me to brilliant academic paediatricians and inspired me to consider this as a future career.

Thank you to Dr Ben Carter for providing statistical guidance and expertise to the project. Finally, I would like to thank the other PISA (PrImary care patient SAfety) team members and co-applicants: Dr Alison Cooper, Professor Anthony Avery, Professor Aziz Sheikh, Dr Donna Luff, Dr Gareth Parry, Dr Huw Prosser Evans, Dr Huw Williams, Dr Julie Rasmussen, Sir Liam Donaldson, Dr Meredith Makeham, Mr Peter Hibbert, and Dr Sukhmeet Panesar for double-coding my data; always providing a listening ear during our weekly team meetings; and for reviewing my manuscripts and providing practical feedback.

Summary

Primary care is responsible for the majority of children's healthcare contact, yet there is a dearth of research into the safety of care provided to children in this setting. Confidential Enquiries highlight the need for improved vaccination, better recognition of seriously unwell children, and improved management of children with chronic conditions. This thesis therefore aimed to explore deficiencies in the vaccination process and in the primary care provided to 'unwell' children.

A cross-sectional mixed methods study of paediatric safety incidents involving vaccination or 'unwell' children, from primary care between 2002-2013 was conducted. The free-texts of 3913 reports submitted to the National Reporting and Learning System were classified to describe: incident types, contributory factors, incident outcomes, and severity of harm outcomes. Additionally, a literature review was conducted to identify potential interventions to address problem areas identified.

Key vaccination-related failures included vaccination with the wrong number of doses, at the wrong time, or with the wrong vaccine. Documentation failures and staff mistakes frequently underpinned these incidents, and vulnerable groups appeared more prone to incidents.

Key incidents involving 'unwell' children were related to: medication provision; and failures of diagnosis, assessment, referral, and communication, primarily related to telephone assessments. Medication errors were often the result of staff mistakes and failing to follow protocols. Incidents related to telephone assessment of 'unwell' children were often precipitated by protocol problems such as failing to assess children using the appropriate protocol.

The findings presented in this thesis provide an overview of paediatric safety problems in primary care, in addition to offering recommendations for improvement. Example recommendations include building IT infrastructure to address vaccination-related documentation discrepancies; electronic transmission of prescriptions to community pharmacies to reduce dispensing errors; and adapting clinical decision software to improve paediatric telephone-based assessments. The hypotheses generated from this work will form the basis of future work.

Abbreviations

BCG	Bacillus Calmette–Guérin
BNF	British National Formulary
CDS	Computerised Decision Support
CPOE	Computerised Physician Order Entry
DTaP/IPV	Diphtheria Tetanus acellular Pertussis/Inactivated Polio
DTaP/IPV/Hib	Diphtheria Tetanus acellular Pertussis/Inactivated Polio/ Haemophilus influenza type B
GP	General Practitioners
Hib	Haemophilus influenza b
Hib/Men C	Haemophilus influenza b/Meningitis C
HIV	Human Immunodeficiency Virus
HMIC	Health Management Information Consortium
HPV	Human Papilloma Virus
ICD-10	International Classification of Diseases - 10
ITS	Interrupted Time Series
LINNAEUS	Learning from International Networks About Errors and Understanding Safety
Men C	Meningitis C
MeSH	Medical Subject Headings
MMR	Measles Mumps Rubella
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
PCV	Pneumococcal Conjugate
PISA	PrImary care patient SAfety
PRN	Pro Re Nata
RCPCH	Royal College of Paediatrics and Child Health
RCT	Randomised Controlled Trial
SIGN	Scottish Intercollegiate Guidelines Network
Td/IPV	Tetanus Diphtheria and inactivated Polio
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

Glossary

Adverse drug reaction	Unintended, undesirable, or unexpected effects of prescribed medications or of medication errors[1]
Adverse event	An undesired patient outcome that may or may not be the result of an error[2]
Avoidable factors	Where there were identifiable failure in the child's direct care by an agency with direct responsibility for a child; where there were latent, organisational, or other indirect failures within one or more agency with direct or indirect responsibility for a child, where there was a failure of design, dilapidation or barriers, or inadequate maintenance by agencies with responsibility for public safety[3]
Care failures	Failures in the healthcare provided directly to the child by an agency (including parents) with direct responsibility for that child[2]
Caregiver	An individual who has responsibility for a child (such as parents)
Child health	A state of complete physical mental and social well-being not merely the absence of disease or infirmity, in children[1]
Chronic condition	A condition which typically requires follow up by health services, including repeated hospital admissions or outpatient appointments, long-term medication use, or use of support services such as physiotherapy[4]
Contributory factor	A circumstance, action, or influence that is thought to have played a part in the origin or development of an incident or to increase the risk of an incident[1]
Contributory incident	A patient safety incident that played a part in the origin or development of another incident or increased the risk of another incident
Error	Deviation in a process of care that may or may not cause harm to patients[1]
Error of commission	An error that occurs as a result of an action taken[1]
Error of omission	An error that occurs as a result of an action not taken[1]

[1] Joint Commission Resources 2005
[2] World Health Organisation 2009
[3] Pearson G 2008
[4] Hardelid P, et al. 2013

Epistemology	The study of knowledge, what constitutes knowledge, and how we obtain it[5]
EU 15+	The 15 countries of the European Union prior to 2004 plus Australia, Canada and Norway[6]
Excess deaths	The difference between the number of deaths observed and the number of deaths that would have occurred given the same death rate as a comparable country
First-access services	The services to which 'unwell' patient initially present (includes primary and emergency care)
Global Trigger Tool	A method to measure all-cause harm using patient records[7]
Harm	A negative patient outcome that includes temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and / or pain requiring intervention[1]
Hazard	A situation or event that introduces or increases the probability of an adverse event arising from a danger or peril, or that increases the extent of an adverse event[1]
Healthcare harm	Harm arising from, or associated with, plans or actions taken during the provision of healthcare rather than an underlying disease or injury[1]
Human error	One category of potential causes for unsatisfactory activities or outcomes[1]
Human factor	Study of the interrelationships between humans, the tools, equipment, and methods they use, and the environments in which they live and work[1]
Iatrogenic	An illness or injury resulting from a diagnostic procedure, therapy, or other element of healthcare[1]
Incident type	A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features[1]
Incident outcome	The impact upon a patient or organisation which is wholly or partially attributable to an incident[1]
Looked-after child	A child under the care of the local authority
Modifiable factors	Extrinsic factors which could potentially be addressed, that are not necessarily related to healthcare[2]
Near miss	Events or situations that could have resulted in an accident, injury, or

[5] Bourgeault I, Dingwall R and DeVries R 2010
[6] Viner RM et al. 2014
[7] Parry G, Cline A and Goldmann D 2012

	illness, but did not, either by chance or through timely intervention[1]
Ontology	The study of reality and how we understand existence[4]
Patient safety incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient[1]
Preventable harm	A negative patient outcome that would not have occurred if the patient had received ordinary standards of care appropriate for the time[1]
Primary care	The provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, practicing in the context of family and community[8]
Pro re nata (PRN)	Take medication as required
Quality of care	The degree to which health services are timely, efficient, equitable, safe, patient-centred, and effective[9]
Recursive	Repeated application of a rule, definition, or procedure to results
Root cause analysis	A systematic process of investigating incidents to identify the multiple, underlying, and latent contributory factors[1]
Substandard care	Failure to apply the principles and practices accepted by a healthcare profession, as expected[1]
Systems error	An error that is not the result of an individual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process[1]
Unsafe care	Failure to make evidence-based clinical decisions to maximise the healthcare outcomes of an individual and failure to minimise the potential for harm[1]
Unwell child	A child with signs, symptoms, diagnoses, or prescribed medications implying illness

[8] Institute of Medicine 1996
[9] Institute of Medicine 2001

Table of contents

Chapter 1: Introduction 1

1.1 Child health background 2

1.1.1 Epidemiology 2

1.1.2 Child health outcomes and care quality 3

1.1.3 Inequalities in child health 5

1.1.3.1 Inverse care law 6

1.1.4 Child health services 7

1.2 Healthcare safety and children 10

1.2.1 Overview of the history of healthcare safety 10

1.2.2 Patient safety in child health 11

1.3 Methods of measuring the burden and assessing the nature of unsafe care and healthcare error 13

1.3.1 Definitions 13

1.3.2 National-level administrative data 14

1.3.3 Case note reviews 14

1.3.4 Incident reporting systems 16

1.4 National Reporting & Learning System (NRLS) 19

1.5 Aims and objectives 22

Chapter 2: Method 24

2.1 Data handling 24

2.1.1 Data sampling 24

2.1.2 Search strategy 24

2.1.3 Data processing 25

2.1.4 Classification frameworks 26

2.1.5 Models of incident analysis 31

2.1.6 Quantitative analysis 35

2.2 Thematic analysis 37

2.2.1 Justification of qualitative method 37

2.2.2 Qualitative sampling 37

2.2.3 Qualitative analysis 38

2.3 Mixed methods synthesis of results 39

2.3.1 Rationale 39

2.3.2 Design 39

2.3.3 Strengthening the analysis 40

2.4 Ethical Approval 41

Chapter 3: Results 42

3.1 Vaccination-related incidents 42

3.1.1 Quantitative results 43

3.1.2 Thematic analysis of vaccination-related reports 73

3.1.3 Mixed methods synthesis of vaccination-related issues 85

3.1.4 Summary 91

3.2 Incidents involving 'unwell' children 92

3.2.1 Overview of included reports involving 'unwell' children 93

3.2.2 Primary incident types 108

3.2.3 Thematic analysis of incident reports involving 'unwell' children 132

3.2.4 Mixed methods synthesis of reported issues involving 'unwell children' 144

3.2.5 Summary 150

3.3 Literature review 151

3.3.1 Methods 152

3.3.2 Results 154

3.3.3 Discussion 194

Chapter 4: Discussion of methods 196

4.1 Summary 196

4.2 Searching the NRLS data 196

4.3 Data processing 197

4.5 Thematic analysis 199

4.6 Reflection on alternative approaches and methods 199

Chapter 5: Discussion of findings 201

5.1 Discussion of vaccination-related findings 202

5.1.1 Summary 202

5.1.2 Context of current literature 202

5.1.3 Recommendations for improvement 204

5.2 Discussion of medication-related findings 205

5.2.1 Summary 205

5.2.2 Context of current literature 205

5.2.3 Recommendations for improvement 208

5.3 Discussion of diagnosis-, assessment-, referral-, and communication-related findings 210

5.3.1 Summary 210
5.3.2 Context of current literature 211
5.3.4 Recommendations to improve telephone assessment 215
5.4 Recommendations for future research 217
Chapter 6: Conclusions 218
References 220
Appendices 240

List of Figures

Figure 1 page 21: flow diagram illustrating the process of reporting incidents to the NRLS and how the NRLS responds to reports 21
Figure 2 page 33: illustrates the Australian Recursive Model of Incident Analysis . 33
Figure 3 page 33: an example of the layout of the Recursive Model of Incident Analysis during data processing in Microsoft Excel. 33
Figure 4 page 40: flow diagram illustrating the processes of mixed methods analysis 40
Figure 5 page 44: flow diagram providing an overview of how the included data were retrieved and its content 44
Figure 6 page 45: scatter chart demonstrating the ages of children involved in reported vaccination-related incidents 45
Figure 7 page 46: scatter chart demonstrating the frequency of primary vaccination-related incidents reported over time 46
Figure 8 page 47: column chart demonstrating which vaccines were involved in reported primary incidents and their frequency 47
Figure 9 page 54: bar chart demonstrating the severity of harm resulting from incidents 54
Figure 10 page 61: a scatter chart illustrating the ages of children receiving the wrong number of doses 61
Figure 11 page 64: scatter chart illustrating the frequency of vaccine-timing incidents in each age group 64
Figure 12 page 67: scatter chart demonstrating the frequency and ages of children receiving the 'wrong vaccine' 67
Figure 13 page 69: scatter chart illustrating the frequency and ages of children reported as suffering adverse reactions to vaccines 69
Figure 14 page 74: illustrating the themes identified, their respective sub-themes and how they overlap 74
Figure 15 page 90: visual model where quantitative and qualitative insights have been combined to summarise the safety issues described by included reports 90
Figure 16 page 94: flow diagram providing an overview of how the included data were retrieved and its content 94
Figure 17 page 95: scatter chart illustrating the frequency and ages of 'unwell' children involved in reported incidents 95

Figure 18 page 97: scatter chart illustrating the frequency of reported incidents involving ‘unwell’ children over time 97
Figure 19 page 110: a scatter chart the frequency and ages of unwell children involved reported in medication-related incidents..... 110
Figure 20 page 117: the frequency and ages of ‘unwell’ children involved in diagnosis and assessment incidents..... 117
Figure 21 page 122: a scatter chart of the frequency and ages of ‘unwell’ children involved in administrative incidents..... 122
Figure 22 page 124: a scatter chart of the frequency and ages of children involved in referral-related incidents 124
Figure 23 page 127: a scatter chart of the frequencies and ages of children involved in communication incidents..... 127
Figure 24 page 133: an illustration of the relationship between the three over-arching themes and their respective sub-themes..... 133
Figure 25 page 149: a visual model of the weakness in the telephone assessment system..... 149
Figure 26 page 154: a flowchart demonstrating the literature review process. ... 154

List of Tables

Table 1 page 25: inclusion and exclusion criteria 25
Table 2 page 29: the severity assessment code matrix (New South Wales Government 2005) 29
Table 3 page 30: National Reporting & Learning System definitions of harm severity (National Reporting and Learning System) 30
Table 4 page 30: WHO International Classification for Patient Safety definitions of harm severity (World Health Organisation 2009) 30
Table 5 page 34: the nine rules of the Australian Recursive Model of Incident Analysis (Hibbert PD et al. 2007;Rees P et al. 2015) 34
Table 6 page 36: illustrates how the ICD-10 codes for children's pre-existing and/ or presenting conditions were grouped 36
Table 7 page 48: the vaccines involved in reported vaccination-related primary incidents 48
Table 8 page 50: the frequency of all incidents (primary and contributory)..... 50
Table 9 page 52: the frequency of contributory factors described for each primary incident (NB: *some reports described more than one type of mistake) 52
Table 10 page 54: demonstrates how many primary incidents had their allocated harm severity upgraded (in blue) and downgraded (in green), and how many kept their pre-allocated harm severity (yellow) (*1 report of moderate harm was upgraded to death) 54
Table 11 page 57: the number primary incidents reported each year within each incident type 57
Table 12 page 58: the frequency and severity of harm described for each age group and for each primary incident type 58
Table 13 page 59: the frequency of contributory factors described for the key primary incident types 59
Table 14 page 60: the vaccines involved in the most frequently reported primary incident types 60
Table 15 page 96: illustrates the severity of harm, the proportion of harmful incidents, and the odds of harm for each age group 96
Table 16 page 99: illustrates the conditions described in the 'unwell' children experiencing safety incidents (N.B.*some children had multiple similar conditions, signs, or symptoms) 99

Table 17 page 100: illustrates the association between harm severity and the types of conditions present in children experiencing incidents 100
Table 18 page 102: the severity and odds of harm associated with each primary incident type 102
Table 19 page 104: the contributory factors described in reports..... 104
Table 20 page 105: the severity of harm classified by reporters and the severity described in reports using WHO definitions (*four reports describing child deaths were upgraded from moderate and severe harms) 105
Table 21 page 107: the outcomes of incidents described in reports and their frequencies (N.B.*some reports include descriptions of multiple types of an outcome)..... 107
Table 22 page 109: the contributory factors described for each of the key primary incident types Note: *some primary incidents had multiple similar contributory factors..... 109
Table 23 page 111: a cross-tabulation demonstrating the relationship between age group and harm severity..... 111
Table 24 page 115: the medications involved in medication-related incidents N.B. *some incidents involved multiple medications 115
Table 25 page 118: cross-tabulation of the relationship between age group and severity of harm 118
Table 26 page 155: a summary of the interventions identified to address each priority area 155
Table 27 page 157: a summary of the key characteristics of included studies 157

Chapter 1: Introduction

The United Kingdom (UK) has one of the worst child mortality rates in Western Europe and the contribution of unsafe healthcare to this high mortality is unknown (Carson-Stevens A et al. 2015;Viner RM et al. 2014). However 26% of child deaths have identifiable failures in care, and primary care is responsible for 90% of healthcare contact (Carson-Stevens A et al. 2015;Pearson G 2008). Issues with primary care quality are apparent through high rates of inappropriate hospital admissions and paediatric referrals, in addition to high mortality rates for diseases dependant on first-access services such as meningitis and pneumonia compared to other Western European countries (Wolfe I et al. 2011;Wolfe I et al. 2013).

This chapter will discuss the landscape of child health and quality improvement globally with particular focus on UK issues. Child health outcomes and associated care quality data will be presented. European care models will be discussed, compared, and contrasted with UK models. The importance of healthcare safety to child health will be reviewed, in addition to the various available methods for assessing the nature and burden of unsafe care.

1.1 Child health background

1.1.1 Epidemiology

Since the turn of the millennium substantial gains in child health have been achieved globally and there has been an accelerated decrease in child mortality. (Bryce J et al. 2013;Wang H et al. 2014). There has been a dramatic shift in the global burden of disease and the prevalence of communicable diseases has decreased (Bryce J et al. 2003;Bryce J et al. 2013;Liu L et al. 2012). The Millennium Development Goals, particularly goal 4 to decrease under-5 child mortality by 67% from 1990 to 2015, instigated this shift in disease burden. Although the Millennium Development Goals have not been fulfilled, they successfully accelerated global improvements in child health (Bryce J et al. 2013).

Child survival in Europe has mirrored improvement in less developed countries: consequently the landscape of child health in Europe has changed. Healthcare amenable deaths from infections are less of a problem whilst deaths from non-communicable diseases are an increasing burden on child health (Liu L et al. 2012;Wang H et al. 2014;Wang H et al. 2012). Non-communicable diseases are responsible for significant child morbidity and mortality, and they account for 79% of disability–adjusted life years lost (Liu L et al. 2012;Wang H et al. 2014;Wang H et al. 2012;Wolfe I et al. 2013). The Global Burden of Disease Study reports that respiratory diseases, neuropsychiatric disorders, congenital abnormalities, and musculoskeletal disorders have the greatest impact on childhood morbidity in Western Europe (Institute for Health Metrics and Evaluation 2010).

The UK has achieved considerable reductions in child mortality but these gains in child health have not matched those of comparable European countries i.e. the EU 15+ that are comparable in terms of health expenditure (Viner RM et al. 2014). This slower decline in child mortality has seen the UK drop from having one of the lowest rates of child mortality rates in Europe to having the highest rate in Western Europe (Viner RM et al. 2014). Annually around 6000 infants, children, and adolescents die in England and Wales, which equates to almost 2000 excess deaths compared to Sweden. Reductions in mortality have largely been in children aged 1-12 years, consequently most deaths (67%) occur in infancy, followed by adolescence (Sidebotham P et al. 2014a;Sidebotham P et al. 2014b;Wolfe I et al. 2014).

1.1.2 Child health outcomes and care quality

The UK performs sub-optimally in numerous measures of child health and wellbeing. Over a quarter of child deaths reviewed in a 2006 Confidential Enquiry had identifiable failures in care, 43% had potentially avoidable factors, and 21% of deaths had modifiable factors considered healthcare amenable i.e. potentially preventable (Pearson G 2008;Wolfe I et al. 2014).

Up to 30% of deaths in infants and adolescents, when mortality peaks, are thought to have modifiable factors (Wolfe I et al. 2014). The high UK infant mortality rate, relative to comparable European countries, likely reflects high rates of preterm birth that are considered preventable and a reflection of the quality of midwifery, obstetric and newborn care (Wolfe I et al. 2014). Viner RM et al. 2014 estimate that such failures culminate in approximately 1000 excess annual infants deaths compared to the European average.

Chronic conditions (e.g. mental health conditions, cancer, respiratory conditions) are estimated - by a recent epidemiological review of UK child deaths using routinely collected vital statistics and administrative health care data - to be responsible for 60-70% of child deaths (Hardelid P et al. 2013). Deaths from chronic conditions pose a considerable problem for the UK and have been identified as a priority area for improvement by child health reviews (Hardelid P et al. 2013;Wolfe I et al. 2014). Mortality from endocrine, respiratory, digestive, and neuropsychiatric disorders is higher in the UK than comparable European countries, and deaths from such non-communicable diseases are not decreasing in line with comparable countries (Institute for Health Metrics and Evaluation 2010;Viner RM et al. 2014;Wolfe I et al. 2014) There is also increasing epidemiological evidence from analyses of World Health Organisation (WHO) mortality data that cancer survival is worse and diagnosed later in the UK (Viner RM et al. 2014;Wolfe I et al. 2014).

A case note review to determine the quality of care delivered to children with diabetes identified that fewer than 6% of children in England receive evidence based care in line with published guidance, thus resulting in poor diabetic control, preventable emergency admissions, and preventable deaths (National Diabetes Audit 2008). Consequently children in England and Wales have poorer diabetic control than children in comparable European

countries: 83% have HbA1c concentrations above target levels and 9% experience diabetic ketoacidosis annually (National Diabetes Audit 2008;Wolfe I et al. 2011).

National UK audits of care quality for childhood epilepsies, using 12 quality indicators, highlighted similar failures: 35% of children did not have an appropriate initial assessment, and access to specialist paediatric neurologists and nurses was not universal (Royal College of Paediatrics and Child Health 2012).

Considerable geographical variation health outcomes exist in the UK and these may reflect variation in care quality. Emergency admissions for children with asthma varied from 25.9/100 000 population in some locations to 641/100,000 in others (Asthma UK 2007). The UK has a higher asthma-related mortality than comparable countries (World Health Organisation Regional Office for Europe 2012). This has been a long-standing problem, and in 2000 the UK was in the lowest EU 15+ quartile for child mortality from non-communicable diseases across all ages (Viner RM et al. 2014;Wolfe I et al. 2011).

Poor primary care quality impacts negatively on secondary and emergency care services. In the UK 75% of asthma-related admissions are deemed avoidable with better primary care. A third of short stay admissions in infants occur for minor illness, which should ideally be managed in the community, and 36% of referrals to paediatricians are deemed inappropriate (Asthma UK 2007;Milne C et al. 2010;Saxena S et al. 2009).

Death rates from diseases that rely heavily on first-access services are arguably a reflection of primary care quality. Compared to other European countries, the UK has high rates of mortality from illnesses that rely heavily on first-access services such as meningococcal infections and pneumonia (Wolfe I et al. 2011;Wolfe I et al. 2014;World Health Organisation Regional Office for Europe 2012). Unsafe care may be partially responsible these results suggesting poor care quality in the UK, and this will be discussed further in section 1.1.3.

1.1.3 Inequalities in child health

Considerable inequalities in health persist in high-income countries particularly in children (Mackenbach JP et al. 2008;Sidebotham P et al. 2014a). This is demonstrated by the variation in child survival by country and population demographic. Differences in child health outcomes are vast within and between countries in Western Europe. Suggested explanations for those variations include: the organisation and quality of healthcare services, social inequalities, and cultural and economic factors (Sidebotham P et al. 2014a).

Key social determinants of health include poverty, inequality, and social policies (Marmot M et al. 2012;World Health Organisation Commission on Social Determinants of Health 2008). Child mortality is not only associated with absolute poverty, but also relative poverty and inequality i.e. imbalanced distribution of wealth (Adamson P 2012;Collison D et al. 2007;Marmot M et al. 2012;Pritchard C and Williams R 2011;Wolfe I et al. 2014;Wolfe I et al. 2013). For example, the Nordic countries with the lowest proportion of impoverished households in Europe have the lowest child mortality rates; and the five high- ncome countries with the highest child mortality rates also have the highest inequalities in household income (Collison D et al. 2007;Pritchard C and Williams R 2011;Sidebotham P et al. 2014a;Wolfe I et al. 2014).

The inverse association of socioeconomic status and childhood mortality is well acknowledged and relative poverty has been demonstrated as a key determinant of child deaths in the United States of America (USA), Australia, and New Zealand, as well as in the UK (Arntzen A and Nybo-Andersen AM 2004;Blakely T et al. 2003;Freemantle N et al. 2009;Gakidou E et al. 2010;Petrou S et al. 2014;Pickett KE and Wilkinson RG 2007;Rodwin VG and Neuberg LG 2005;Sidebotham P et al. 2014a;Spencer N 2004). Poor socioeconomic status has been associated with child mortality from a range of causes such as suicides, poisoning, and cancer, in particular acute lymphoblastic leukaemia as well as sudden infant death syndrome (Agerbo E et al. 2002;Edwards P et al. 2006;Kong KA et al. 2010;Lightfoot TJ et al. 2012;Pickett KE and Wilkinson RG 2007;Sidebotham P et al. 2014a;Spencer N 2004;Wood AM et al. 2012).

When child poverty is defined as the number of households, with children, in which the disposable household income is less than 50% of the median disposable household income for that country, the UK has one of the highest rates of child poverty among high income

countries (Adamson P 2012). However, it is worth noting that numerous definitions of child poverty exist and that the UK has high rates of relative poverty rather than absolute poverty (Adamson P 2012). Currently 35% of UK households with children are estimated to have insufficient income for acceptable standards of living (Padley M and Hirsch D 2014;Wolfe I et al. 2015). Child mortality statistics reflect the high rates of relative poverty and the marked social inequalities present in the UK (Wolfe I et al. 2014) Standards of living are predicted to worsen, due to reduced public service funding and continued economic pressures (Wolfe I et al. 2015). Therefore, the importance of access to high quality healthcare is argued to become ever more apparent to mitigate further deterioration of child health outcomes (Viner RM et al. 2014;Wolfe I et al. 2014).

1.1.3.1 Inverse care law

Over 40 years ago Tudor Hart described the inverse care law: provision of "good medical care tends to vary inversely with the need for it in the population served" (Hart JT 1971). This phenomenon has persisted and children tend to suffer disproportionately, as childhood is a particularly vulnerable period (Webb E 1998). The inverse care law is clearly visible in children of vulnerable and marginalised populations such as: refugees, travellers, and ethnic minority groups that have above average mortality (Alio AP et al. 2010;Anachebe NF 2006;Sidebotham P et al. 2014a;Webb E 1998;Wolfe I et al. 2011). For example rates of mortality, preterm birth, and communicable diseases in Roma children far exceed those of the general population across Europe (Wolfe I et al. 2013). A range of complex and interacting factors have been proposed to underlie these trends including access to healthcare, socioeconomic disadvantage, poor living conditions, higher rates of consanguinity, and genetic predispositions (Alio AP et al. 2010;Sidebotham P et al. 2014a;Smith GD 2000).

It has been noted that children in refuges who greatly need healthcare have poor access to it (Webb E et al. 2001). Their child health records tend to be incomplete, and developmental screening and vaccination uptake in this population is sub-optimal (Webb E et al. 2001). In addition they have unmet mental health needs compounded by their past experiences, which are often violent and abusive (Webb E et al. 2001).

1.1.4 Child health services

Since the 20th century the relative contribution of healthcare to population health has increased as living conditions improved in response to industrialisation (Wolfe I et al. 2014). Access to high quality healthcare can modify the negative effect of biological, social, cultural, and financial factors on child health (Sidebotham P et al. 2014a;Wolfe I et al. 2014).

A unique and equitable attribute of the UK National Health Service (NHS) is that it is free at the point of delivery, and 90% of contact with healthcare providers occurs via primary care services delivered in community settings. Countries with successful primary care systems tend to achieve better population health outcomes (Institute of Medicine 1996;Starfield B 1991;Starfield B 1994;Starfield B et al. 2005). There is no consensus on the optimum organisation of primary care for children and numerous models exist.

Primary care for children differs considerably between European countries in terms of organisation, the provision of out-of-hours care, the professionals providing care, and the training that care providers receive (Wolfe I et al. 2013). The organisation and therefore the role of primary care can range from acting as a gateway to specialist services and paediatricians, as in the UK and the Netherlands, or access to paediatricians may be unlimited as in Sweden (Ahgren B 2003;Schäfer W et al. 2009;Wolfe I et al. 2011;Wolfe I et al. 2013). Out-of-hours care has become increasingly centralised in many European countries with groups of general practitioners (GPs) providing out-of-hours care and telephone triaging becoming more prevalent. Differences in the organisation of first-access services, including out-of-hours care, likely accounts for the large variation in rates of inappropriate emergency admissions (Ahgren B 2003;Wolfe I et al. 2011;Wolfe I et al. 2013).

In the UK first-access services, within primary care, are primarily (although not exclusively) the responsibility of and delivered by GPs, whereas in Germany and France they are delivered predominantly by primary-care-based paediatricians, and in Sweden they are delivered by co-located and collaborating GPs and primary-care-based paediatricians (Ahgren B 2003;Nolte E and McKee M 2008;Wolfe I et al. 2011;Wolfe I et al. 2013). This collaboration includes nurse-led care, which has become the norm for the management of certain conditions like asthma in Sweden. There are considerable differences in healthcare professionals' training between countries: for example, GPs in

Sweden undergo at least three months specialist training in paediatrics whereas in the UK GPs may undergo no postgraduate paediatric training (Ahgren B 2003;Wolfe I et al. 2011;Wolfe I et al. 2013).

The organisation of health services for children largely influences how chronic conditions are managed, for example in the community or hospital setting, and by paediatricians, nurses, or GPs (Wolfe I et al. 2011;Wolfe I et al. 2013). There is a relative paucity of policy directives in European countries on the management of chronic paediatric conditions compared with adult care (Wolfe I et al. 2013). Consequently large variations exist between countries in the delivery of healthcare to children with chronic conditions.

The Swedish model of paediatric primary care delivery has been argued to be the gold standard design; this comprises multidisciplinary teams including GPs, paediatricians, and children's nurses, co-located in primary care centres (Ahgren B 2003;Wolfe I et al. 2013). This model was designed to improve continuity of care and paediatric care quality by increasing multidisciplinary collaboration (Ahgren B 2003). In contrast the UK model is arguably the poorest for child health.

The quality of primary care for children has been neglected in the UK despite children accounting for over 20% of GP consultations (Gill PJ et al. 2011;Hippisley-Cox J et al. 2007;Royal College of General Practitioners 2008). The pay for performance quality indices which incentivise disease management in general practice almost completely overlook management of paediatric diseases: <3% of quality and outcome framework (QOF) indicators for general practices in England and Wales are relevant to children (Wolfe I et al. 2013). Wolfe I et al. 2013 also criticise the system for incentivising competition and professional self-interest rather than collaboration.

Despite a lack of consensus on how best to organise primary care to meet the needs of children, the epidemiological changes in the burden of disease and the child health needs warrant a change from the traditional hospital-centric model, designed to treat acute illnesses, to increasing care in the community and better equipping primary care to manage chronic conditions (Wolfe I et al. 2011;Wolfe I et al. 2013). The Healthcare Commission reports that 46% of UK trusts provide poor paediatric care in the community and that less focus is needed on hospital care and more on the management of chronic conditions in the community (Healthcare Commission 2007). The changing needs of the paediatric population must also be reflected in how primary care is funded, for example

Sweden, Italy, France, Germany, and the Netherlands have substantially more doctors per child than the UK (Royal College of Paediatrics and Child Health 2008;Wolfe I et al. 2011;World Health Organisation).

There is no gold-standard method of measuring the quality of child healthcare and the literature evaluating care quality to date in the UK has largely focused on disease-specific indicators, child death reviews, and mortality statistics. Use of mortality data as a surrogate measure of care quality has considerable limitations: the data are prone to numerous biases, mortality data lacks context, meaningful analysis of mortality data is difficulty – highlighted by the internal heterogeneity of the 'cause of death' categories used by Viner RM et al. 2014; and the data are likely confounded at least partially by unknown factors (Hardelid P et al. 2013;Hardelid P and Gilbert R 2013;Johnston BD 2014). Therefore, any conclusions about care quality originating from mortality data, or from comparing mortality data between countries, must be interpreted cautiously. The methods available to measure healthcare quality will be discussed further in Section 1.3.

1.2 Healthcare safety and children

1.2.1 Overview of the history of healthcare safety

High quality healthcare is defined by the Institute of Medicine as: safe, equitable, patient-centred, timely, efficient, and effective (Committee on Quality of Health Care in America Institute of Medicine 2001). The importance of high quality healthcare has been highlighted in section 1.1 and healthcare safety is an integral component of this. This section will discuss the background of paediatric safety including research conducted to date and current gaps in the evidence.

The principle of patient safety and healthcare harm is not new. Thomas Inman first coined the phrase *"primum non nocere"* also known as "first do no harm" in 1860; today this is considered a fundamental concept in medical ethics (Sokol DK 2013). Patient safety as a field however has only gained traction since the turn of the millennium, in response to high-profile healthcare scandals such as the Bristol Heart Inquiry in the UK, and the USA Institute of Medicine report 'To err is human'.(Kennedy I 2001;Kohn LT et al. 1999) The mortality rates of infants undergoing heart surgery in Bristol was double that of comparable hospitals in England (Kennedy I 2001). Similarly in the USA, annual mortality from healthcare errors was greater than from road traffic accidents, breast cancer, or Acquired Immune Deficiency Syndrome (Kohn LT et al. 1999).

Unfortunately two decades on, the landscape of patient safety has not changed significantly and healthcare tragedies continue, as evidenced by the Francis report on Mid-Staffordshire (Francis R 2013;Landrigan CP et al. 2010). The failures and recommendations for improvement published in the Francis report echo those of the Bristol Heart Inquiry. For example, healthcare professionals had been reporting and raising concerns about the safety of care provided in both the Bristol Royal Free in the early 1990s and more recently in Mid Staffordshire, long before the organisations themselves recognised and investigated these failings (Francis R 2013;Kennedy I 2001). Similarly in both cases data demonstrating above average mortality in the respective institutions were readily available, but the gravity of the situation was not acknowledged. It is therefore unsurprising that healthcare organisations are repeatedly criticised for their failure to learn (Francis R 2013;Kennedy I 2001).

Efforts to measure and improve patient safety have largely focused on the hospital rather than the community setting (Carson-Stevens A et al. 2015;Rees P et al. 2015). There has

also been little focus on paediatric safety, which is reflected in the absence of this topic from UK policy directives (Carson-Stevens A et al. 2015;Rees P et al. 2015).

1.2.2 Patient safety in child health

Children are particularly susceptible to unsafe care. Children who are very young, socially deprived, or have complex medical conditions are particularly vulnerable to adverse events (Sidebotham P et al. 2014a). They typically depend on parents or caregivers to recognise illness, take them to a healthcare professional, provide medical histories to physicians, and administer treatment (Wolfe I et al. 2011). Children also depend more on the people surrounding them to recognise unsafe care and to question the care they receive (Carson-Stevens A et al. 2015).

The epidemiology of disease, healthcare needs, and physiology of children differ significantly to those of adults. Numerous diseases are specific to childhood, and the effect of disease in children varies in terms of the signs and symptoms they present with and the speed at which they deteriorate (Walsh KE et al. 2014;Wolfe I et al. 2011). Differences in physiological reserve partially account for these differences (Walsh KE et al. 2014).

The epidemiology of disease, healthcare needs, and physiology, also vary by age, within the paediatric population (Wolfe I et al. 2011). The heterogeneity of this population- ranging from neonates to adolescents- poses safety challenges that are unique to the specialty of paediatrics. For example, children often require weight-based medication that can involve complex calculations requiring skill and familiarity with prescribing and administering medications, predisposing them to medication errors (Carson-Stevens A et al. 2015;Walsh KE et al. 2014).

The culminations of these vulnerabilities to unsafe care result in substantial estimates of iatrogenic harm in this population. Approximately 15-35% of hospitalised children are estimated to suffer an adverse event, and in the UK 26% of deceased children have identifiable failures in care (Pearson G 2008;Walsh KE et al. 2014). Estimates of the incidence of adverse events in children in primary care in the UK- where 90% of patient contact occurs-do not exist (Carson-Stevens A et al. 2015).

Medication errors have been estimated to be three times as common in children compared with adults (Department of Health 2000;Wong IC et al. 2009). Consequently these have been the main focus of the limited research into paediatric safety, although most studies focus on secondary care errors (Carson-Stevens A et al. 2015). Children appear particularly prone to tenfold medication errors, especially neonates and those with chronic conditions requiring complex treatment (Doherty C and Mc Donnell C 2012;Ligi I et al. 2008). The catastrophic impact of medication errors is demonstrated by numerous high-profile cases in the UK such as Richie William's death from inadvertent intrathecal rather than intravenous administration of vincristine, for which two doctors faced charges of manslaughter (Dyer C 1999).

The student's recent publication reported paediatric safety incidents from general practice and showed that vaccination-related errors were among the most frequently reported and harmful safety incidents affecting children (Rees P et al. 2015). These errors included inadvertent administration of the wrong vaccine, the wrong number of vaccine doses, and administration at the wrong time. The sometimes-catastrophic effect of deviating from the vaccination schedule has been demonstrated by child deaths from vaccine-preventable infections and recent Measles outbreaks in the UK and USA (Greaves F and Donaldson L 2013;Harnden A et al. 2009).

Child death reviews highlight safety incidents in primary care such as: failure to recognise and manage severe infection, failure to vaccinate, and failure to follow up patients. Those with chronic conditions contribute substantially to UK child deaths (Harnden A et al. 2009). Thomson MJ et al. 2006 highlight failures in first-access services within primary care by reporting that 50% of children with diagnosed meningococcal infection had been sent home from their first consultation, delaying diagnosis of a life-threatening infection.

The litigation costs of missed diagnoses in children equates to over £20million in the past 13 years (Wolfe I et al. 2011). These safety incidents underpin the poor UK performance in numerous measures of paediatric care quality, as highlighted in section 1.1.

Approximately 6000 children die each year in England and Wales, 20% of these deaths are thought potentially preventable with better care, however it is unclear how many of these deaths were the result of a patient safety incident (Pearson G 2008;Sidebotham P et al. 2014b).

1.3 Methods of measuring the burden and assessing the nature of unsafe care and healthcare error

Efforts to improve care quality to date have been hindered by unreliable data on the prevalence, burden and nature of substandard care. However, before paediatric care quality can be addressed and improved, widespread and reliable measurement of the scale of the problem, including the most frequent and harmful sources of substandard care, is required (Walsh KE et al. 2014). These measurements must be both accurate and precise (Thomas EJ and Petersen LA 2003). Several methods exist for assessing care quality; key methods will be presented and their respective attributes and weaknesses discussed.

1.3.1 Definitions

Numerous terms exist to describe the outcomes of unsafe care and different methods focus on different outcomes such as: preventable harms, all harms, and near misses.

Preventable harm is defined as a negative patient outcome "that would not have occurred if the patient had received ordinary standards of care appropriate for the time"(World Health Organisation 2009). Harm, preventable or unpreventable, is defined as a negative patient outcome that includes "temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain requiring intervention" (World Health Organisation 2009).

Near misses however also encompass errors that do not result in harm and are defined as "events or situations that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention" (World Health Organisation 2009). Near misses represent an important group of errors because the failures and system weaknesses underpinning them tend to be the same as those contributing to harmful errors. Unfortunately near misses can be difficult to detect and are often overlooked by certain measurement methods. Similarly some methods focus solely on preventable harm whereas others focus on all harm arguing that what constitutes preventable harm is continuously evolving (Parry G et al. 2012)

1.3.2 National-level administrative data

The Royal College of Paediatrics and Child Health (RCPCH) conducted a retrospective epidemiological review of all-cause mortality in UK children, using nationally representative and coded longitudinal administrative data linked to supplementary data sources such as birth and death certificates (Hardelid P et al. 2013). These datasets are likely to be linked to national-level longitudinal primary care data, mental health services data, and data on emergency department attendances and intensive care stays in the near future (Dattani N et al. 2013;Hardelid P et al. 2013). There has been no national-level measurement of paediatric care quality in the UK. However, these data could be monitored for poor quality care using pre-specified care quality indicators and their respective ICD-10 codes, to estimate the burden of substandard care, as exemplified in the USA by the Harvard practice medical study (Brennan TA et al. 1991;Brennan TA et al. 2004;World Health Organisation 2010).

There are numerous benefits to using nationally collected longitudinal administrative data. However, utilising these data effectively is expensive and time consuming; and it is widely acknowledged that the data are too crude to provide meaningful information about the complexities of care. Despite the availability of national epidemiologic data about child health, their value is limited by the quality of available data and the systems providing data (Fraser J et al. 2014). For example, a Confidential Enquiry highlighted that 35% of child death certificates had an incorrect cause of death recorded (Fraser J et al. 2014;Wolfe I et al. 2014). Considerable delay in death registration and certification combined with inaccurate and incomplete records limit the utility and depth of learning that can be gained from this approach. However, the RCPCH advocates supplementing data linkage of routinely collected data with in-depth case note reviews to address these criticisms (Hardelid P et al. 2013).

1.3.3 Case note reviews

Historically patient medical records have been used to measure the incidence and burden of substandard care (Parry G et al. 2012). A random sample of medical records are reviewed using pre-defined ‘quality indicators’ to identify the proportion of children receiving appropriate care, and the proportion receiving substandard care. This approach provides case note reviewers with the opportunity to identify detailed clinical information to understand and contextualise the care quality incident. Traditionally this method has

been used to estimate the incidence of substandard care and to investigate the types of failures leading to poor care quality (Mangione-Smith R et al. 2007b;Sari ABA et al. 2007;Vincent C et al. 2001). Gill P et al. 2014 have developed quality indicators for children in UK family practice, however they have not yet been tested. The extent of substandard care can be monitored temporally and the impact of improvement initiatives assessed with this approach, locally and nationally.

Reviews may be disease focused e.g. care quality in children with asthma, or they may be restricted to serious cases or specific child deaths. Disease-based reviews of care quality in live children are also becoming increasingly popular and allow crude comparisons of care quality with other countries (Asthma UK 2007;Wolfe I et al. 2014). They are conducted annually in the UK for diabetic care and the RCPCH have recently finished a three-year audit of epilepsy care quality (Royal College of Paediatrics and Child Health 2012).

Reviews of medical records are expensive, time-consuming, labour-intensive, inquisitorial and prone to incomplete ascertainment (Mangione-Smith R et al. 2007b;Parry G et al. 2012;Sari ABA et al. 2007;Vincent C et al. 2001). For example, this method relies on the content and the quality of medical records, which are often subjective or incomplete. Hardelid P et al. 2013 have demonstrated that the issue of incomplete medical records or ascertainment can be overcome–at least partially–by linking data sources.

1.3.3.1 Trigger tools

Trigger tools offer an alternative and more efficient approach to reviewing medical records compared with traditional methods of systematically reviewing complete records. This method of harm detection and measurement includes selecting a random sample of medical records for case note review (Chapman SM et al. 2014). These records are then systematically searched, typically by a trained professional, for 'triggers' which are a predefined list of events that suggest patient harm such as hypoglycaemia (Chapman SM et al. 2014). Records where triggers are identified are reviewed in-depth to determine whether the trigger represents an adverse event in that patient. When adverse events and harm are suspected, second reviewers that are typically clinicians, confirm the occurrence of harm and its severity (Chapman SM et al. 2014).

Tools such as the Global Trigger Tool have been tested and developed for adult care in specific care settings including: acute hospitals, surgery, critical care, and primary care (Classen DC et al. 2011;Griffin FA and Classen DC 2008;Griffin FA and Resar RK 2009;Parry G et al. 2012;Resar RK et al. 2006;Singh R et al. 2009). Fewer paediatric-specific trigger tools exist, however they have been developed for hospital setting (Agarwal S et al. 2010;Chapman SM et al. 2014;Larsen GY et al. 2007;Matlow AG et al. 2011;Muething SE et al. 2010;Sharek PJ et al. 2006;Takata GS et al. 2008). A UK based paediatric trigger tool for use in hospitals was only recently developed and to the student's knowledge no primary care specific paediatric trigger tools exist (Chapman SM et al. 2014).

This method is more sensitive than comparable methods since it detects more adverse events (Parry G et al. 2012). Several factors may underlie this sensitivity: trigger tools focus on harm rather than error, and they do not rely on recognition and reporting of error or harm, they are therefore more likely to detect errors of omission (Chapman SM et al. 2014;Parry G et al. 2012). Additional attributes include the low cost associated with the use of this tool to obtain relevant data for improvement, and the ability of this method to provide reliable data, making it suitable for learning at a local level. Studies using trigger tools have shown high inter-rater reliability between reviewers (Chapman SM et al. 2014). However the validity of estimates of harm measurements generated by trigger tools is dependent on the accuracy and completeness of documentation.

The application of trigger tools is currently labour intensive although electronic medication records could support the automated detection of triggers in the future (Chapman SM et al. 2014;Parry G et al. 2012;Walsh KE et al. 2014). Despite the high reliability and harm detection rate of trigger tools, they were designed to complement other methods of harm detection rather than replace them (Chapman SM et al. 2014;Parry G et al. 2012;Walsh KE et al. 2014).

1.3.4 Incident reporting systems

Reporting systems are a well-established resource widely used in healthcare to provide insights into unsafe and poor quality care (Rees P et al. 2015). The purpose of an incident reporting system is to enable an organisation and its staff to learn from human and system errors to prevent their reoccurrence (Vincent C 2007;World Alliance for Patient Safety 2005). A successful reporting system relies on staff submitting reports, good quality descriptions, high quality analysis of reports, and responding to those findings to improve

safety (World Alliance for Patient Safety 2005). High-risk organisations such as those in the nuclear, petrochemical, and aviation industry value the contribution of safety reports (World Alliance for Patient Safety 2005). They facilitate identification of system weaknesses that require remedy to prevent disaster. The healthcare industry has followed the lead of such industries in their approach to safety, including the development of incident reporting systems.

Incident reporting systems vary in terms of: their purpose, who reports, what is reported, how to report, the analysis of reports, and the dissemination of findings (World Alliance for Patient Safety 2005). Reports tend to come from healthcare professionals although there is increasing patient participation in this field and some reporting systems are open to receiving reports from patients, families and patient advocate groups. Some reporting systems only receive reports of adverse drug reactions, for example, the yellow card system in the UK, whereas other systems receive reports of any adverse event such as the national reporting system in Denmark (World Alliance for Patient Safety 2005). These reports are analysed using various classifications and some reports may prompt more detailed investigations such as a root cause analysis (National Patient Safety Agency). The findings of analysis, including recommendations for improvement are then disseminated to stakeholders such as reporters.

Reporting systems can be used to inform improvements at the national or local level. At the national level, aggregating large quantities of data enables detection of rare incidents that would otherwise be missed (Rees P et al. 2014). For example, the UK National Reporting and Learning System (NRLS) was integral in detecting the association of bone cement implantation syndrome and the use of cement in hip fracture surgery (Panesar SS et al. 2009a;Panesar SS et al. 2009b). However hazards particular to a hospital or ward can also be detected by analysing reports submitted locally, for example, to identify out-dated or faulty equipment. Reporting can result in improvement. For example, through circulating alerts about significant new hazards such as drug side effects; by disseminating learning from serious incidents not only to the institution where the incident occurred but to other institutions; and by generating recommendations for best practice to mitigate identified hazards and system failures (World Alliance for Patient Safety 2005).

Incident report data have successfully informed over 300 studies in the published literature. Such research has identified problem areas in secondary care requiring improvement including: reliable insulin administration, early detection of surgical

complications, and lithium prescribing and monitoring, highlighting the potential value of incident report data (Cresswell KM and Sheikh A 2008;Lamont T et al. 2011a;Lamont T et al. 2011b;Lamont T et al. 2010;Lamont T et al. 2011c).

Despite their unique advantages, such as being well placed to detect near misses, incident reporting systems have widely published weaknesses. The Achilles heel of incident reporting systems is their inability to provide a complete picture of healthcare safety due to under-reporting (Vincent C 2007;Vincent C et al. 2008;Vincent CA 2004). A case note review concluded that only 7% of detected incidents are reported to the UK reporting system, and that those incidents reported are subject to numerous biases (Sari ABA et al. 2007). Variability in the content of reports and what gets reported between different professional groups, wards, and organisations creates 'reporting bias', which is a considerable challenge for those seeking to interpret meaning and generate learning from reports.

The Berwick report emphasises the importance of a well-designed reporting system within every healthcare organisation (Department of Health 2013). The aim of such a system is not to capture all incidents, or to capture them representatively, but to provide a window into the hazards and system failures that impact patient care. Many claim that we are drowning in big data. The challenge is to effectively utilise data that are routinely collected, such as incident report data. Well publicised healthcare failures such as those in Mid-Staffordshire and the Bristol Heart Inquiry would not necessarily have been prevented with increased data collection (Francis R 2013;Kennedy I 2001). Numerous reports and complaints of unsafe care were made at these institutions and sufficient data were collected by the organisations to demonstrate worrying trends in mortality, yet these trends went unacknowledged (Panesar SS et al. 2013b).

The WHO is developing a minimal information model for patient safety reporting, which will allow international comparison of incident report data (World Health Organisation). The limitations of incident reporting systems are well known and perhaps over-emphasised as they provide vast quantities of data for learning (Carson-Stevens A et al. 2015). Many believe that incident report data are under-valued and that they could be better utilised globally to provide insights into the safety of healthcare, and to facilitate improvements in care quality.

1.4 National Reporting & Learning System (NRLS)

Patient safety incident reporting systems provide one lens through which to view human and system failures that may result in harm to patients. This is the purpose of the NRLS which collects reports of any "unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS funded care" in England or Wales, to identify risks at a national level(National Reporting and Learning System).

The NRLS was established in 2003 in response to a governmental report 'An Organisation with a Memory', which criticised the ability of the NHS to identify and address serious failures in healthcare at that time (Department of Health 2000). It was managed by the National Patient Safety Agency (NPSA) – an independent body established in 2000 whose purpose was to "implement and operate the [NRLS] – to improve patient safety by reducing the risk of harm through error"(Department of Health 2001). However, control of the NRLS was transferred to the NHS commissioning board in 2012.

Despite calls for mandatory reporting of adverse events and specific near misses, at its creation the NRLS was completely voluntary and anonymous. The intention was to minimise defensive reporting and disincentives to reporting, such as blame or fear of retribution encouraging full and candid reporting (Department of Health 2000;Francis R 2013). In addition, the NPSA did not have the power to enforce mandatory reporting and the purpose of reporting was to galvanise learning rather than to detect and compare failures between healthcare organisations. However, in 2010 reporting of incidents resulting in severe harm or patient death became mandatory (Francis R 2013).

Staff and patients are encouraged to report and this can be done directly and independently to the NRLS online. Staff can also report incidents within their place of work using local reporting procedures, and in specialties such as anaesthesia they can complete specialty-specific reports (Francis R 2013). All reports submitted locally are analysed by that parent healthcare organisation for 'local learning' and then all reports are anonymised and uploaded to the NRLS by a designated person for 'national learning' (see Figure 1) (Donaldson LJ et al. 2014;Rees P et al. 2015).

Every report form contains 'essential information' such as patient age, but the layout and appearances of report forms vary between organisations. For example, some include instructions to reporters about what information to include and others do not. NRLS reports contain multiple categorical variables that include patient age range, location,

care setting, country, and severity of harm. They also contain free-text information about what happened, potential causes, and suggestions for future prevention (Donaldson LJ et al. 2014;Rees P et al. 2015).

The NHS commissioning board cannot scrutinise every report submitted to the NRLS; it receives over 65,000 paediatric related reports per annum, despite considerable under-reporting (Carson-Stevens A et al. 2015).–The detail and accuracy of information included in reports is at the discretion of reporters, who often report with hindsight, and are prone to inherent human biases (Donaldson LJ et al. 2014;Rees P et al. 2015). Despite these limitations, the NRLS has a well-established infrastructure, and receives large quantities of rich data that can be used for learning and hypothesis generation (Rees P et al. 2015).

The insights offered by incident report data and the potential benefits of its analysis are clear despite its limitations, yet no systematic analysis of primary care-related paediatric safety incidents submitted to the NRLS has been conducted to date.

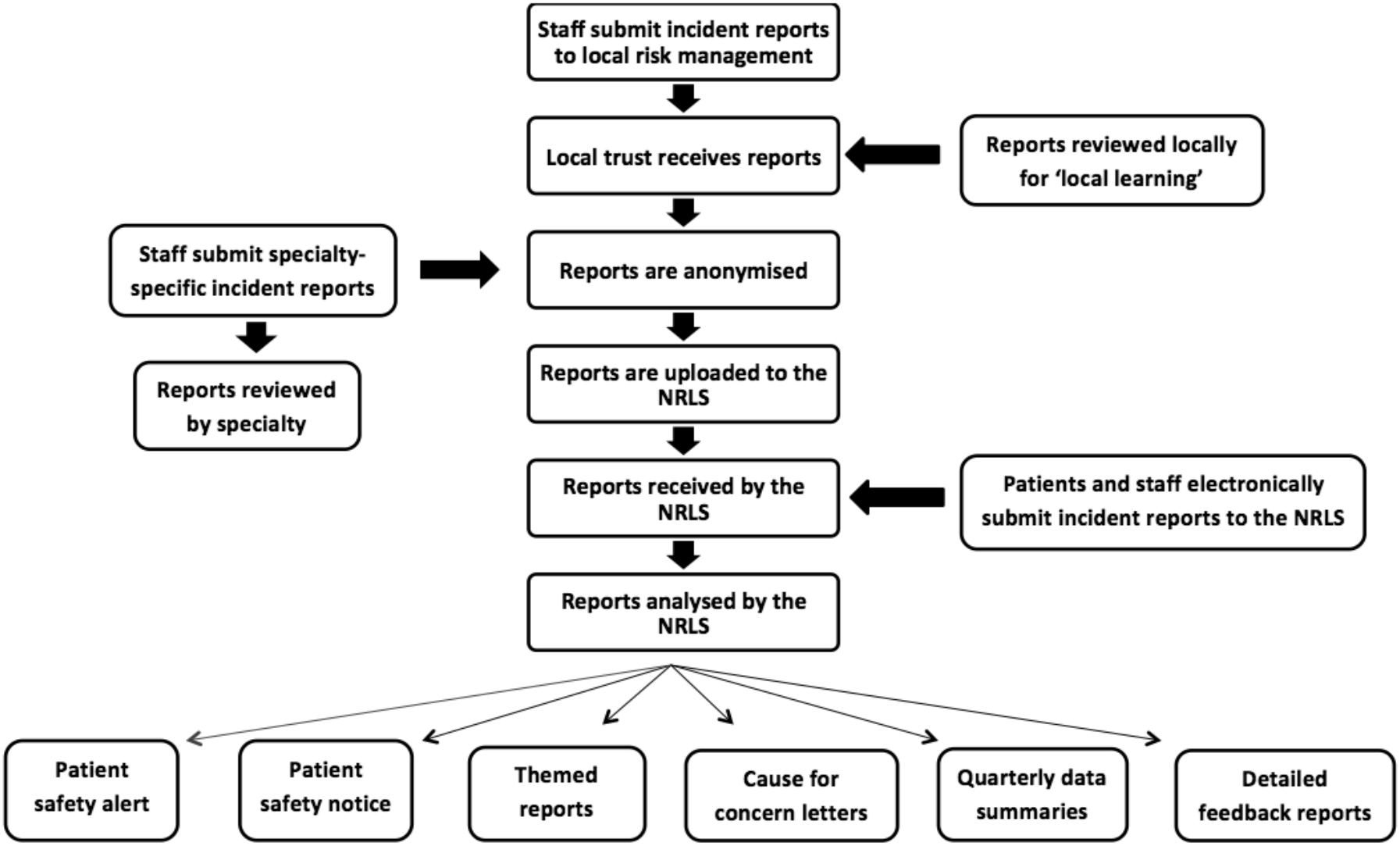


Figure 1 page 21: flow diagram illustrating the process of reporting incidents to the NRLS and how the NRLS responds to reports

1.5 Aims and objectives

1.5.1 Aim

To explore the nature, contributory factors, severity, and outcomes of paediatric safety incident reports related to vaccination in primary care

1.5.1.1 Objectives

- Provide an overview of the data included and processed, and present key quantitative findings

- Present the key themes and sub-themes identified from thematic analysis of purposively sampled reports, and describe how these themes relate to each other

- Combine the insights gained from the quantitative and qualitative analysis, and explain how the qualitative insights relate to the quantitative findings

1.5.2 Aim

To explore the nature, contributory factors, severity, and outcomes of paediatric safety incident reports involving ‘unwell’ children in primary care

1.5.2.1 Objectives

- Provide an overview of the data included and processed, and present key quantitative findings

- Present the key themes and sub-themes identified from thematic analysis of purposively sampled reports, and describe how these themes relate to each other

- Explain how the qualitative insights related to the quantitative findings

1.5.3 Aim

To conduct a literature review to identify quality improvement interventions tested, or implemented to improve either the paediatric vaccination process or care for ‘unwell’ children.

Chapter 2: Method

This chapter will describe how the student decided to utilise the NRLS data to best achieve the aims and objectives previously described. The methods used to sample, search, process, and analyse the NRLS data will be presented, whilst justifying how they were chosen and comparing them to alternative methods. The methods used to conduct the literature review will be presented alongside the literature review in section 3.3, as the review question and inclusion criteria are dependent on the results presented in sections 3.1 and 3.2.

2.1 Data handling

2.1.1 Data sampling

Of 272,884 primary care-related incident reports, 20,118 reports involving children were identified on applying a filter to the patient age-related columns in Microsoft excel. These reports were searched using the search strategies.

2.1.2 Search strategy

The student designed two search strategies for maximal recall of vaccination-related incidents and incidents related to 'unwell' children (Appendix 2.1 and 2.2). Previously analysed reports were reviewed to extract key terms and alternative spellings/ misspellings of these terms pertinent to the above topics. This list of vaccination-related key terms derived from the reports themselves was combined with lists of vaccine brands and vaccine generic names from the children's British National Formulary (BNF) (Paediatric Formulary Committee 2013). Similarly the search strategy to identify reports of 'unwell' children was iterated using appropriate terms from the International Classification of Disease 10 (ICD-10) (World Health Organisation 2010).

Both search strategies were reviewed and adapted by clinicians (the student's supervisors). All paediatric reports were imported into a qualitative software package (NVIVO 9, QSR International), where the key terms were used to search the reports. Alternative spellings, synonyms and abbreviations used in the NRLS reports were identified using NVIVO text search functions and these additional terms were incorporated into the search strategy to maximise its sensitivity.

2.1.3 Data processing

Once the relevant reports were identified the student imported them into a separate password protected Microsoft Excel document. The free text components of reports were read and the incident types, potential contributory factors, severity of harm and incident outcomes were classified. The vaccines involved in the vaccination-related incidents were noted. The pre-existing and/ or presenting diagnosis signs or symptoms of 'unwell' children were classified using ICD-10; and the medications involved in incidents were classified using the children's BNF. The inclusion and exclusion criteria are listed in Table 1. During data processing potentially severe near misses, and rare or theoretically important reports were logged for subsequent qualitative analysis.

Table 1 page 25: inclusion and exclusion criteria

Inclusion	Exclusion
Incidents in children aged <18 years	Reports without a pre-allocated age group
AND Incidents occurring in primary care	Incidents occurring in secondary care but reported by primary care
AND Incidents occurring between 2002-2013	Incidents involving child maltreatment, sexual abuse, fabricated or induced illness, emotional abuse, or neglect
AND Vaccination-related incidents **OR** incidents involving *'unwell'* children defined as children with any described symptoms, signs, diagnoses, or prescribed medications implying illness	Incidents without free-text descriptions

2.1.4 Classification frameworks

In order to comprehensively describe the detailed free-text descriptions contained within reports, the student sought to classify incident types, contributory factors, incident outcomes, and severity of harm. Existing classifications were reviewed for suitability (Computer Sciences Corporation 2015;Dovey SM et al. 2002;Jacobs S et al. 2007;Kostopoulou O and Delaney B 2007;Makeham MA et al. 2002;Makeham MA et al. 2008;Rubin G et al. 2003;The Netherlands: Eindhoven University of Technology ;West D et al. 2005;World Health Organisation 2009).

I had originally intended to use the Learning from International Networks about Errors and Understanding Safety in Primary Care [LINNAEUS Euro-PC] taxonomy to classify reports. This taxonomy was designed for use in primary care to classify incident type and had been used in previous studies (Martijn LLM et al. 2013;Rosser W et al. 2005;Woolf SH et al. 2004). During the student's previous work with NRLS data, the incident type and contributory factors frameworks were separated into two parent categories: system factors and human factors mirroring the LINNEAUS taxonomy, and contributory incidents were in both the incident descriptor framework and contributory factors framework (Rees P et al. 2015). These frameworks were not 'user friendly', had extensive overlap, and codes within frameworks were not mutually exclusive.

The student re-organised the incident type and contributory factor frameworks, and this re-organisation was influenced by the WHO International Classification for Patient Safety (World Health Organisation 2009). The amended incident descriptor framework included incidents and contributory incidents, aggregated under ten parent codes: administration, documentation, referral, diagnosis and assessment, treatment and procedures, medications and vaccines, investigations, communication, care equipment, and 'other'. The system and human factors e.g. referral process and referral decision, remained although would now have the same parent code e.g. referral; this facilitated the process of logically classifying incidents.

The 'new' contributory factors framework included contributory factors only, and not contributory incidents, as it had previously. These contributory factors were re-organised under four parent categories: patient/caregiver factors, staff factors, equipment/ vaccine/ medication factors, and organisational factors, mirroring Eindhoven's

Classification and WHO International Classification for Patient Safety (The Netherlands: Eindhoven University of Technology ;World Health Organisation 2009).

Previous studies had used the ICD-10 to classify incident outcomes, however the student decided that the ICD-10 was too extensive for use with this dataset (World Health Organisation 2010). Conversely during a previous study, the student used Vincent's typology of harm to classify the type of harm outcomes resulting from incidents and found this framework too broad (e.g. there were only 6 types of harm) (Vincent C et al. 2013). Therefore, an in-house framework grounded in UK NRLS data was created.

Therefore, three of the four frameworks used were developed 'in-house', grounded in UK primary care data, and iterated extensively to accurately capture the descriptions of incidents, contributory factors and outcomes within reports.

Prior to deciding on a framework to classify harm severity the student reviewed three of the most frequently used frameworks: the NRLS classification, severity assessment code matrix, and WHO International Classification for Patient Safety (National Reporting and Learning System ;New South Wales Government 2005;World Health Organisation 2009). Tables 3-5 demonstrate the definitions of harm severity used in each classification: there is little variation in the definitions of harm at the patient level but the severity assessment code matrix classifies harm more comprehensively.

The severity assessment code matrix was piloted on small sample of reports to classify the severity of harm at the patient, staff, services, financial, and environmental levels where free-text descriptions allowed (New South Wales Government 2005). However, as reports only described harm at the patient level the student decided that such a comprehensive classification matrix was unnecessary and incompatible with this dataset.

The student decided to classify harm severity using the WHO International Classification for Patient Safety as the categories mirror those of the NRLS (no harm, low harm, moderate harm, severe harm, death) but the definitions are more comprehensive (National Reporting and Learning System ;World Health Organisation 2009). This will also aid comparison with previous and future studies of this nature.

All reports submitted to the NRLS contain a harm severity decided by the reporter at the originating healthcare organisation. The reporter-allocated harm severity was only used

during data processing when there was insufficient detail in the free-text descriptions to re-classify the severity of harm using the WHO International Classification for Patient Safety. Thus, the severity of harm was upgraded or downgraded from the reporter-allocated harm severity when additional information was available, and the free-text descriptions of harm severity differed to the reporter-allocated harm severity.

Table 2 page 29: the severity assessment code matrix (New South Wales Government 2005)

Severity of harm	Minimum	Minor	Moderate	Major	Serious
Patient level	Patients with No injury or increased level of care or length of stay	Patients requiring Increased level of care including: • Review and evaluation • Additional investigations • Referral to another clinician	Patients with permanent reduction in bodily functioning (sensory, motor, physiological, or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following: • Increased length of stay as a result of the incident • Surgical intervention required as a result of the incident	Patients suffering a major permanent loss of function (sensory, motor, physiological or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following: • Suffering significant disfigurement as a result of the incident • Patient at significant risk due to being absent against medical advice • Threatened or actual physical or verbal assault of patient requiring external or police intervention	Patients with death unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management or: • Suspected suicide • Suspected homicide Or any of the following: • National sentinel events • Procedures involving the wrong patient or body part • Suspected suicide in hospital • Retained instruments • Unintended material requiring surgical removal • Medication error involving the death of a patient • Intravascular gas embolism • Haemolytic blood transfusion • Maternal death associated with labour and delivery • Infant discharged to the wrong family
Staff level	No injury or review required	First aid treatment only with no lost time or restricted duties	Medical expenses, lost time or restricted duties or injury / illness for 1 or more staff	Permanent injury to staff member, hospitalisation of 2 staff, or lost time or restricted duty or illness for 2 or more staff or pending or actual WorkCover prosecution, or threatened or actual physical or verbal assault of staff requiring external or police intervention	Death of staff member related to work incident or suicide, or hospitalisation of 3 or more staff
Visitors level	No treatment required or refused treatment	Evaluation and treatment with no expenses	Medical expenses incurred or treatment of up to 2 visitors not requiring hospitalisation	Hospitalisation of up to 2 visitors related to the incident / injury or pending or actual WorkCover prosecution	Death of visitor or hospitalisation of 3 or more visitors
Services level	Services: No loss of service	Reduced efficiency or disruption to agency working	Disruption to users due to agency problems	Major loss of agency / service to users	Complete loss of service or output
Financial level	No financial loss	Loss of assets replacement value due to damage, fire etc. to $50K	Loss of assets replacement value due to damage, fire etc. $50K to $100K or loss of cash/investments/assets due to fraud, overpayment or theft to $10K	Loss of assets replacement value due to damage, fire etc. $100K-$1M, loss of cash/investments/assets due to fraud, overpayment or theft $10K-$100K or WorkCover claims $50K-$100K	Loss of assets replacement value due to damage, fire etc. > $1M, loss of cash/investments/assets due to fraud, overpayment or theft >$100K or WorkCover claims > $100K
Environmental level	Nuisance releases	Off-site release contained without outside assistance	Off-site release contained with outside assistance or fire incipient stage or less	Off-site release with no detrimental effects or fire that grows larger than an incipient stage	Toxic release off-site with detrimental effect. Fire requiring evacuation

Table 3 page 30: National Reporting & Learning System definitions of harm severity (National Reporting and Learning System)

Severity of harm	No harm	Low harm	Moderate harm	Severe harm	Death
Definitions	Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care	Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care	Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care	Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care	Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care

Table 4 page 30: WHO International Classification for Patient Safety definitions of harm severity (World Health Organisation 2009)

Severity of harm	No harm	Mild harm	Moderate harm	Severe harm	Death
Definitions	Patient outcome is not symptomatic or no symptoms detected and no treatment is required	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required	Patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function	Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function	On balance of probabilities, death was caused or brought forward in the short term by the incident

2.1.5 Models of incident analysis

Patient safety incidents are typically complex with multiple factors preceding them. The free text in each incident report can provide sufficient detail to identify the related incidents and contributory factors. Numerous studies have summarised free-text descriptions of these complex events by selecting only one incident type, predominantly the most important or severe, the first incident occurring in the chain of causality, or the final incident in the chain of causality (Donaldson LJ et al. 2014;Dovey SM et al. 2002;Magrabi F et al. 2011;Panesar SS et al. 2013a).

The student did not want to reduce or summarise the rich free-text descriptions within reports and sought to capture the complex relationships described within them. Other studies aiming to do this categorised multiple incidents and contributory factors, and some did this chronologically to model the chain of causality (Rees P et al. 2015;Suresh G et al. 2004;Woolf SH et al. 2004). However this approach gave rise to confusion between incidents–particularly contributory incidents–and contributory factors i.e. there was significant overlap between them (Hibbert PD et al. 2007;Rees P et al. 2015;Suresh G et al. 2004).

To address the above issues the student decided to use the Australian Recursive Model of Incident Analysis to organise and order data processing (Hibbert PD et al. 2007). This facilitates consistency in the application of codes and allows in-depth classification of reports. Additionally, unlike other models, the recursive model has clear rules differentiating primary incidents, contributory incidents, and contributory factors (Hibbert PD et al. 2007). This approach was therefore compatible with the frameworks developed in-house i.e. there was no overlap between the incident descriptor framework and the contributory factor framework.

There are nine incident analysis rules in this model: the primary incident type is the incident chronologically proximal to the patient prior to harm/outcome (or potential harm) (Table 5) (Hibbert PD et al. 2007). Therefore, by definition, the outcome of the primary incident type cannot be an incident it can only be an outcome. Incidents that occur prior to the primary incident type (more distal to the patient) that played a part in the occurrence of the primary incident are by definition contributory incidents. Contributory factors cannot be incidents in their own right, such as a child being looked-after; these are found in the contributory factors framework. These sequential incidents

are coded in reverse chronological order, which is similar to the approach used in a root cause analysis. (Figures 2 and 3) Working backwards from the primary incident type and mapping out the sequence of incidents, contributory incidents, and contributory factors, allows us to reach the root cause (where there is sufficient detail).

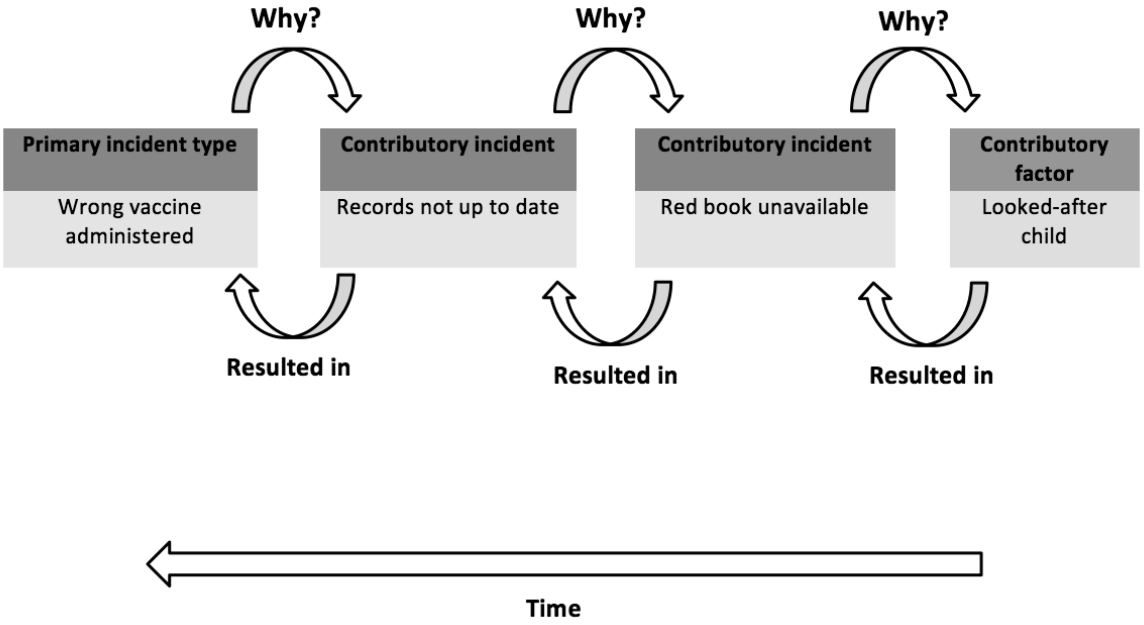


Figure 2 page 33: illustrates the Australian Recursive Model of Incident Analysis

Incident Types						Number of incidents	Contributory Factors		Number of contributory factors
Wrong vaccine administered	6.11.3.1	Records not up to date	2.1.3	Red book unavailable	2.1.1.1	3	Looked-after child	1.5	1

Figure 3 page 33**:** an example of the layout of the Recursive Model of Incident Analysis during data processing in Microsoft Excel.

Table 5 page 34: the nine rules of the Australian Recursive Model of Incident Analysis (Hibbert PD et al. 2007;Rees P et al. 2015)

Incident Analysis Rules	Rule Example
1. An incident has a set of contributory factors and / or contributory incidents	Missed diagnosis (incident) because the physician did not adequately examine the patient (contributory incident) and the physician had inadequate knowledge (contributory factor)
2. An incident can contribute to another incident	Missed diagnosis (contributory incident) resulted in a patient not receiving a timely referral to the hospital (primary incident)
3. Contributory factors cannot be incidents in their own right	A mistake (contributory factor *not* an incident) resulting in the wrong prescribed medication dose (primary incident)
4. An incident has a set of outcomes	Wrong prescribed medication dose (primary incident) resulting in a medication overdose and hospital admission (outcomes)
5. An incident can be an outcome of another incident	Records not up to date (contributory incident) resulting in the wrong prescribed medication (primary incident and outcome)
6. Some outcomes cannot be incidents in their own right	Admission to hospital (outcome) following the wrong prescribed medication (primary incident)
7. An outcome of an incident could be a contributory incident to another incident	Communication incident between care providers (contributory incident) resulting in records not being up to date (contributory incident and outcome), resulting in a referral incident (primary incident)
8. An incident can be designated the primary incident type – the incident proximal to the descriptive patient outcome	Communication incident (incident) leading to inaccurate records (incident), leading to the wrong prescribed medication (primary incident type)
9. The outcome of a primary incident cannot be an incident	Admission to hospital (outcome) following the wrong prescribed medication dose (primary incident type)

2.1.6 Quantitative analysis

Prior to analysis, the types of conditions present in 'unwell' children classified using the ICD-10 were aggregated into thirteen broad categories (Table 6).

The processed data underwent descriptive analysis to illustrate the frequency distribution of variables including: age, time, incident types, contributory factors, severity of harms, outcomes, types of conditions and medications or vaccines implicated in incidents. The relationships between these variables were explored using numerous cross-tabulations for example: incident type by age, incident type by contributory factors, primary incident type by contributory incidents, contributory factor one by contributory factor two, incident type by diagnosis, incident type by harm, incident type by outcome *etc*. This provided descriptions of temporal trends, highlighted potential associations between variables and combinations of contributory factors.

The relationship between the primary incident type and contributory incidents, primary incident type and contributory factors, and various contributory factors with each other were examined to identify clusters of factors.

Table 6 page 36: illustrates how the ICD-10 codes for children's pre-existing and/ or presenting conditions were grouped

Type of condition	ICD 10 codes
Infections	A00-99; B00-99
Cancer and blood	C00-97; D00-89; R70-79
Skin and musculoskeletal system	L00-99; M00-99; Q65-79; R20-23; R25-29
Neurological and sensory system	G00-99; H00-95; Q00-Q07; Q10-18
Respiratory system	J00-99; Q30-34; R04-6; R09.0-3
Mental and behaviour	F00-99; X60-84
Injuries	S00-99; T00-98; V01-X59; X85-Y09; Y10-Y34; Y35-36; Y40-84; Y85-89
Circulatory system	Q20-28; R00-03; R09.8
Digestive and genitourinary system	K00-93; N00-99; Q35-37; Q38-45; Q50-56; Q60-64; R10-19; R30-39; R80-82
Endocrine, metabolic and nutrition	E00-90
Non-specific signs and symptoms	R07; R40-46; R47-49; R50-69; R83-89; R90-94; R95-99
Pregnancy, chromosomal other congenital disorders	O00-99; P00-96; Q80-89; Q90-99

2.2 Thematic analysis

2.2.1 Justification of qualitative method

Thematising data features in numerous types of qualitative methods such as grounded theory and ethnography and should therefore be considered a fundamental tool of qualitative analysis (Holloway I and Todres L 2003); (Braun V and Clarke V 2006). Despite this overlap Braun V and Clarke V 2006 argue that it should also be considered a standalone method.

An attribute of thematic analysis is its flexibility: it is not constrained to a particular epistemology or ontology. The student recognised that it was important to take a realist approach and capture the content of reports i.e. what reporters wrote. However, the student also recognised the importance of seeking the underlying meaning of the reports' content i.e. what the reporters meant or implied, which is consistent with an idealist approach (Bourgeault I et al. 2010;Denzin NK and Lincoln YS 2011). Thematic analysis offered the flexibility to use both ontological approaches, realist and idealist, where the data allowed, to augment learning (Braun V and Clarke V 2006).

Braun V and V Clarke 2006 describe two thematic analysis methodologies: theoretical and inductive. A mixture of these was used in this study. Analysis was grounded in the data (data-driven) in an inductive manner. New theoretical insights about the human and system failures underpinning incidents were noted and sought, and there was no pre-defined framework. However, Braun V and Clarke V 2006 argue that data cannot be coded in an epistemological vacuum and prior data processing and clinical knowledge did inform the student's theoretical insights, which in turn influenced sampling. These theoretical insights were further explored through thematic analysis of the purposively sampled reports.

2.2.2 Qualitative sampling

Reports that provided new insights, and supported or contradicted emerging theories during classification, were selected for qualitative analysis, providing a purposive sample of reports.

2.2.3 Qualitative analysis

Purposively sampled reports were imported into NVIVO 9 (QSR International), and read and re-read for familiarisation with the data. Systematic searching of the data was conducted to identify deviant or noteworthy cases. Broad brush coding using word frequency queries in NVIVO (also known as content analysis) was conducted for orientation to the data. After immersion in the data, segments of free-text underwent open coding in an inclusive descriptive manner, line by line, to capture every nuance and contextual factor, to preserve the reports' meaning and not summarise or reduce the data ((Bryman A 2012;Glaser BG and Strauss AL 2009;Miles MB and Huberman AM 1994;Pope C and Mays N 1995;Pope C et al. 2000). Nodes were created in NVIVO for this purpose, which often incorporated key words or phrases used in the reports (in-vivo codes) to preserve reporters' views. Often multiple nodes were created for the same section of text where the description satisfied inclusion into multiple nodes. Semantic (descriptive) features and latent (interpretative) features were coded. A constant comparative approach was used, this involved comparing each node with previously coded text to develop analytic categories, an iterative process (Denzin NK and Lincoln YS 2011;Lacey A and Luff D 2001).

Descriptive nodes were extracted and underwent analysis at the latent and interpretive level, where the reports were re-examined to extract underlying meaning and inference. Overlapping nodes were then merged into subthemes that created an index system (Bazeley P 2007). Free-text was re-coded using this index system. Sub-themes were refined, and combined to form over arching themes. The relationships between these sub-themes and overarching themes were mapped, analysed and interpreted (Pope C et al. 2000). Themes were not determined by the prevalence of a concept but its perceived clinical and theoretical importance. Themes and the hierarchy of sub-themes within them were examined, adapted, and refined to ensure internal homogeneity and external heterogeneity. Where necessary, data were re-coded for consistency and comprehensiveness: typical of the organic process of qualitative analysis (Braun V and Clarke V 2006).

Theoretical insights were concurrently documented to create an audit trail and aid reflexivity (Bazeley P 2007).

2.3 Mixed methods synthesis of results

A mixed method is defined as “integrating quantitative and qualitative data collection and analysis in a single study” (Creswell JW 2013).

2.3.1 Rationale

Mixed methods were considered most appropriate for this study due to the complex nature of the data and the study’s aim (O'Cathain A 2013;O'Cathain A et al. 2007). Using a combination of quantitative and qualitative methods facilitated ‘sense making’ defined as “the active process of assigning meaning to ambiguous data”. This process enabled a more comprehensive analysis, by providing greater insight into the data than one method could have alone (Bourgeault I et al. 2010;Denzin NK and Lincoln YS 2011;Morse JM 2003). Combining the insights gained from the analyses increased the yield of findings to provide additional nuanced information, that would otherwise have overlooked (O'Cathain A 2013;O'Cathain A et al. 2007).

2.3.2 Design

Cresswell JW and Clark VLP 2007 highlight four aspects to consider when designing a mixed methods study: timing, priority, mixing, and theorising perspectives. The student decided to adopt a sequential explanatory strategy for this study (Creswell JW and Clark VLP 2007). There was no primary data collection in this study which is the main ‘timing’ consideration, but the data processing did guide qualitative sampling and subsequent analysis, a concept called facilitation (Sandelowski M 1993). The student conducted the quantitative and qualitative analyses sequentially not concurrently (Figure 3).

The priority (or weighting) was given to the quantitative data to provide insights into the more prevalent issues identified in the data, and the qualitative insights supplemented these findings. During the qualitative analyses the student aimed to highlight important, rare, context-specific issues that would be missed by the quantitative analysis alone, to provide an additional perspective on the data. The student compared and linked the findings of the thematic analysis to the quantitative findings.

The qualitative data supported and provided additional insights into the quantitative findings, the quantitative and qualitative data were therefore ‘embedded’, rather than ‘integrated’ where the quantitative and qualitative data

are merged, or 'connected', where data are mixed across phases of data collection and analysis (Creswell JW 2013;Creswell JW and Clark VLP 2007). There were no 'a priori' theories informing the design of this research, it was largely inductive in nature

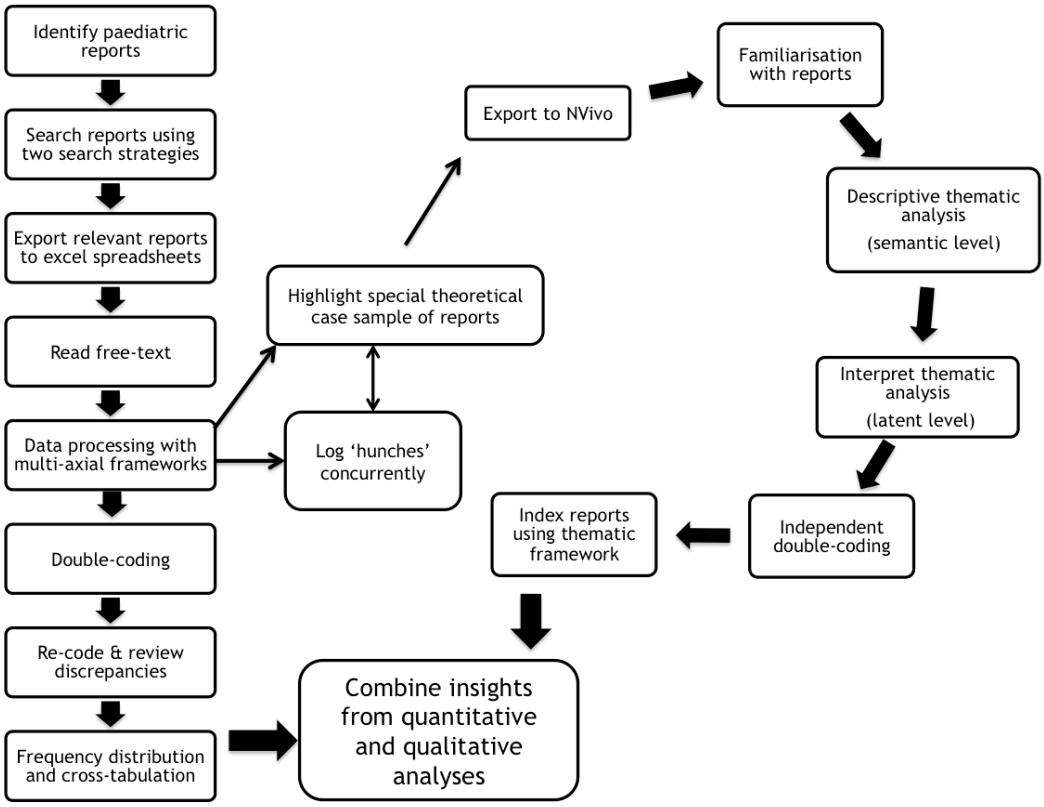


Figure 4 page 40: flow diagram illustrating the processes of mixed methods analysis

2.3.3 Strengthening the analysis

Key attributes of rigorous research include: validity/ credibility, reproducibility, and generalisability (Green J and Thorogood N 2009;Lacey A and Luff D 2001). Triangulating the findings of both quantitative and qualitative analyses increases the internal validity and credibility of results and subsequent confidence in findings (Glik DC et al. 1986). This is in keeping with the positivism and realism perspective: there is a single reality and corroborating and converging multiple

measures can facilitate a more accurate description and understanding of that reality (Bourgeault I et al. 2010).

The reliability of findings, in terms of the consistency and reproducibility of results, was ensured through independent thematic analysis of 100% of the qualitatively sampled reports in addition to double coding of a 20% random sample of reports using the classification frameworks. Kappa statistics were calculated to evaluate inter-rater reliability.

The student and her colleagues (involved in double-coding) undertook root cause analysis training prior to data processing. Weekly team meetings were held to discuss discrepancies between coding, iterations to the classifications, and complex reports. These meetings were recorded and all amendments and decisions were logged providing an audit trail.

Statistical generalisability was not possible with this data, largely as a result of data biases such as under-reporting, although conceptual generalisability, an aim of rigorous qualitative research, was sought (Bourgeault I et al. 2010).

2.4 Ethical Approval

Aneurin Bevan University Health board research risk review committee waived the need for ethical review given the anonymised nature of data (ABHB R and D Ref number: SA/410/13).

Chapter 3: Results

3.1 Vaccination-related incidents

This section presents the results of a mixed methods analysis of vaccination-related safety incident reports involving children in primary care. The student will:

3.1.1 provide an overview of the data included and processed, before presenting more in-depth findings from the exploratory quantitative analysis of included data.

3.1.2 present the key themes and sub-themes identified from thematic analysis of purposively sampled reports, and describe how those themes relate to each other.

3.1.3 combine the insights gained from the quantitative and qualitative analysis to inform a visual model illustrating the weaknesses in the process of routine childhood vaccination, and explain how the qualitative insights relate to the relevant quantitative findings.

3.1.1 Quantitative results

3.1.1.1 Overview of reported vaccination-related incidents in primary care

This section will describe the vaccination-related reports included after data processing (coding with the multi-axial frameworks). Of 2288 reports identified through free-text searches, 1735 reports were included and 553 excluded (see Figure 5). Excluded reports included: those describing non-vaccination related incidents (n=464), system issues which did not result in a patient safety incident (n=65), and those with insufficient free-text information (n=24). The search strategy was designed for maximum sensitivity due to the difficulty of searching these data, hence the low specificity, i.e. the high number of reports, excluded. Kappa statistics of inter-rater reliability were high ($k=0.77$; $p<0.001$).

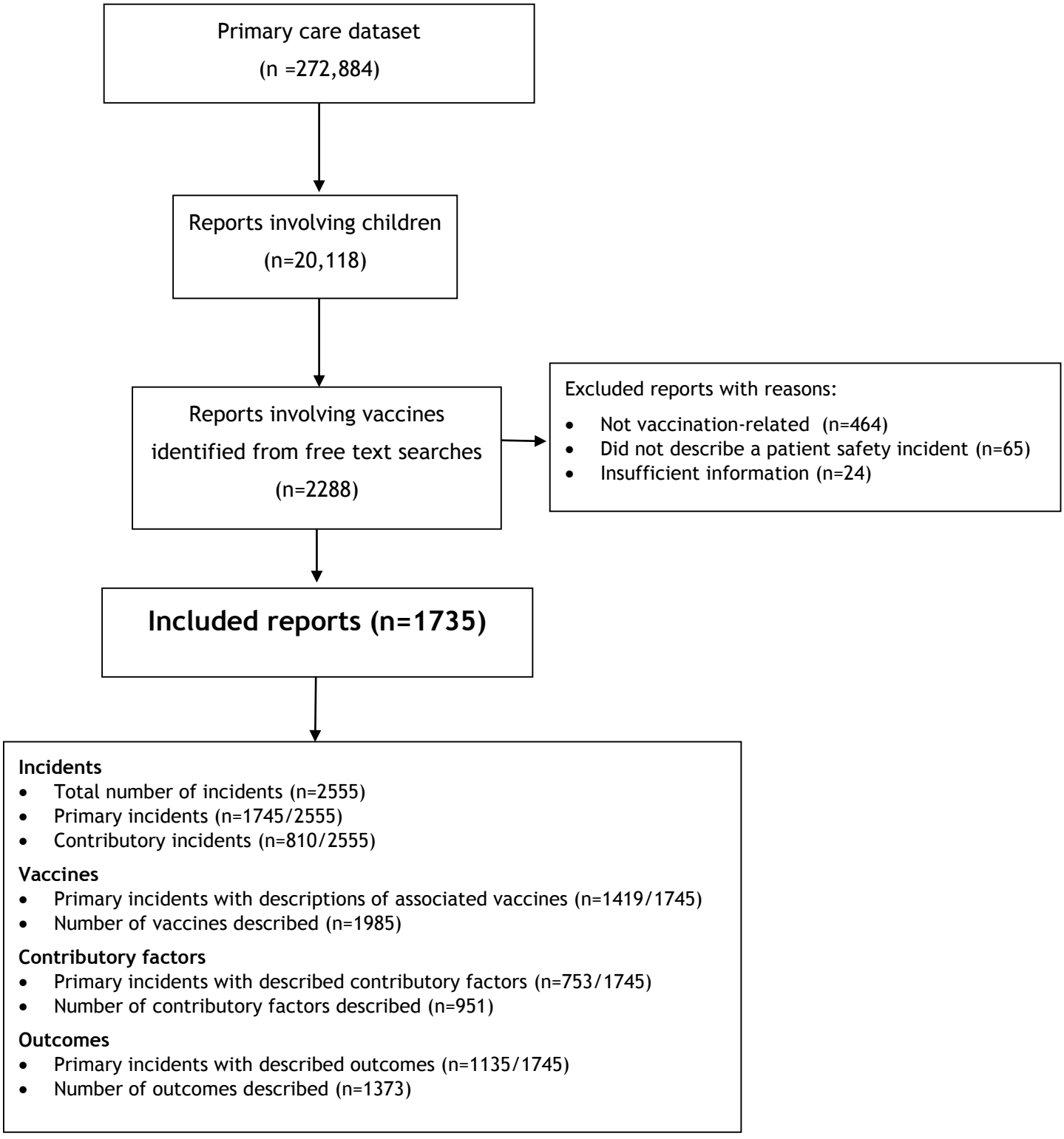


Figure 5 page 44: flow diagram providing an overview of how the included data were retrieved and its content

3.1.1.1.1 Reported ages in vaccination-related incident reports

Primary vaccination-related incidents were most frequently reported in those aged less than one year old, other than a spike of incidents in those aged five years old, the frequency gradually decreased as from those aged one to eight years old, followed by a small increase in incidents in the adolescent years (see Figure 6). This crudely reflects the frequency of vaccinations for each age group specified in the national vaccination schedule.

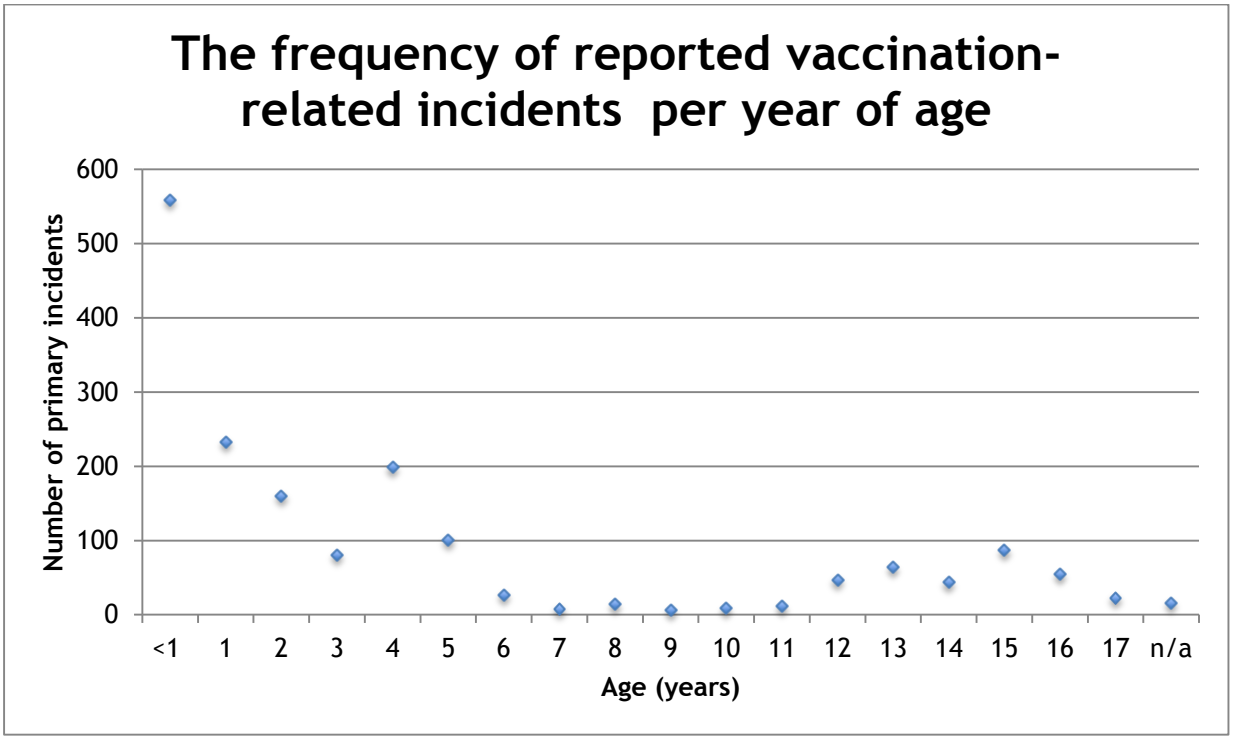


Figure 6 page 45: scatter chart demonstrating the ages of children involved in reported vaccination-related incidents

3.1.1.1.2 Temporal trends in reported vaccination-related safety incidents

The number of reported primary vaccine related incidents increased steeply between the years 2002-2007, they peaked in year 2007 at 279 reports then decreased steadily from 2007 to 2013 but remained above 100-reports a year (see Figure 7). These likely reflect reporting culture rather than the trends in the occurrence of vaccination-related incidents in practice.

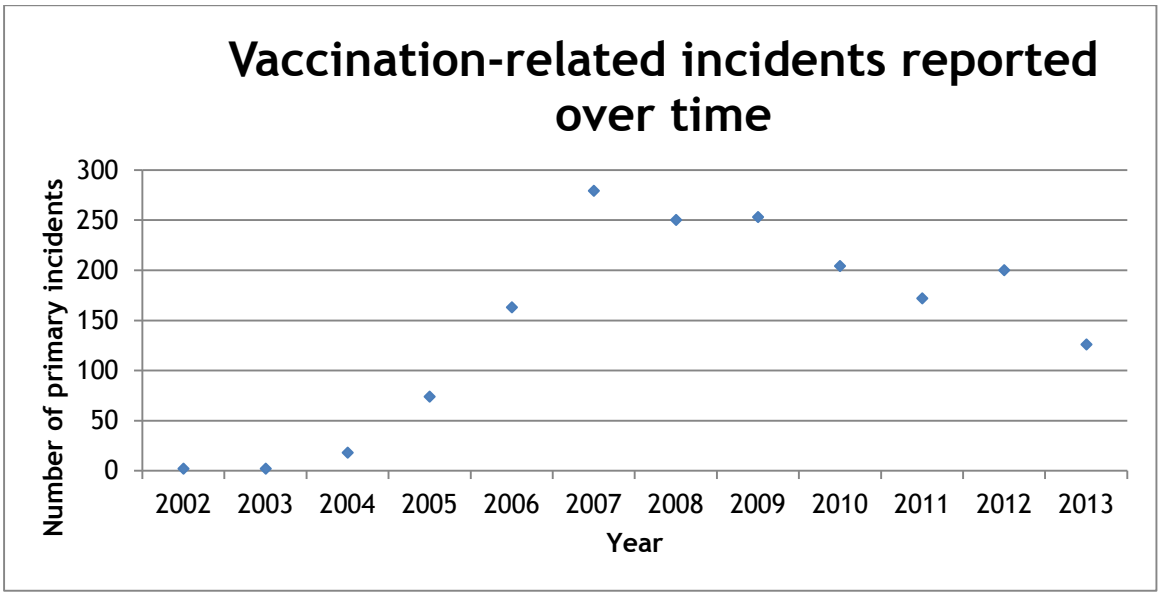


Figure 7 page 46: scatter chart demonstrating the frequency of primary vaccination-related incidents reported over time

3.1.1.1.3 Vaccines involved in reported safety incidents

The 1745 included primary incidents involved 21 types of vaccine and 1985 vaccines in total (see Table 7 and Figure 8). Most reports of primary incidents (n=1419; 81.3%) described the vaccines involved in the incidents, and some involved multiple vaccines, hence the involvement of 1985 vaccines (Table 7). The most frequently described vaccines were those included in the national immunisation schedule, in particular the MMR[10] (n=361), PCV[11] (n=307), DTaP/IPV/Hib[12] (n=241), Men C[13] (n=226), Hib/ Men C[14] (n=195), DTaP/IPV[15] (n=175), and HPV[16] (n=125) vaccines, account for 82.1% of all vaccines involved in primary incidents (Figure 8).

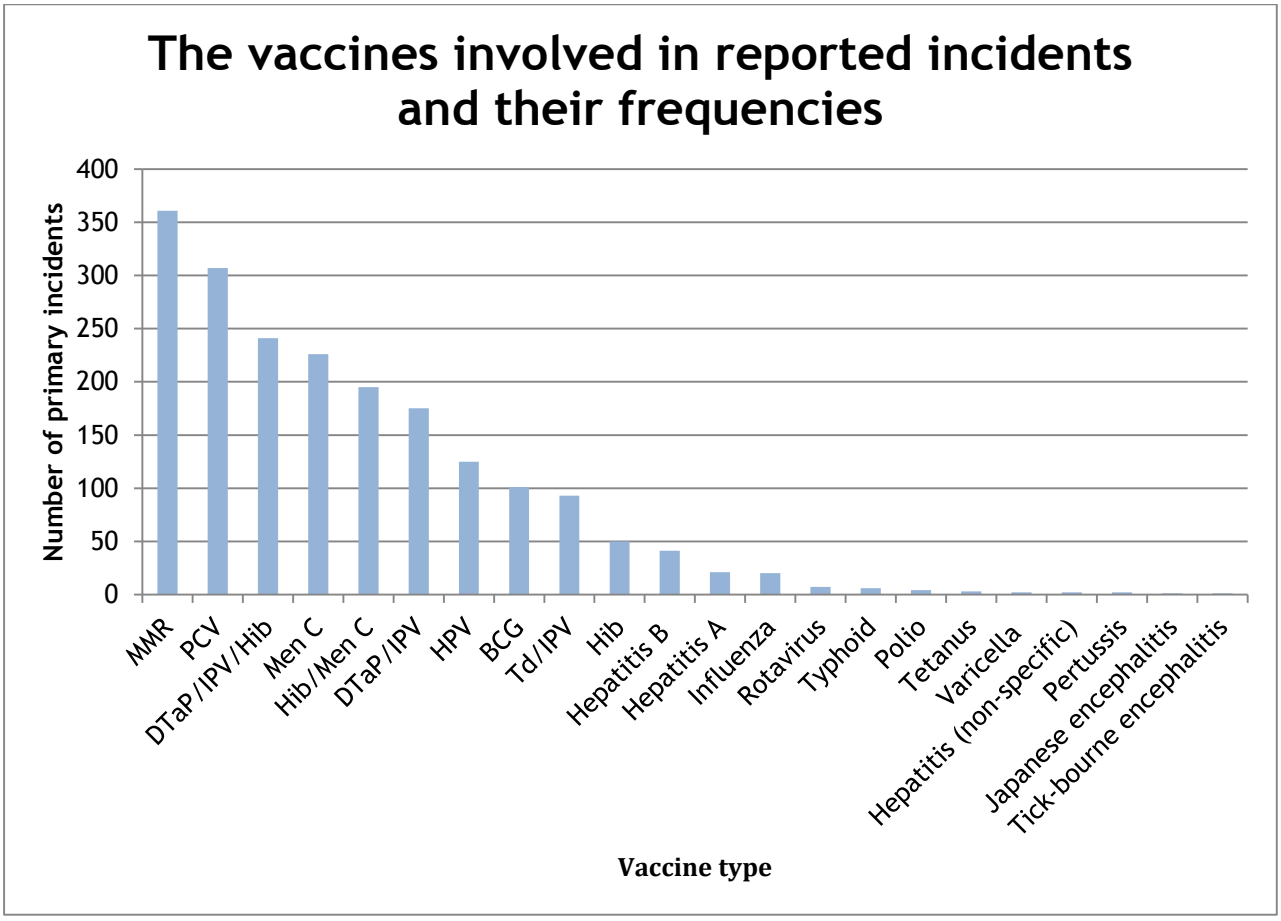


Figure 8 page 47: column chart demonstrating which vaccines were involved in reported primary incidents and their frequency

[10] Measles Mumps Rubella (MMR)
[11] Pneumococcal conjugate (PCV)
[12] Diphtheria Tetanus acellular Pertussis/Inactivated Polio/ Haemophilus influenza type B (DTaP/IPV/Hib)
[13] Meningitis C (Men C)
[14] Haemophilus influenza b/Meningitis C (Hib/Men C)
[15] Diphtheria Tetanus acellular Pertussis/Inactivated Polio (DTaP/IPV)
[16] Human Papilloma Virus (HPV)

Table 7 page 48: the vaccines involved in reported vaccination-related primary incidents

Vaccine	No harm	Low harm	Moderate harm	Death	N codes (%)
Measles Mumps Rubella (MMR)	86	269	6	0	361 (18.2)
Pneumococcal conjugate (PCV)	140	160	4	3	307 (15.5)
Diphtheria Tetanus acellular Pertussis/Inactivated Polio/ Haemophilus influenza type B (DTaP/IPV/Hib)	97	142	1	1	241 (12.1)
Meningitis C (Men C)	103	122	1	0	226 (11.4)
Haemophilus influenza b/Meningitis C (Hib/Men C)	70	123	2	0	195 (9.8)
Diphtheria Tetanus acellular Pertussis/Inactivated Polio (DTaP/IPV)	29	145	1	0	175 (8.8)
Human Papilloma Virus (HPV)	52	59	14	0	125 (6.3)
Bacillus Calmette–Guérin (BCG)	42	52	7	0	101 (5.1)
Tetanus Diphtheria and inactivated Polio (Td/IPV)	15	65	13	0	93 (4.7)
Haemophilus influenza b (Hib)	13	37	0	0	50 (2.5)
Hepatitis B	24	10	7	0	41 (2.1)
Hepatitis A	10	11	0	0	21 (1.1)
Influenza	11	8	1	0	20 (1.0)
Other	6	9	1	0	16 (0.8)
Rotavirus	5	2	0	0	7 (0.4)
Typhoid	2	4	0	0	6 (0.3)
Total	699	1218	57	4	1985 (100)

3.1.1.1.4 Vaccination-related incidents

The 1745 primary incidents were described within 1735 reports since ten reports described more than one independent safety incident. Included reports therefore described 1745 primary incidents, and 2555 incidents in total (when including the 810 contributory incidents) (Figure 5, see Appendix 3.1 for the frequencies of each combination of incidents). Most incidents involved vaccine administration (n=1368). Within this group frequent incidents included administration of the wrong number of doses (n=476), administration of the wrong vaccine (n=318), and administration of vaccines at the wrong time (n=295). Incidents involving vaccine documentation were also frequently described (n=461), in addition to office administration issues (n=216; see Table 8).

Table 8 page 50: the frequency of all incidents (primary and contributory)

Vaccination-related incident	N codes
Vaccination	
Vaccine administration	
Wrong number of doses	476
Wrong vaccine	318
Wrong timing	295
Not administered	83
Wrong dose	57
Out of date	49
Wrong patient	30
Non-specific	23
Contraindicated	21
Wrong site	6
Used needle	5
Wrong storage	4
Wrong route	3
Adverse reaction	148
Reconstitution error	59
Vaccine prescribing and dispensing	33
Insufficient vaccine supply	13
Batch recall	4
Non-specific	1
Documentation	
Records not up to date	261
Record availability	123
Records inaccurate/ unclear	74
Other documentation	2
Administration	
Appointment management	137
Transfer of information	67
Other administration	11
Communication	146
Procedural skills error	88
Referral for vaccination	5
Environmental hazard	5
Medication error	2
Professionalism	2
Treatment decision	1
Lab investigation error	1
Transport errors	1
Insufficient assessment	1
Total	2555

3.1.1.1.5 Factors contributing to vaccination-related incidents

Of the 1745 primary incidents, 753 (43.2%) described 951 contributory factors (see Appendix 3.2 for the frequency of each combination of contributory factors). Staff factors were most frequently described (n=453), these included staff mistakes (n=240) and failure to follow protocols (n=186) (see Table 9). Patient and caregiver factors were also frequently described (n=246). These included their behaviour (n=74), their geographical characteristics (n=64), their knowledge (n=48), and health (n=37). Organisational factors, such as working conditions (n=52), and continuity of care (n=48), education and training (n=36), and organisational protocol failure (n=27), were implicated in 163 incidents. Finally, vaccine factors such as failure (n=36), packaging (n=25), storage (n=25), and design (n=3) contributed to 89 incidents.

Table 9 page 52: the frequency of contributory factors described for each primary incident (NB: *some reports described more than one type of mistake)

Contributory factors - *definition*	N (%)
Patient/ caregiver factors	
Patient/ caregiver behaviour – *the way in which patients or caregivers act or conduct themselves*	74 (7.8)
Non-adherence	60
Non-disclosure	12
Other	1
Violence	1
Patient/ caregiver geography – *the area where patients live*	64 (6.7)
New to area	62
Access difficulties	2
Patient health – *factors relating to the patient's physical and mental wellbeing*	37 (3.9)
Allergy	22
Non-specific	4
Disability	4
Immunocompromised	3
Abnormal coagulation	2
Pregnancy	2
Patient/ caregiver knowledge – *insufficient knowledge or inadequate application of knowledge*	48 (5)
Looked-after child – *children not in the care of their parents e.g. in foster care*	18 (1.9)
Patient/ caregiver language – *patient or caregiver unable to communicate in English*	5 (0.5)
Staff factors	
Mistake – *cognitive lapses*	*240 (25.2)
Non-specific mistake	139
Similar vaccine appearances	45
Distraction	22
Misreading	18
Inattention	10
Similar patient names	9
Failure to follow protocol - *not adhering to organisational guidelines*	186 (19.6)
Knowledge - *insufficient knowledge or inadequate application of knowledge*	19 (2)
Fatigue/ stress - *extreme tiredness, mental or emotional strain*	5 (0.5)
Other factors	3 (0.3)
Equipment/ vaccine factors	
Failure of equipment/ vaccine - *the equipment or vaccine is faulty*	36 (3.8)
Equipment/ vaccine packaging - *the packaging is impractical inadequate or faulty*	25 (2.6)
Equipment/ vaccine storage - *inadequate impractical storage*	25 (2.6)
Poor equipment/ vaccine design - *the design is impractical, inadequate or faulty*	3 (0.3)
Organisational factors	
Working Conditions - *factors relating to the work environment*	52 (5.5)
Continuity of care - *issues with the co-ordination of services*	48 (5)
Education and training - *insufficient education and training of staff*	36 (3.8)
Inadequate guidelines or protocols - *existing guidelines not fit for purpose*	27 (2.8)
Total	951 (100)

3.1.1.1.6 Severity of harm resulting from vaccination-related incidents

Most reports (n=1077; 61.7%) described harm of some sort including: three deaths, 67 incidents of moderate harm, and 1007 incidents of low harm (Figure 9). However the pre-allocated harm severity entered by reporters differs considerably to the harm severity using the WHO definitions (Table 10). Prior to classification using the WHO definitions, included primary incidents were mostly classified (by reporters) as not harmful (n=1390; 79.7%). Many (n=775) primary incidents were upgraded, 739 were upgraded from no harm to low harm, 35 from no harm to moderate harm, and 1 incident from moderate harm to death. Fewer were downgraded in terms of harm: 27 were downgraded to no harm and 21 to low harm. The differences are as a result of numerous primary incidents being up-graded and downgraded in terms of harm severity–based on the outcomes described by reports.

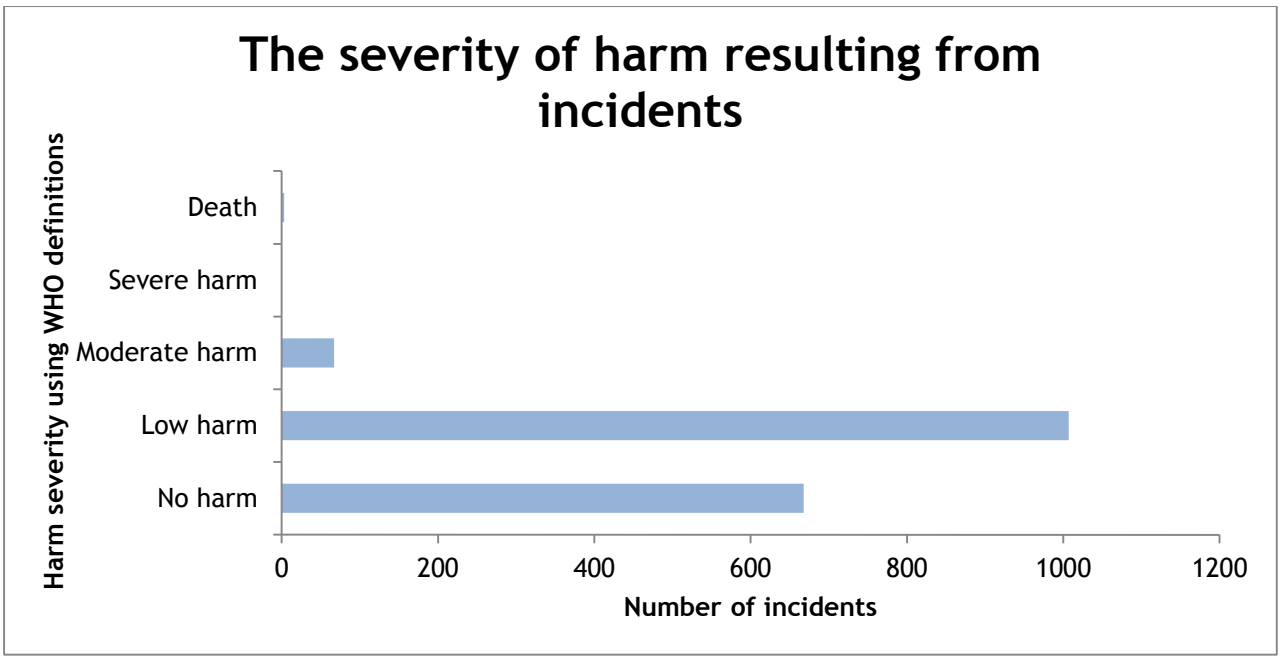


Figure 9 page 54: bar chart demonstrating the severity of harm resulting from incidents

Table 10 page 54: demonstrates how many primary incidents had their allocated harm severity upgraded (in blue) and downgraded (in green), and how many kept their pre-allocated harm severity (yellow) (*1 report of moderate harm was upgraded to death)

Re-coded harm severity using WHO definitions	Reporter-allocated severity in reports					
	No harm	Low harm	Moderate harm	Severe harm	Death	N codes
No harm	641	24	2	1	-	668
Low harm	739	247	21	-	-	1007
Moderate harm	10	25	32	-	-	67
Severe harm	-	-	-	-	-	0
Death	-	-	1*	-	2	3
N codes	1390	296	56	1	2	1745

3.1.1.1.7 Outcomes of vaccination-related incidents

Most primary incidents (n=1135; 65%) described outcomes and many described multiple outcomes; therefore 1373 outcomes are described for 1135 primary incidents. The most frequently described outcomes were patient inconvenience (n=801)[17] such as: receiving unnecessary treatment (n=481) and requiring additional treatment (n=379). Other outcomes described included clinical patient harm (n=205) such as injuries (n=72) and fainting (n=64), and exposing the patient to risk (n=139), for example by leaving them vulnerable to vaccine preventable diseases (n=108).

[17] Note some reports described multiple types of patient inconvenience

3.1.1.2 Primary Incident Types

This section will present a more in-depth analysis of the incident types that were harmful and described most frequently. The primary incident types described by reports mostly involved vaccine administration incidents (n=1282/1745; 73.5%), however adverse vaccine reactions (n=146), procedural issues (n=57), and communication incidents with patients and caregivers (n=51) were also evident. For the purposes of this study adverse drug reactions included any unintended, undesirable, or unexpected effects of prescribed medications or of medication errors (Joint Commission Resources 2005). The relationship between these incident types, time of report submission, harm severity, contributory factors and the vaccines involved are presented in Tables 11-14. Appendices 3.1 and 3.2 demonstrate the frequencies of combinations of incidents and contributory factors.

3.1.1.2.1 Vaccine administration

Vaccine administration primary incidents included administering the wrong number of doses (n=476), administering vaccines at the wrong time (n=294), and administering the wrong vaccine (n=249). These account for 79.5% of vaccine administration primary incidents and following the Pareto Principle (that 80% of the problem can be addressed by focusing on 20% of the issues – which was originally a principle of welfare economics) this section will focus on these three types of administration primary incidents (NHS Scotland 2015).

Table 11 page 57: the number primary incidents reported each year within each incident type

Primary incident types	Number of reports per incident type per year													N codes
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	N/A	
Vaccination														
Administering														
Wrong number of doses	1	2	1	23	42	100	60	75	51	38	53	29	1	476
Wrong timing	-	-	2	8	24	47	52	35	38	28	34	26	-	294
Wrong vaccine	-	-	12	15	28	45	34	29	26	21	19	19	1	249
Not administered	-	-	-	2	8	4	35	9	5	6	7	4	-	80
Wrong dose	-	-	-	6	7	7	4	8	9	6	7	3	-	57
Out of date	-	-	-	2	3	7	6	12	8	5	4	2	-	49
Non-specific	-	1	-	-	6	7	3	-	1	1	4	-	-	23
Contraindicated vaccine	-	-	-	-	2	1	3	5	-	-	8	1	-	20
Wrong patient	-	-	2	3	1	-	-	1	2	3	3	1	-	16
Wrong site	-	-	-	-	-	-	1	-	4	-	1	-	-	6
Used needle	-	-	-	-	-	-	-	2	-	1	1	1		5
Wrong storage	-	-	-	-	-	1	2	1	-	-	-	-	-	4
Wrong route	-	-	-	-	-	-	-	1	-	-	1	1	-	3
Adverse reaction	-	-	1	2	10	12	8	26	31	19	29	8	-	146
Vaccine prescribing and dispensing	-	-	-	-	2	11	3	2	1	4	1	2	-	26
Reconstitution error	-	-	-	-	-	-	3	-	-	1	-	-	-	4
Batch recall	-	-	-	-	-	-	-	4	-	-	-	-	-	4
Insufficient supply	-	-	-	-	-	-	1	-	-	-	-	-	-	1
Non-specific	-	-	-	-	-	1	-	-	-	-	-	-	-	1
Documentation														
Records not up to date	-	-	-	2	3	12	7	4	8	20	5	5	-	66
Records inaccurate/ unclear	-	-	-	1	4	4	3	4	3	4	5	3	-	31
Records unavailable	-	-	-	-	-	-	2	-	2	-	-	2	-	6
Procedural error	-	-	-	4	9	6	10	11	5	5	4	3	-	57
Administration														
Appointment management	-	-	-	-	4	2	5	9	5	1	6	7	-	39
Transfer of information	-	-	-	-	2	2	1	4	2	-	-	4	-	15
Other	-	-	-	-	-	1	-	-	-	-	-	1	-	2
Communication														
With patients/ caregivers	-	-	-	6	7	8	7	8	-	6	5	4	-	51
Between healthcare professionals	-	-	-	-	-	-	-	1	-	1	-	-	-	2
Environmental hazard	-	-	-	-	1	-	-	2	1	1	-	-	-	5
Referral for vaccination	-	-	-	-	-	-	-	-	1	-	2	-	-	3
Professionalism	-	-	-	-	-	-	-	-	1	-	1	-	-	2
Medication error	-	-	-	-	-	-	-	-	-	1	-	-	-	1
Transport	-	-	-	-	-	1	-	-	-	-	-	-	-	1
N primary incidents	1	3	18	74	163	279	250	253	204	172	200	126	2	1745

Table 12 page 58: the frequency and severity of harm described for each age group and for each primary incident type

	Severity of harm				
Age	No harm	Low harm	Moderate harm	Death	N codes
Under 28 days	15	7	3	-	25
1 month to 1 year	307	246	13	3	569
2 to 4 years	206	433	9	-	648
5 to 11 years	41	133	5	-	179
12 to 17 years	99	188	37	-	324
Incident Type					
Vaccination					
Administering	438	824	17	3	1282 (73.5)
Wrong number of doses	28	447	1	-	476
Wrong timing	239	44	8	3	294
Wrong vaccine	97	150	2	-	249
Not administered	14	65	1	-	80
Wrong dose	26	31	-	-	57
Expired vaccine	3	46	-	-	49
Non-specific	10	13	-	-	23
Contraindicated vaccine	14	5	1	-	20
Wrong patient	2	14	-	-	16
Wrong site	1	2	3	-	6
Used needle	3	2	-	-	5
Wrong storage	-	4	-	-	4
Wrong route	1	1	1	-	3
Adverse reaction	-	103	43	-	146 (8.4)
Prescribing and dispensing	26	-	-	-	26 (1.5)
Reconstitution error	-	4	-	-	4 (0.2)
Batch recall	4	-	-	-	4 (0.2)
Insufficient supply	1	-	-	-	1 (0.1)
Non-specific	1	-	-	-	1 (0.1)
Documentation	97	5	1	-	103 (5.9)
Records not up to date	62	3	1	-	66
Records inaccurate/unclear	29	2	-	-	31
Record availability	6	-	-	-	6
Administration	50	4	2	-	56 (3.2)
Appointment management	36	3	-	-	39
Transfer of information	12	1	2	-	15
Other	2	-	-	-	2
Procedural errors	4	53	-	-	57 (3.3)
Communication	44	9	-	-	53 (3)
With patients or caregivers	42	9	-	-	51
Between HCPs	2	-	-	-	2
Other	3	5	4	-	12 (0.7)
N codes	668	1007	67	3	1745

Table 13 page 59: the frequency of contributory factors described for the key primary incident types

Contributory factors	Primary incident type					
	Wrong number of doses	Wrong vaccine	Wrong timing	Adverse reaction	Procedural error	Communication with patients and caregivers
Patient/ caregiver factors						
Patient/ caregiver behaviour						
Non-adherence	1	-	1	2	39	-
Non-disclosure	5	-	1	2	-	-
Other	-	-	1	-	-	-
Patient/ caregiver geography						
New to area	36	1	13	-	-	-
Access difficulties	-	-	2	-	-	-
Patient health						
Allergy	-	-	-	18	-	-
Other health issues	-	-	1	2	-	-
Disability	-	-	1	-	-	-
Coagulation problems	-	-	-	1	-	-
Pregnancy	-	1	-	-	-	-
Patient/ caregiver knowledge	40	-	4	-	-	1
Looked-after child	8	1	3	-	-	1
Patient/caregiver language	1	-	4	-	-	-
Staff factors						
Mistake						
Non-specific mistake	47	35	19	-	-	4
Similar vaccine names	1	37	-	-	-	-
Misread	10	3	1	-	-	-
Distracted	2	8	2	-	-	1
Inattention	3	4	-	-	-	-
Similar patient names	4	-	-	-	-	-
Failure to follow protocol	63	37	35	1	-	4
Knowledge	3	6	3	-	1	-
Fatigue/stress	-	5	-	-	-	-
Other factors	1	-	1	-	-	-
Equipment/ vaccine factors						
Failure of equipment/ vaccine	-	1	2	-	10	-
Equipment/ vaccine storage	-	10	-	-	-	-
Equipment/ vaccine packaging	1	3	-	-	-	-
Organisational factors						
Working conditions	10	14	12	-	-	-
Continuity of care	15	-	22	-	-	-
Education and training	6	10	11	-	1	1
Inadequate protocol or guidelines	3	3	3	-	-	1
N codes	260	179	142	26	51	13

Table 14 page 60: the vaccines involved in the most frequently reported primary incident types

Type of administration incident	Vaccine type														
	MMR	PCV	DTaP/IPV/Hib	Men C	Hib/Men C	DTaP/IPV	HPV	BCG	Td/IPV	Hib	Hep B	Other	Hep A	Flu	N codes
Wrong number of doses	156	75	63	49	77	87	8	20	36	16	0	5	3	1	596
Wrong timing	48	91	83	37	29	7	16	14	2	2	21	6	1	0	357
Wrong vaccine	41	85	56	87	61	49	8	3	23	1	1	5	6	4	430
Not administered	12	2	5	13	4	3	1	6	1	28	1	0	1	0	77
Wrong dose	12	1	1	7	3	1	2	9	0	0	5	1	5	3	50
Expired vaccine	12	0	1	2	4	7	1	5	1	3	1	1	2	2	42
Contraindicated vaccine	2	1	0	1	0	2	0	5	1	0	0	2	0	2	16
Wrong patient	7	1	4	2	1	1	2	0	1	0	0	0	0	0	19
Other	2	5	2	3	4	1	2	5	0	0	2	3	0	2	31
Adverse reaction	19	14	9	5	2	9	52	4	20	-	-	2	-	-	136
Communication with patients or caregivers	25	4	1	-	-	1	10	2	1	-	-	1	-	1	46
Procedural error	8	3	2	3	3	3	3	3	1	-	-	-	-	1	30

3.1.1.2.2 Wrong number of doses administered

Children receiving the wrong number of doses were mostly aged less than 6 years old. These incidents were frequently reported in those aged 0-2 years (n=141), decreasing in those aged three to four years (n=23), and increasing again in those aged four to six years (n=131). (Figure 10)

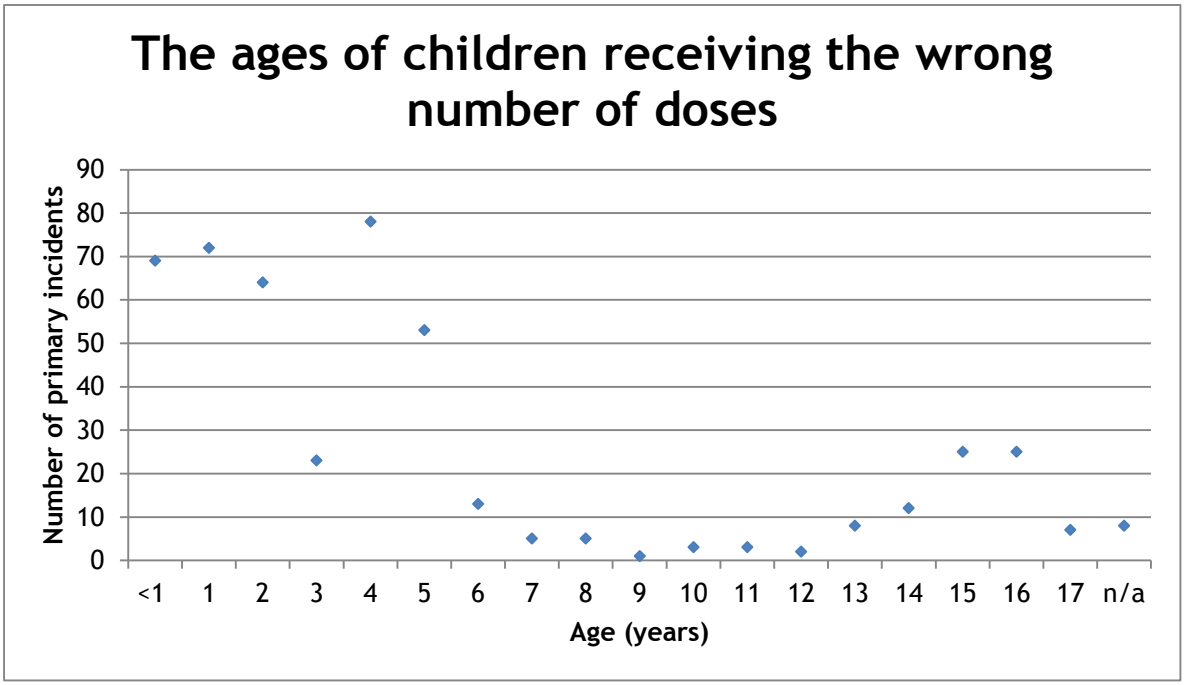


Figure 10 page 61: a scatter chart illustrating the ages of children receiving the wrong number of doses

Most incidents of administering the wrong number of doses were harmful (n=448; 94.1%); this was typically because the child had received an unnecessary additional vaccination and thus met the criteria for 'low harm' (Table 12). However, one of these incidents, where a child suffered an adverse reaction and required hospitalisation, resulted in moderate harm. The vaccines often involved in these incidents were MMR (n=156), DTaP/IPV (n=87), and Hib/Men C (n=77), which are given routinely and in multiple times as part of the childhood vaccination schedule (Table 14).

These incidents were often preceded by other contributory incidents (see Appendix 3.1 for the frequencies of each combination of incidents). Documentation failures such as out of date (n=128), unavailable (n=45,) or inaccurate documents (n=15) were frequently implicated. Three forms of vaccination documentation were described in reports: parental held records (red books), GP records, and child health records (in a public health

repository). Discrepancies between these records accounts for some of the various documentation failures described above i.e. not all three records were available, accurate, or checked prior to vaccine administration.

Multiple vaccine administration incidents were occasionally described in the same report (see Appendix 3.1 for the frequencies of incident combinations). For example, 50 children received the wrong number of vaccine doses, because the wrong vaccine had been administered (a contributory incident). Similarly 6 children received the wrong number of doses because they received someone else's vaccination i.e. the wrong child was vaccinated. Other contributory incidents included: communication errors (n=26), and issues with appointments (n=19).

Patient and caregiver factors frequently contributed to these incidents (Table 13, see Appendix 3.2 for the frequency of each combination of contributory factors). For example, patient and caregiver knowledge-such as not knowing which vaccines were needed or had been previously received-was implicated in 40 of these incidents. Other patient and caregiver factors included being new to the area and general practice (n=36), and eight incidents were partly the result of a child being 'looked after' (in Local Authority care). Staff factors contributing to incidents include: not following protocols (n=60) (intentionally or unintentionally) such as failing to check all the appropriate documentation prior to administration; and mistakes (n=67) such as misreading vaccine names (n=10). Fewer organisational issues were described, however poor continuity of care (n=15) and insufficient staffing (n=10) were described as contributing to some incidents.

Example reports of administration of the wrong number of vaccine doses

Example 1: "Patient presented with stepmother for pre - school booster. Written consent from father was brought but parental held record was not available. Nurse explained she was giving repevax [DTaP/IPV] and MMR. The following day stepmother called expressing concern that MMR had already been given in 2004. Incomplete documentation of initial dose of MMR."

Example 2: "Child placed with adoptive parents who were advised by Social Worker to attend the GP to complete primary vaccinations. Attended surgery with parental held records but no family practice records were available. Only two immunisations were recorded in the parental held record. Immunisation given with consent. Later informed by Social Services that child had already completed her primary immunisations. Family practice records checked and confirmed above."

Example 3: "Patient received the third primary immunisation twice, in error, once in Ghana and once at the health centre. Mother failed to notify the Health Visitor of the first immunisation."

3.1.1.2.3 Wrong timing

Most children receiving vaccines at the wrong time were aged less than 1 year old (n=175). The frequency of these incidents decreased steeply to 43 and 27 in those aged 1-2 years and 2-3 years respectively. The number of incidents then plateaued as the children increased in age (Figure 11). Administration of vaccines at the wrong time included incidents where vaccination had been delayed, and incidents where the vaccine has been administered contrary to the national recommended schedule for example, administering vaccines within two weeks of each other rather than the recommended four.

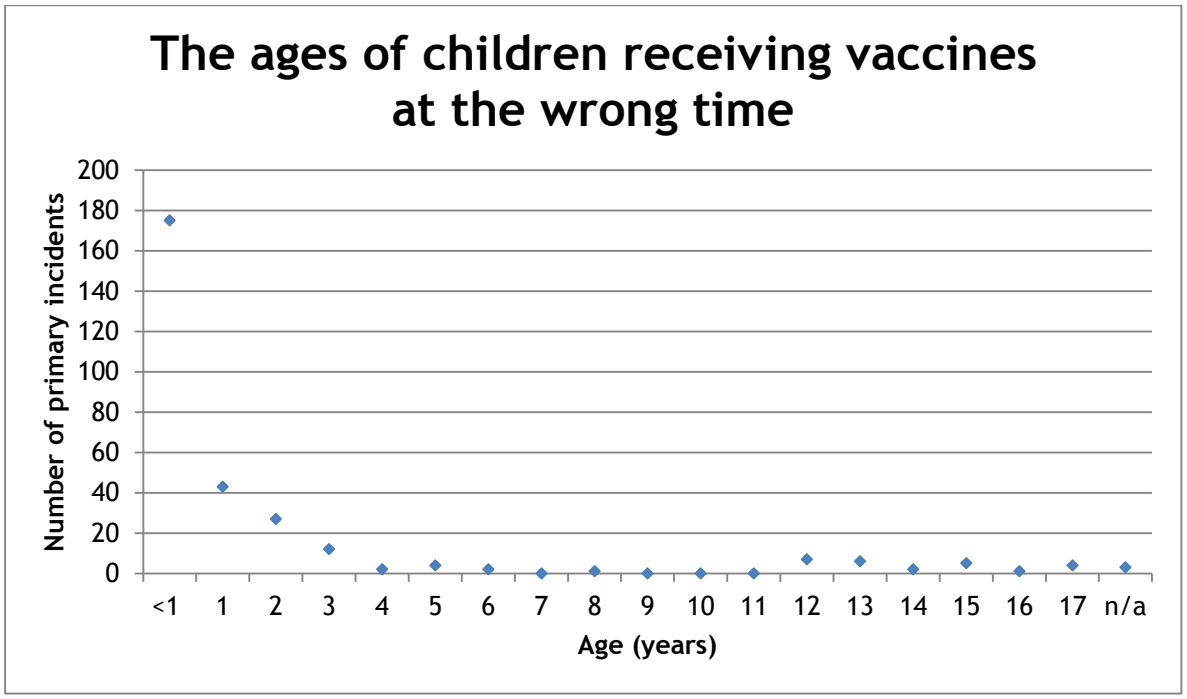


Figure 11 page 64: scatter chart illustrating the frequency of vaccine-timing incidents in each age group

Vaccines typically involved were Pneumococcal conjugate (PCV) (n=91, 31%), Diphtheria Tetanus acellular Pertussis/Inactivated Polio/ Haemophilus influenza type B (DTaP/IPV/Hib) (n=83, 28%), and the MMR (n=48, 16%) (Table 14).

The proportion of incidents resulting in harm was less for this group (wrong timing) than other vaccine administration incidents; however incidents in this group were more harmful in terms of severity (Table 12). Of 294 incidents, 55 (18.7%) were harmful: eight of these were cases of moderate harm, and three were deaths. The children suffering moderate

harm tended to be newborns who required prophylactic Hepatitis B or BCG[18] vaccination but in whom administration was delayed or not in line with current guidelines- therefore exposing these infants to unnecessary risk. The three children who died had pneumonia and meningitis, and were all delayed in receiving the appropriate vaccinations, which if received may have prevented infection. The 44 incidents of low harm typically described children who required additional vaccinations for adequate immunity.

Incidents contributing to these timing issues involved: appointment management difficulties (n=60), documentation failures (n=31), communication errors (n=21), transfer of documentation between care settings (n=16), and administering the wrong vaccine (n=12) (see Appendix 3.1 for the frequencies of each combination of incidents).
Poor continuity of care (n=22) –at organisational level- such as health visitors not receiving birth notifications from secondary care was described as contributing to these incidents (Table 13, see Appendix 3.2 for the frequency of each combination of contributory factors). These incidents tended to occur in patients who were new to the area, looked-after, who had (or whose caregivers had) poor knowledge. Staff deviating from protocols (n=32) and making mistakes (n=22) were also implicated.

[18] Bacillus Calmette–Guérin (BCG)

Examples of reports describing vaccination timing-related incidents

*Example 4: "An infant died from a streptococcal pneumonia - which could have been prevented if the child had received childhood immunisations. The mother stated she was not aware that her child should be immunised and the child was not registered at a family practice until *** Identified areas of concern include: - the management of the child immunisation processes, family practice registration processes and notifying child health of non-registered patients."*

Example 5: "Patient's relative contacted health visitors regarding her child's immunisations, she reported she had not received any appointments for her child's third primary immunisations. Child health computer had recorded wrongly that the child had his third immunisations on the same day as he had his second immunisations. The patient received his third primary immunisations late because of this. Child health would not have been aware of this if the parent had not contacted the service."

Example 6: "Patient was scheduled for Hib/MENC vaccine; staff checked his immunisation record and became aware that he already had this immunisation. At this point I made an error. I told the mother that we could give the MMR / Prevenar. Mother's English is not perfect and she agreed. As I came to record the immunisation, I realised my error there was a two-week gap between immunisations not 4."

3.1.1.2.4 Wrong vaccine administered

Children reported as receiving the wrong vaccine were largely aged less than one year old (See Figure 12). Many incidents (n=249) involved administration of the wrong vaccine, most of these were harmful (n=152; 61%) as children who received the wrong vaccine had often received an unnecessary treatment and then also required additional treatment (the vaccine that was originally required) (see Table 12).

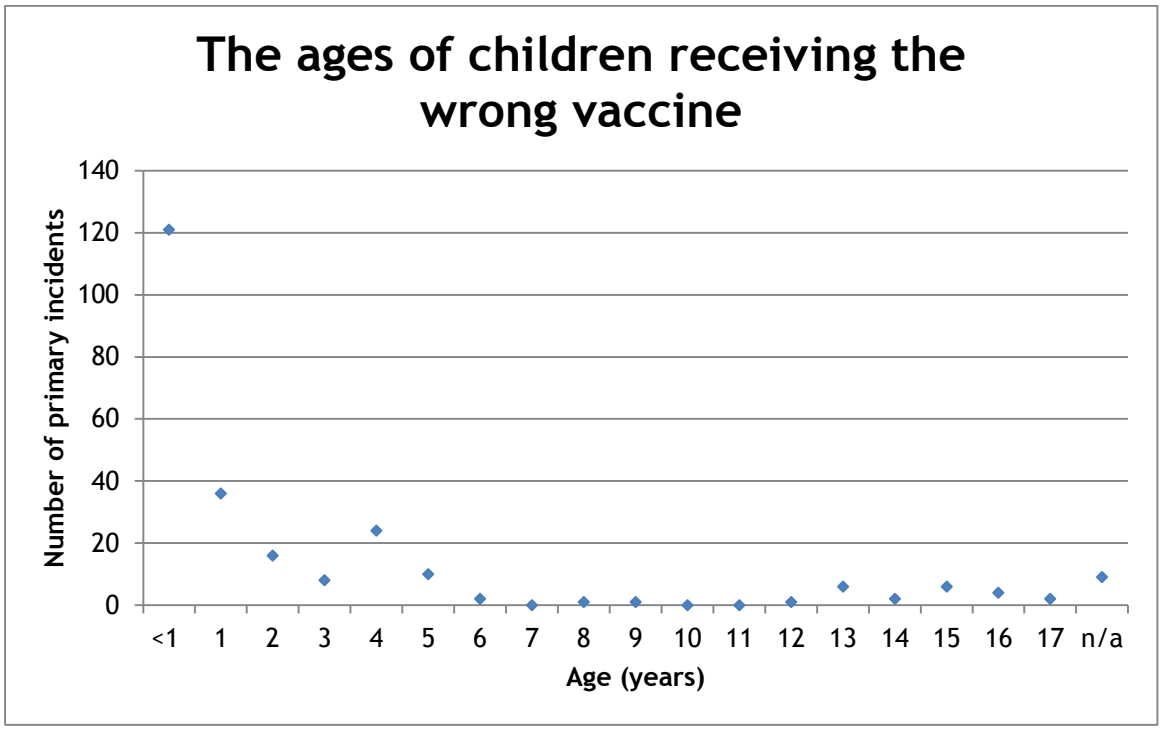


Figure 12 page 67: scatter chart demonstrating the frequency and ages of children receiving the 'wrong vaccine'

The vaccines most frequently involved in these incidents include: Men C (n=87), PCV (n=85), and Hib/ Men C (n=61) (Table 14). Often when a single Men C vaccine was scheduled e.g. at 3 months children wrongly received either PCV (n=40) (scheduled at 2 and 4 months), or a Hib/ Men C combination vaccine (n=31).

These incidents were not often preceded by other incidents such as documentation failures (n=18), and vaccinating the wrong patient (n=6) (see Appendix 3.1 for the frequencies of each combination of incidents). However incidents were often the result of staff failures such as: failing to follow protocols, and mistakes (n=87) such as confusing similar vaccines (n=37). Ambiguous packaging (n=13) was also described as contributing to

these mix-ups (Table 13, see Appendix 3.2 for the frequency of each combination of contributory factors).

Example reports of administration of the wrong vaccine

Example 7: "Mother took her five-month-old baby to her GP for his second DTaP/IPV/Hib vaccination. The Staff Nurse administered the wrong injection because she did not consult his medical records. The baby was given an MMR vaccination that should not be given until he is 13 months old. Staff Nurse says she was distracted during the appointment. The Nurse will re - train and demonstrate her competency through supervision."

Example 8: "The patient attended for booster immunisations. I proceeded to give the vaccination and documented the batch number. Later I realised that I had given the patient the wrong immunisations. I had confused the patient with another patients ' who was also due unscheduled immunisations."

3.1.1.2.5 Adverse reactions to vaccines

Adverse reactions were described as the primary incident by 146 reports: all of these were harmful including 103 cases of low harm and 43 cases of moderate harm (Table 12). Most of these were in adolescents (Figure 13). The children suffering moderate harm were sent to the emergency department with various symptoms: left sided weakness, altered consciousness, rash, vomiting, shortness of breath, slurred speech, dilated pupils, fevers, and seizures. Some needed adrenaline and some had head injuries as a result of losing consciousness. Most of the moderately harmful reactions (n=26/43) were the result of either HPV (n=13) or Td/IPV[19] (n=13) vaccines.

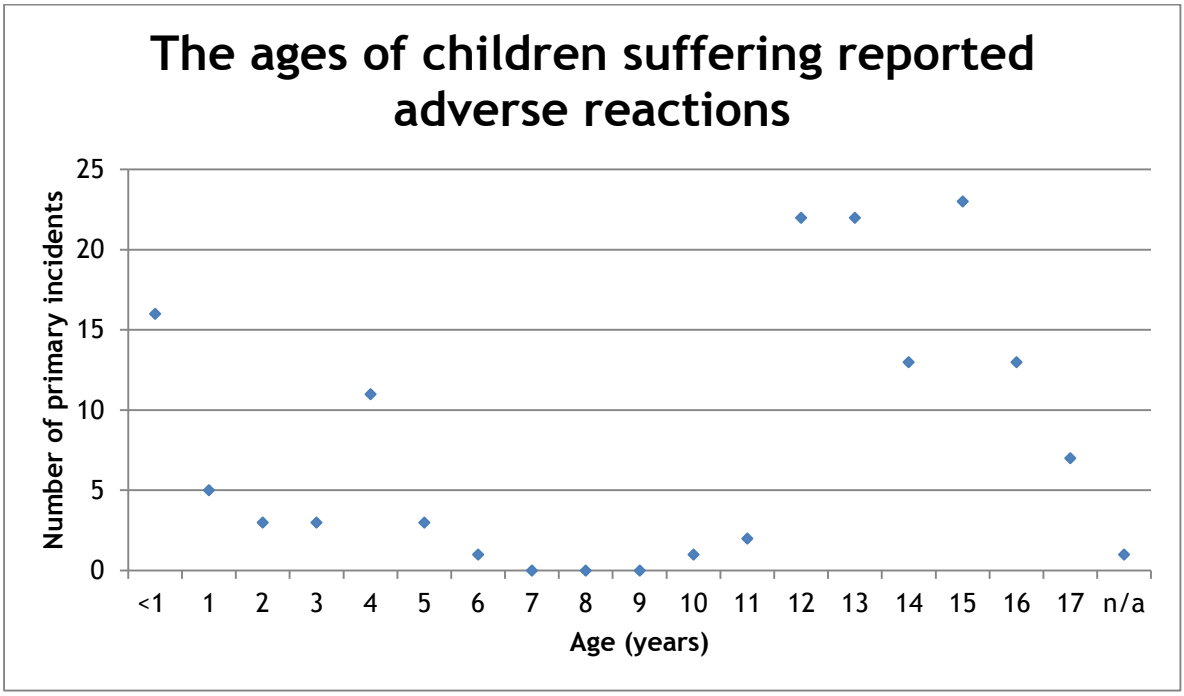


Figure 13 page 69: scatter chart illustrating the frequency and ages of children reported as suffering adverse reactions to vaccines

Most reports (n=117, 80%) described the vaccines involved in each incident, of which there were 136 (Table 3.8). Approximately a third of adverse reactions described were from HPV vaccination (n=50) in adolescents. Other frequently described vaccines included: Td/IPV (n=20), MMR (n=19), and PCV (n=14). Some children had pre-existing medical conditions that were not communicated to the health care professionals either by the child or the caregiver prior to vaccination (particularly in schools where caregivers typically provide this information on consent forms sent via their children).

[19] Tetanus Diphtheria and inactivated Polio (Td/IPV)

Communication incidents contributed to some (n=4) of these incidents (see Appendix 3.1 for the frequencies of each combination of incidents).

Patient allergy was the most frequently described contributory factor (n=18). This includes patients with known allergies and those in whom the allergy was unknown prior to the incident (Table 3.7, see Appendix 3.2 for the frequency of each combination of contributory factors). Other patient contributory factors included having medical conditions (n=3) that predispose to adverse vaccine reactions e.g. immune thrombocytopenia.

Example reports of adverse reactions

Example 9: "Administered hepatitis vaccine 1st dose at 11:15am. At 11:30 he complained of feeling extremely unwell, faint and nauseous. His blood pressure was 67 / 45. He began to shake uncontrollably complaining of feeling hot then very cold. He then complained of feeling tired and wanting to sleep and had a severe headache; he kept slipping in and out of consciousness but came to when I shouted his name. I asked school staff to call for an ambulance and to contact his parents. His mum arrived and informed me he had allergies to cow milk, tomatoes, citrus fruits, however had not put this information on the vaccine consent form, although these allergies were not contraindications. Mum also stated C recently attended A&E with similar symptoms. Taken to A&E by ambulance. Yellow Card completed."

Example 10: "Child received revaxis [Diphtheria Tetanus acellular pertussis and Inactivated Polio] immunisation at school. Has known nut allergy but never been allergy tested and has no Epi pen. 45 minutes later he returned with slurred speech, disorientated and feeling dizzy. He appeared very pale. Assisted to lay down with legs raised and began to complain of a strange tight feeling in his throat and his lips appeared to be blue in colour."

Example 11: "Telephone call received today by parent expressing concern that her daughter had reacted to her third HPV vaccination. Mum concerned that she felt that she had not received enough information prior to the injection. Mum reported her symptoms as - double vision with peripheral vision loss, nausea, fatigue and headache."

3.1.1.2.6 Vaccination-related procedural errors

There were 57 procedural errors e.g. scratching a child with the vaccine needle, and 50 of these were in children aged less than five years old. Most (n=53, 93%) of these were harmful as they resulted in injuries (n=42) or a child requiring an additional vaccination or treatment (n=11) (Table 3.6). No contributory incidents were described; however, most reports (50, 88%) described contributory factors, of which there were 51 (Table 3.7, see Appendix 3.2 for the frequency of each combination of contributory factors). Most incidents were the result of poor patient or caregiver adherence (n=39) e.g. not holding the child appropriately during the procedure (hence most of these incidents occurring in those aged less than five years old), some were the result of equipment issues (n=10), and one was the result of poor staff knowledge (n=1) and education (n=1).

Example reports of procedural errors

Example 12: "Patient attended for MMR father relaxed his hold of patient during administration of immunisations causing a scratch to his right arm and MMR to be expelled from syringe doctor contacted further dose of MMR given with parents' agreement."

Example 13: "Whilst giving MMR vaccination the child pulled the syringe out I administered the vaccination as per policy but the child had two puncture sites on his thigh parents witnessed incident and are aware."

Example 14: "Patient attended surgery together with mother for her PC vaccine mother was asked and also shown to hold patients arms and legs on giving the injection patient grabbed my right hand causing the needle to scratch her near the injection site scratch was cleaned and a plaster applied."

Example 15: "When attempting to give patient his meningitis C vaccine, his mother who was crying loosened her grab of him. The baby wriggled and unfortunately sustained a linear scratch about an inch long. Mum became even more upset. I reported the incident to the Health visitor who had a chat with mother and tried to calm her down. Mother eventually relaxed and agreed for me to proceed with vaccination baby."

3.1.1.2.7 Communication with patients/ caregivers about vaccination

Communication issues with caregivers and patients–such as failure to gain adequate consent for vaccination–were described as the primary incident type in 51 reports and 39 of these were related to consent. Most incidents involved children aged less than five years old (n=28, 55%) and were not harmful (n=42, 82%) (Table 3.6). Low harm was described by nine reports largely due to parental distress after their child received a vaccine they did not wish their child to receive.

Most reports described the vaccines involved (n=44, 86%), and almost half of these communication incidents were about the MMR vaccine (n=25) (Table 3.8). The HPV vaccine was also involved in some (n=10) communication incidents.

Example reports of communication incidents

Example 16: "Patient was brought by her mother for pre - school booster injections for pertussis, diphtheria, tetanus and polio. She was also given an injection for measles, mumps and rubella which was not on the appointment card and mother had not intended she should have. Immunisation was given by 2 practice nurses. Mother held child during procedure. The mother of the child had contacted the police when she realised what had happened, claiming her child had been assaulted as a result. At that time the police had taken advice from the CPS and as a result they would not be pursuing charges. Subsequent the member of staff has received a summons to appear before the local magistrate's court. It appears the mother is pursuing this matter privately."

Example 17: "During HPV vaccination sessions, clients consent form was signed by her mother indication that she did not want her vaccination. Her form had not been separated from positive consent forms. I then signed form indication client has refused."

3.1.2 Thematic analysis of vaccination-related reports

Three overarching themes were identified from reports: vulnerability to vaccination incidents; responsibility for childhood vaccinations; and fragmented or substandard services. These will be presented, along with their respective sub-themes, and their overlap, and illustrated in a visual model (Figure 14). The association between these themes and quantitative findings will be discussed further in the mixed methods section. To support the findings discussed in this section, edited extracts of free-text have been provided. These examples include the more extreme and the more typical cases to illustrate the breadth of each theme.

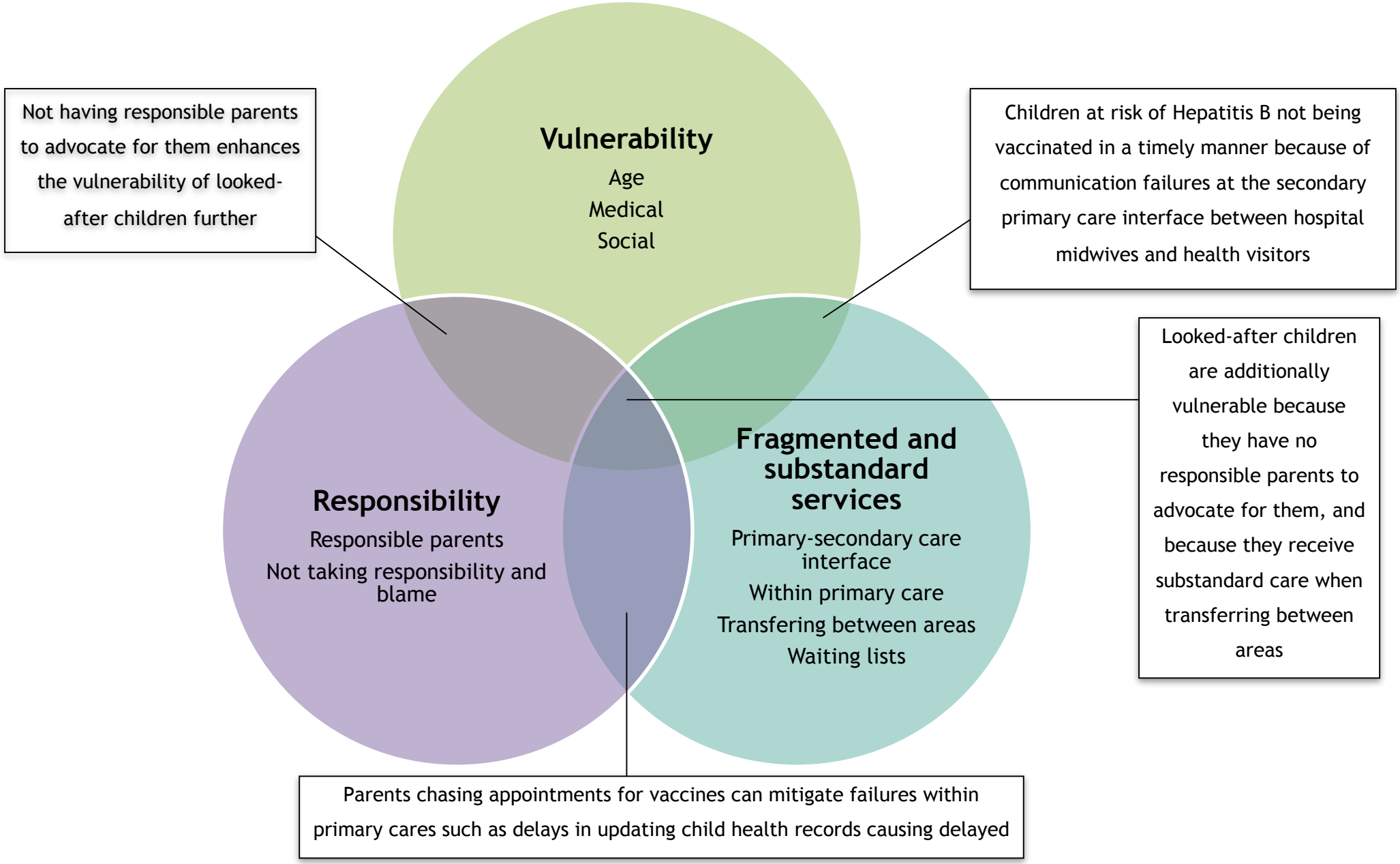


Figure 14 page 74: illustrating the themes identified, their respective sub-themes and how they overlap

3.1.2.1 Vulnerability

3.1.2.1.1 Age-related vulnerabilities

Age featured in various forms: children received adult vaccine doses, or vaccines contraindicated in their age group; additionally there were issues around consent and acknowledging Gillick competence i.e. the child's capacity to provide consent.

Examples

Example 18: "Patient reported that in her opinion her right to choose whether to be immunised had been ignored by a staff member (despite her parent consenting to the vaccine), and that she had been restrained physically by 1 staff whilst another staff approached from behind and administered without her consent."

Example 19: "Child patient was administered with Adult Hepatitis A vaccine (Havrix Monodose) instead of the paediatric dose (Havrix Junior Monodose)."

*Example 20: "During the morning I gave 50 vaccinations to adults at approximately 10:30 am - a child *** came for vaccination I had assumed that he was eligible for the older child dose of 0.5mls Pandemrix [Swine flu] - and I gave this. This was an error - since at 9 and under he should have had 0.25mls Pandemrix."*

Example 21: "4 year old attended with parents for seasonal flu vaccine. Prescription issued within GP surgery and collected from pharmacy. On reading patient information states that the vaccine (Enriza) is not to be administered to children under 5 due to increase in convulsions."

3.1.1.1.2 Medically vulnerable children

Medically vulnerable children were repeatedly described as experiencing vaccination-related incidents, including children who were pregnant, receiving immunosuppressant treatment for cancer, or at risk of Tuberculosis, HIV[20] or Hepatitis B.

Pregnant adolescents were receiving vaccines that are contraindicated in pregnancy because the young adult did not disclose the pregnancy, they are unaware of the pregnancy themselves, or the healthcare professional forgot that pregnancy was a possibility in this age group (an area of overlap with the age sub-theme). Such incidents did not feature frequently but are important to consider due to the high incidence of teenage pregnancies and the potential for harm to occur to mother and baby.

Examples

Example 22; "Pupil was vaccinated twice when pregnant. Asked at both sessions if possibility of pregnancy and not declared at the time of vaccination. Pupil did not know she was pregnant."

Example 23: "Patient was booked in for a whooping cough vaccine, patient attended appointment with practice nurse, practice nurse administered a HPV vaccine in error, and patient was 28 weeks pregnant. . Patient wished to make a formal complaint, full investigation in progress."

The potential harm to immunosuppressed children receiving contraindicated vaccines is also significant. These incidents were partially a reflection of the inadequate knowledge of healthcare professionals and failures at the specialist secondary- primary care interface (this will be discussed further within the fragmented and substandard services section 3.1.2.3). Caregivers (with first-hand knowledge of their child's medical history were described both as trying to prevent these incidents (raising concerns) and contributing to them by disclosing incorrect information to healthcare professionals (this responsibility theme will be discussed further in the next section).

[20] Human Immunodeficiency Virus (HIV)

Example

Example 24: "Baby received routine immunisations in baby clinic when consultant baby is under had written to surgery requesting baby not receive immunisations until he is one year post chemotherapy. Mother believed baby should have immunisations and he had received two flu vaccines between two sessions of chemotherapy. GP had seen letter from consultant and had put a note on baby record. Note on baby records was not dated and was believed to be automatic warning."

Children who were at risk of Tuberculosis and Hepatitis and who therefore required vaccination were often involved in incidents. These vaccines are not routinely scheduled vaccinations, the need for them is typically identified antenatally, they are arranged by the hospital postnatally and this requirement is then communicated to community midwives or health visitors. Looked-after children requiring these vaccines appeared even more vulnerable to incidents; such children also feature in the subsequent sub-theme of social vulnerability. A subset of these children at-risk of Tuberculosis and Hepatitis B had HIV positive mothers; the BCG vaccine is contraindicated in these children until they have been confirmed as HIV negative - these additionally vulnerable new-borns were occasionally described as 'slipping through' the safety net and almost all receiving BCG vaccines. Poor care co-ordination between secondary care and health visiting, or midwifery and health visiting, were repeatedly described as the reason for these 'near-misses' (an area of overlap with the fragmented and substandard services section 3.1.2.3).

Examples

*Example 25: "A mother brought her baby to the BCG clinic at ****. During the consultation I was made aware by the mother that she was HIV positive. This is a contraindication to the baby receiving BCG vaccination until baby has been screened and given the all clear by the paediatricians. This was explained to the mother and reasons given. I gave apologies for the inconvenience and advised her that I would be looking into the reasons for her receiving the appointment. Health visitor did not adhere to agree process by not indicating on the form that the mother was HIV positive."*

Example 26: "At Lac Review on 14.4.11 was highlighted that child overdue 2nd Hep B vaccine no entry made in red book, discharge note did not indicate Hep B given at birth, no indication GP made aware of follow up. There appears to have been no contact with the GP surgery to indicate this would need following up at all."

Example 27: "Baby discharged with request to give a BCG vaccination. Appointment arranged and consent obtained from the mother using an interpreter. BCG given but when the records were updated it was noted that the ward had given the BCG prior to discharge."

Example 28: "Audit of outcome for baby born to Hepatitis B positive mother received in child health department 6 / 7. Midwife written on bottom 'sincere apologies for not completing paperwork at delivery'. Notification received so late after delivery, very real risk that child would not have received 2nd and 3rd dose."

3.1.1.1.3 Socially vulnerable children

A proportion of vulnerable children such as looked-after children, asylum seekers, and immigrants suffered vaccination-related incidents as a result of these vulnerabilities. The systems in place failed these vulnerable children who often had inaccurate or no medical records, had difficulty accessing care, and some had difficulty communicating with healthcare professionals in English. For example one looked-after child had no vaccine records because whilst in her mother's care the vaccines had been administered at a private health centre. Other looked-after children suffered incidents because their new carers did not have historical knowledge of the child i.e. past medical histories to accurately consent for immunisations or to inform healthcare professionals of the child's eligibility for vaccinations. Not having a caregiver safety net appeared to be an underlying factor in these incidents (this overarching theme of responsibility will be discussed further in the next section 3.1.2.2).

Examples

Example 29: "Baby in foster placement. Health visiting team not informed. No handover from social worker or previous health visitor. Foster carer attended clinic with baby asking for assessment of baby as not seen by health visitor since in her care. Lack of capacity in team to carry out a schedule of growing skills in a timely fashion. In this case the social worker had assumed that the foster carer would inform the HV attached to her GP that she had care of a young baby and would arranged for necessary health care e.g. routine immunisations. The social worker did not explicitly ask the foster carer to do so. She did not do so and was expecting the health visitor to contact her, when the HV did not know about the placement."

Example 30: "The nurse realised she had given a 2nd immunisation after only 18 days. Health Visitor felt bad about errors and not entering information on computer, she did follow procedure and did check the list but family had no red book for whatever reason (perhaps because they are asylum seekers)."

*Example 31: "Child placed with adoptive parents. Mum advised by Social Worker to attend surgery to complete primary vaccinations. Attended surgery on with child health record, no health records available or medical records. Only two Immunisations recorded in red book, immunisation given with consent. Informed by ***** Social Services that child had already completed her primary immunisations."*

3.1.2.2 Responsibility

3.1.2.2.1 Not taking responsibility/ blame

Some reports were written in a way that implied that parents, grandparents, healthcare professionals, or the children themselves were the cause of incidents. Blaming of caregivers was described in the context of them not arranging appointments in a timely manner, not holding the child appropriately during administration, forgetting to bring red books, or failing to disclose important medical information. Caregivers are typically responsible for providing school nurses with consent forms (which contain information about contraindications) via children; failing to alert school nurses to vaccine contraindications via these consent forms was described by some reports. Non-adherent children were occasionally described in a way that justified the incident. These reports reflect a culture of blame, and emphasise the importance of numerous people's roles in ensuring safe childhood vaccination and in turn the need for shared responsibility rather than blame.

Examples

Example 32: "Child given single antigen meningitis C vaccine instead of combined meningitis & Hib vaccine (Menitorix) child's records of immunisation on practice computer were confusing so nurse checked with a colleague which vaccine to give. Agreed to give menitorix but selected meningitec brand from fridge and gave this. Also grandmother who had brought child was quite anxious adding to the stress of the situation."

Example 33: "3 month old baby came for BCG immunisation - Mum assured me that BCG had not been given before, no record in child health record. Baby fulfilled criteria and BCG was given. Upon recording the immunisation on RIO it was recorded as having been given on 20th December 2011."

Example 34: "Patient is a 5 year old who has Down syndrome and is very lively. Her mother brought her to the surgery for her preschool immunisations. She did not have the red book with her, and was not appointed on the computer sheet. Due to the liveliness of the child, minimal discussion took place regarding injections and preschool booster and MMR was given. The mother was very upset when this was explained as she had not given consent for the MMR. I have informed the Dr."

Example 35: "Twins presented with their parents for immunisations, both were very distraught and it was suggested to the parents that one child had their immunisations at a time, but the children got even more distressed. The nurse went through the correct procedure and asked the relevant questions of the parents. The children were not listed on the hard copy of the schedule for pre - school boosters, but this was not uncommon, the nurse checked their medical records (the children were being very vocal and fraught at the time). The twins had received an additional immunisation."

3.1.2.2.2.Responsible caregivers

Several reports described caregivers advocating for their children e.g. challenging healthcare professionals decisions and actions, chasing appointments, and consequently preventing incidents from occurring, and mitigating harm to their child.

Examples

Example 36: "Mum called this office to inquire when she would receive an appointment for her baby's 3rd immunisations. She was concerned about the delay as she had been waiting since November 2009 and what consequences this would have on her child."

Example 37: "Visited patient awaiting BCG, as requested by consultant at Great Ormond Street Hospital. Parents of child have made repeated requests of a variety of professional in care of their child to find out why this has not yet been responded to."

Example 38: "Paternal Concern / Complaint raised with BCG health visitor when giving BCG at community clinic. Initially when child was born there was nobody on hospital shift to give BCG - parents were told that an appointment would be sent within a few weeks for the hospital BCG clinic. Father of child reported that his wife had phoned the hospital at least 40 - 50 times in the past 5 months trying to obtain an appointment. They did not keep a record of who they spoke to on any occasion and never heard anything back and no appointment followed. . Due to travelling to India in early September they contacted their health visitor who referred to community clinic - BCG given by community service within 2 weeks of referral."

3.1.2.3 Fragmented and substandard services

3.1.2.3.1 Services at the secondary-primary care interface

Several reports described underlying system level service failures. Issues at the secondary-primary care interface were repeatedly described such as health visitors not receiving birth notifications (without these alerting them to the child's presence, vaccinations would not be organised in a timely manner). Additionally widespread communication failures between hospitals or midwives and health visitors-particularly with regards to a child's need for BCG or Hepatitis B vaccinations- underpinned several incidents.

Example

Example 39: "Audit of outcome for baby born to Hepatitis B positive mother received in child health department 6 / 7. Midwife written on bottom 'sincere apologies for not completing paperwork at delivery'. Notification received so late after delivery, very real risk that child would not have received 2nd and 3rd dose."

3.1.2.3.2 Services within primary care

Incidents involving routine childhood vaccinations were occasionally the result of miscommunication between GP surgeries/ health visitors and the child health administrative department (the public health repository of childhood vaccination records). In adolescent children poor continuity of care was described between general practice and school.

Examples

Example 40: "Mother did not receive invitation for vaccination from child health department for routine immunisations. On investigation problem with consent form being processed. Baby now missed all primary vaccinations due to this incident."

Example 41: "Telephone call from parent concerned that his child had been admitted to hospital with suspected Meningitis and this possibly could be due to not receiving an appointment for immunisation due to delay in inputting results. The results of the first vaccinations have been entered onto the child health system in order to schedule the remaining vaccinations due. Additional bank staff has been approved to deal with the backlog of inputting. Existing staff have been offered overtime hours to assist with backlog. Work priorities have been discussed with the Child Health manager to ensure that inputting of vaccinations is dealt with as an urgent priority."

3.1.2.3.3 Services on transferring between areas

Children who had moved from one locality (GP surgery) to another were also described as suffering fragmented care (records not being transferred in a timely manner, healthcare professionals in the new location not being aware of a child's presence; or difficulty registering for primary care) and vaccination-related incidents occasionally resulted from this.

Examples

*Example 42: "The family informed me via an interpreter that they had moved from **** to ****on *****. On that date I contacted the health visitor in that area and requested that she visit the family at home to complete an inward transfer visit and complete the 6 week health visitor contact. Today **** I was informed by the admin staff that the *****health visitors had returned the notes to me and they would not be visiting this child because he was not registered with their local GP. The child has therefore not received any immunisations or an 8 week development check with the GP or health visitor."*

*Example 43: "GP failed to advise health visiting team of transfer into area from London in ****. Not on System One, therefore 2 children not being called for routine appointments. One child missed offer of 2.5 year development review, the other not called for 12 & 13 month immunisations and 1 year development review."*

Example 44: "Visited patient awaiting BCG, as requested by consultant at Great Ormond Street Hospital. Parents of child have made repeated requests of a variety of professional in care of their child to find out why this has not yet been responded to. Today I was advised by respiratory nurses that they are simply taking contact details for people requiring BCGs as there is no - one in post to provide this service. Informed previous post holder on long term sick and new recruit not yet in post."

3.1.2.3.4 Waiting lists

Substandard services were also described in the form of long and unacceptable waiting lists for newborns in need of BCG vaccine- leaving them at unnecessary risk of developing Tuberculosis.

Example

Example 45: "The baby was born to parents of mixed heritage and he will be travelling to Turkey at 4 weeks of age although eligible for BCG the baby was not referred until birth and there is a 6 week waiting list therefore he will not receive BCG before he travels."

3.1.3 Mixed methods synthesis of vaccination-related issues

This section will highlight how the themes and sub-themes identified relate to the quantitative findings, and present a visual model summarising the key weaknesses in the process of routine childhood vaccination delivery, created by combining insights from both analyses (Figure 15).

3.1.3.1 Vulnerability and associated incidents

Vulnerable children featured in a variety of incidents. The age of children made them vulnerable to certain types of incidents such as dosing errors for non-routine vaccines including: BCG, Hepatitis B, and travel vaccines. The excess doses in young children also had the potential to be larger than in older children e.g. 10 fold dosing errors were described in babies. Other incidents where the age of children made them vulnerable involved: administration of contraindicated vaccines such as flu vaccines in under 5s and HPV in pregnant teenagers; and receiving vaccines at the wrong time such those under 1 receiving the MMR - a live vaccine.

Incidents involving medically vulnerable children typically involved administration of contraindicated vaccines. However in those at risk of BCG and Hepatitis B, delays in vaccination were typical, in addition to dosing errors, administration of BCG at the wrong site or route (subcutaneously instead of intramuscularly) and administration of duplicate vaccines. These were largely because of poor co-ordination of care and documentation issues.

Socially vulnerable children appeared vulnerable to most vaccination-related incidents. They were vulnerable to documentation incidents (not having vaccine records or having inaccurate or out-dated records), communication failures, and poor access to primary care. Consequently they received the wrong number of doses, the wrong vaccines, and vaccines at the wrong time.

3.1.3.2 Responsibility and associated incidents

Responsible caregivers were largely described as advocating for their children when appointments had not been received i.e. vaccination was delayed, and when appointments had been sent or consent had been sought for the wrong vaccine. Not taking responsibility and blaming others was an overarching theme present in most incident types, particularly in procedural errors, communication incidents, administering the wrong vaccine, administering vaccines at the wrong time, and administering the wrong number of doses. For example, caregivers were blamed for documentation incidents i.e. 'red books' not being available, which contributed to most incident types, and not holding their child appropriately, which contributed to procedural errors. Children were also blamed for distracting health care professionals that resulted in administration of the wrong number of doses, administration of the wrong vaccine, and procedural errors.

3.1.3.3 Fragmented substandard services and associated incidents

Delayed vaccination (administration of vaccines at the wrong time) was frequently the result of: failures at the primary-secondary care interface, communication failures within primary care, failures when transferring between primary care localities, and long waiting lists. Some children received contraindicated vaccines e.g. BCG without being confirmed HIV negative as a result of failures at the primary-secondary care interface, and within primary care. Substandard services on transferring between areas typically resulted in documentation incidents, which then contributed to a variety of vaccination-related incidents.

3.1.3.4 Visual model of weakness in the vaccination process

A visual model has been created by synthesising insights from the quantitative and qualitative analysis, to display the weaknesses in the process of routine vaccination –it therefore does not apply to travel vaccines or vaccines exclusive to at-risk groups (Figure 15). Each step in the cycle represents a potential incident and example contributory factors are illustrated in yellow. At each step the child is dependent on a human or system to ensure no incidents occur. This dependency (and therefore responsibility for the child) is demonstrated at three levels: caregivers, frontline staff, and administrative system. The themes identified are over-arching and are pertinent to multiple steps in this cycle.

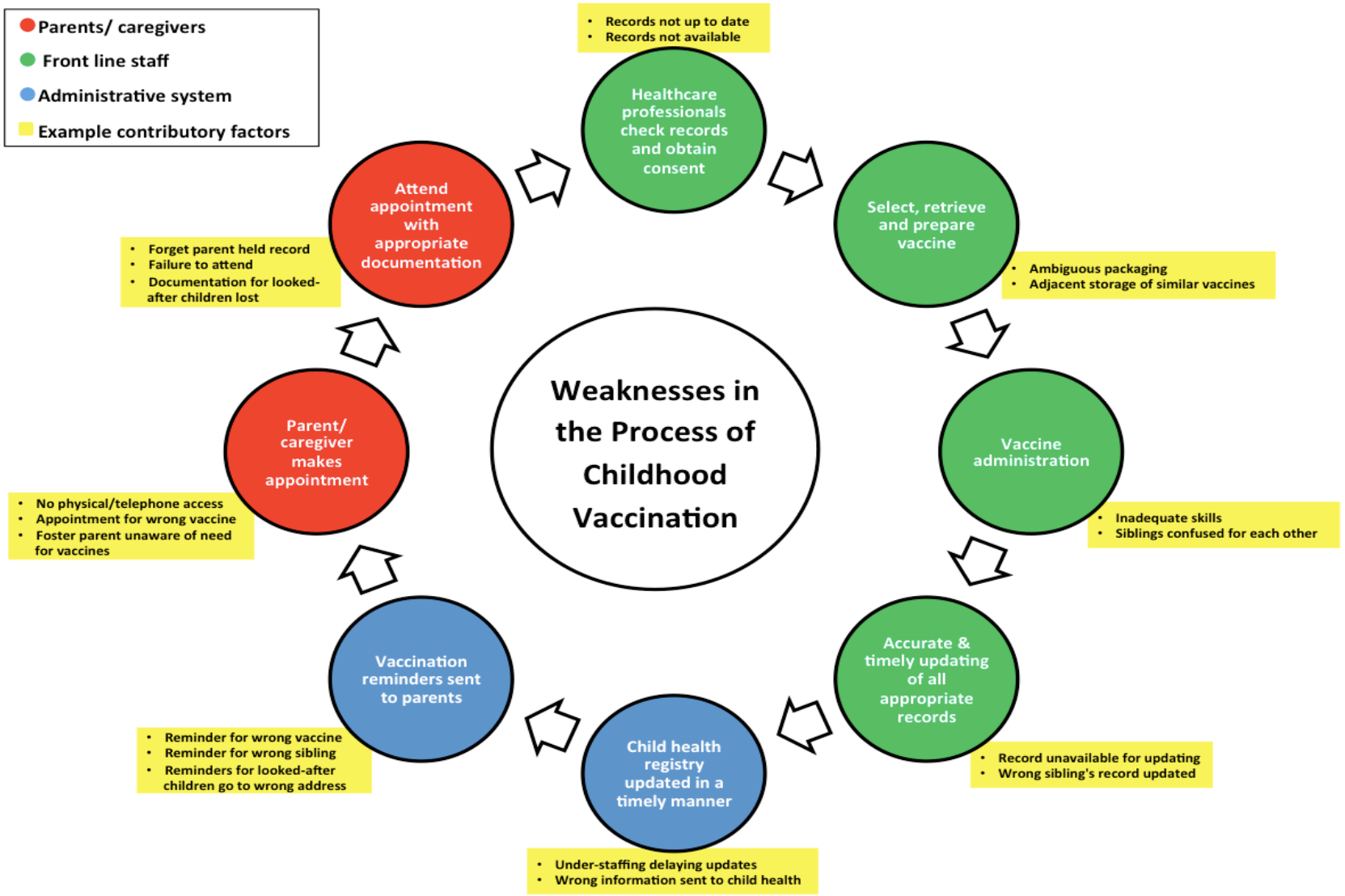


Figure 15 page 90: visual model where quantitative and qualitative insights have been combined to summarise the safety issues described by included reports

3.1.4 Summary

This analysis of vaccination-related incidents identified several priority areas requiring improvement: administration of the wrong number of doses, administration of vaccines contrary to the national vaccination schedule, and administering the wrong vaccine. To address these weaknesses, failures in documentation, and appointment management must be addressed. Factors frequently underlying these incidents were related to staff mistakes, failure to follow protocols, inadequate working conditions, and patient and caregiver factors such as behaviour, knowledge, and geography.

A key theme related to these incidents was the tendency for reporters to blame caregivers for certain failures which pre-disposed children to vaccination incidents. Also children who were medically or socially vulnerable appeared more susceptible to certain failures, which often culminated in a vaccination-related incident.

3.2 Incidents involving ‘unwell’ children

In this section the student will present the results of a mixed methods analysis of safety incident reports involving 'unwell' children in primary care. The student will:

3.2.1 provide an overview of the data included and processed, before presenting this study’s key quantitative findings in more-depth

3.2.2 present the key themes and sub-themes identified from thematic analysis of purposively sampled reports, and describe how these themes relate to each other

3.2.3 explain how the qualitative insights related to the quantitative findings

3.2.1 Overview of included reports involving 'unwell' children

Of 3636 reports identified from free-text searches, 2178 were included (see Figure 16). Excluded reports: described incidents which did not involve unwell children (n=436), described incidents which only involved vaccination or child protection issues (n=440); did not describe poor care quality (n=398); and contained insufficient information (n=184). Cohen's kappa statistic for inter-rater reliability was high ($k=0.72$; $p<0.01$).

Figure 16 page 94: flow diagram providing an overview of how the included data were retrieved and its content

3.2.1.1 The ages of ‘unwell’ children involved in reported incidents

Unwell infants and pre-school children (aged less than five years old) were most frequently involved in incidents (n=1103) (see Figure 17 and Table 15). Over 25% of incidents involved unwell infants (aged <one completed year), the number of incidents reported for each subsequent age group, decreased suddenly to 124 in those aged one to two years, peaked in those aged two to three years (n=182) and decreased and plateaued between 56-106 incidents in those aged 4-18 years. Those aged 12-17 years had the highest odds of harm (Table 15).

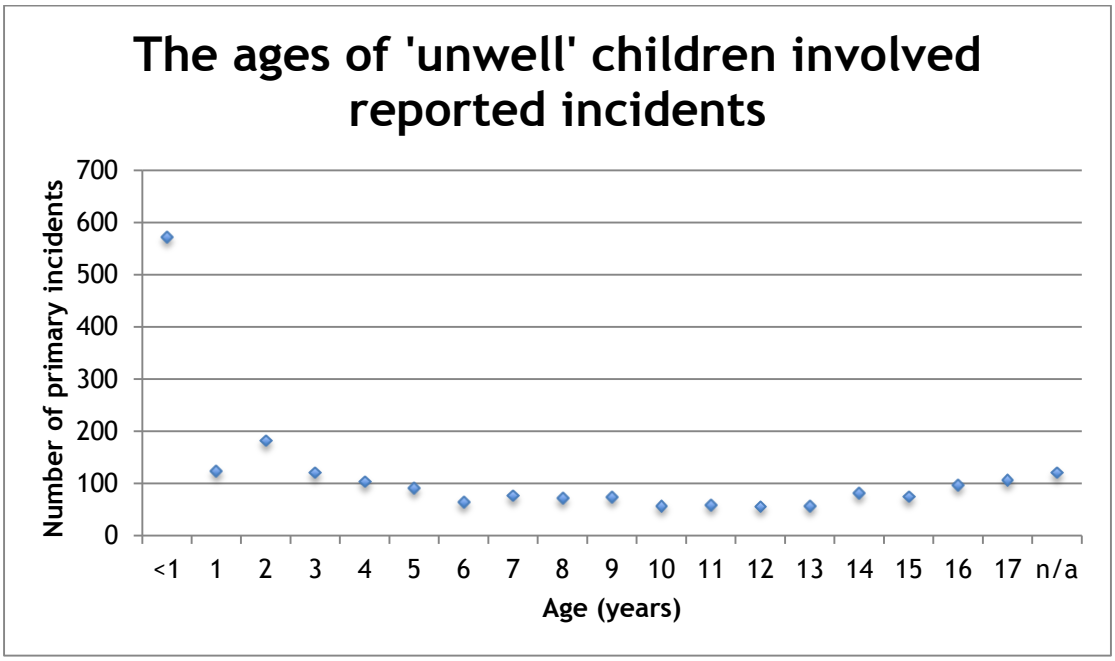


Figure 17 page 95: scatter chart illustrating the frequency and ages of ‘unwell’ children involved in reported incidents

Table 15 page 96: illustrates the severity of harm, the proportion of harmful incidents, and the odds of harm for each age group

Age range	Severity of harm					N primary incidents (% harmful)	Odds of harm
	No harm	Low harm	Moderate harm	Severe harm	Death		
Under 28 days	72	16	11	4	-	103 (30.1)	0.43
1 month to 1 year	360	77	43	8	3	491 (26.7)	0.36
2 to 4 years	397	85	48	8	4	542 (26.8)	0.37
5 to 11 years	378	109	48	8	3	546 (30.8)	0.44
12 to 17 years	326	100	68	13	2	509 (36)	0.56
N primary incidents	1533	387	218	41	12	2191 (30)	0.43

3.2.1.2 Temporal trends in reported incidents involving ‘unwell’ children

Included reports described incidents occuring between 2005–2013, the number of incidents reported increased from 49 incidents in 2005 to 438 incidents in 2011, this decreased to 299 incidents in 2013 (Figure 18).

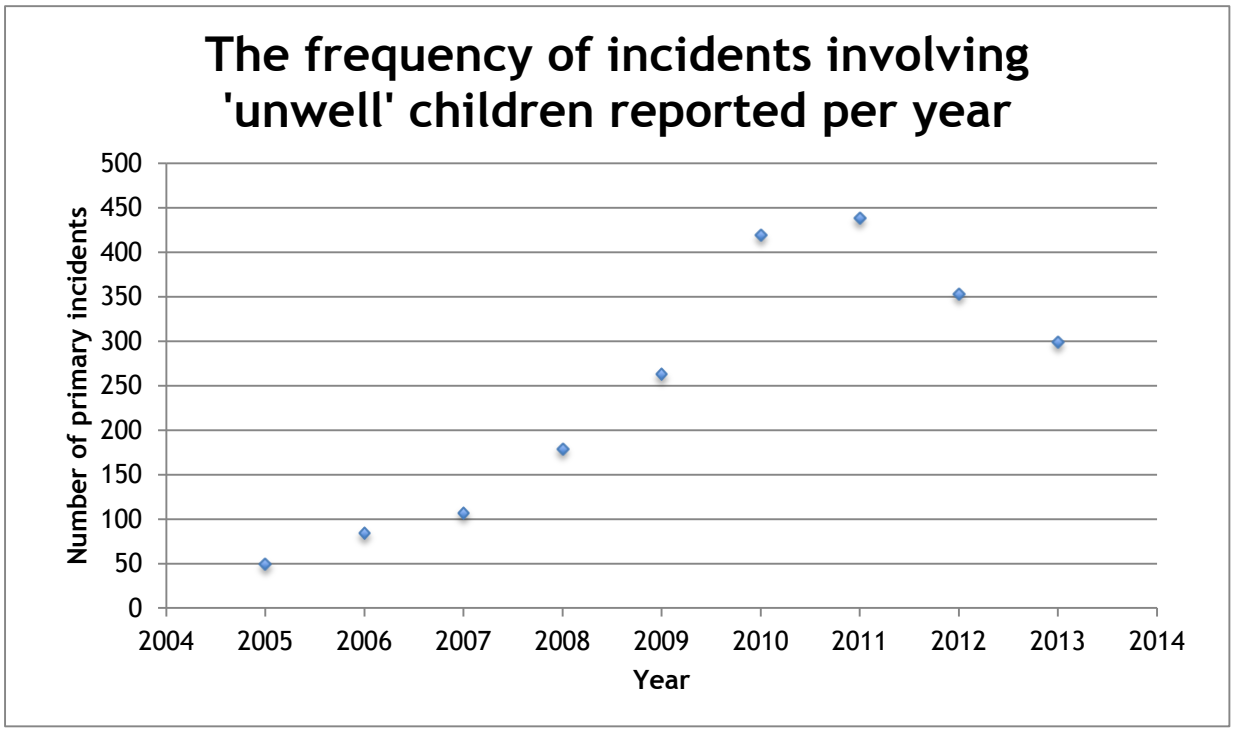


Figure 18 page 97: scatter chart illustrating the frequency of reported incidents involving ‘unwell’ children over time

3.2.1.3 Classification of diseases, signs or symptoms in 'unwell' children

To meet the criteria for inclusion, reports must have described an incident involving an 'unwell' child. 2032 primary incidents had associated diagnoses, signs or symptoms that enabled classification using the ICD-10, and 347 described multiple diagnoses, signs or symptoms. Of the 2032 primary incidents with associated conditions described, 1039 involved acute presentations (95 of which were in children with chronic conditions) and 699 incidents involved children with chronic conditions.

'Unwell' children experiencing safety incidents (n=1225) were frequently suffering from: respiratory disorders, non-specific signs and symptoms (such as fever), injuries, or digestive and genitourinary disorders (see Table 16). Children with digestive or genitourinary conditions, endocrine metabolic or nutrition conditions, and neurological or sensory conditions had the highest odds of harm from a reported safety incident (see Table 17).

Table 16 page 99: illustrates the conditions described in the 'unwell' children experiencing safety incidents (N.B.*some children had multiple similar conditions, signs,

Type of condition	N primary incidents
Respiratory system	387*
Cough, dyspnoea, tachypnoea, wheezing	127
Asthma	123
Respiratory infection	76
Other	69
Injuries	289*
Head injuries	123
Poisoning/ overdose accidental or of undetermined intent	42
Limb injuries	38
Burns and corrosion	28
Other	60
Non-specific signs and symptoms	281*
Fever	133
Altered consciousness, behaviour, emotions	77
Reduced food and fluid intake/ weight loss/ failure to thrive	44
Digestive and genitourinary system	268*
Disorders of oral cavity, salivary gland and jaw	74
Vomiting	69
Abdominal pain	32
Disorders of stomach, oesophagus, and duodenum	22
Genitourinary disorders	21
Other	69
Skin and musculoskeletal system	245*
Rash	79
Altered skin colour	76
Other	91
Neurological and sensory system	231*
Epilepsy	126
Ear and eye disorder	61
Cerebral palsy and paralytic syndromes	18
Other	34
Mental and behaviour disorders	221*
Non-specific mental health issue	65
Intentional self-harm	59
Behaviour and emotional disorders with onset in childhood and adolescence	34
Disorders of psychological development	29
Mood disorders	21
Other	20
Infections	201
Non-specific infection	116
Intestinal infectious disease	49
Viral infections characterised by skin and mucous membrane lesions	12
Other	24
Endocrine, metabolic, and nutrition disorders	116*
Diabetes mellitus	72
Metabolic disorders	24
Other	21
Pregnancy, chromosomal and 'other' congenital conditions	67*
Cancer and blood	52*
Other	51
Circulatory system	50*
Total	2459

Table 17 page 100: illustrates the association between harm severity and the types of conditions present in children experiencing incidents

(N.B. * some children had multiple types of a condition; [T] some children had multiple conditions)

Type of condition	No harm	Low harm	Moderate harm	Severe harm	Death	N primary incidents (% harmful)	Odds of harm	N codes
Respiratory system	307	40*	32	7*	1	387* (20.7)	0.26	395
Non-specific signs and symptoms	216*	31*	26*	4	4*	281* (23.1)	0.30	337
Injuries	217*	36	31	4	1	289* (24.9)	0.33	291
Digestive and genitourinary system	160*	68*	28*	9	3*	268* (40.3)	0.68	287
Skin and musculoskeletal system	180*	34	24*	6	1	245* (26.5)	0.36	259
Neurological and sensory system	152*	46*	28*	4	1*	231* (34.2)	0.52	239
Mental and behaviour disorders	150*	45	19*	7	-	221* (32.1)	0.47	228
Infections	139	46	12	2	2	201 (30.8)	0.45	201
Endocrine, metabolic, and nutrition	69	23*	19	4	1	116* (40.5)	0.68	117
Pregnancy, chromosomal, other congenital	42*	15*	9*	1	-	67* (37.3)	0.60	71
Cancer and blood	38	11*	1	2	-	52* (26.9)	0.37	53
Circulatory system	34*	3	11*	2	-	50* (32)	0.47	53
Other	34	10	7	-	-	51 (33.3)	0.50	51
Number of primary incidents	1738[T]	408[T]	247[T]	52[T]	14[T]	2459[T] (29.3)	0.41	2582

3.2.1.4 Incident types involving ‘unwell’ children

The 2178 reports described 2191 primary incidents (hence the 2191 incidents referred to hereforth), and 1401 contributory incidents, therefore 3592 incidents were described in total (see Figure 16 and Appendix 3.3 for the frequencies of each combination of incidents). The most frequently described incident types involving ‘unwell’ children were those related to diagnosis and assessment (n=885), medication provision (n=873) adminstrative issues (n=429), communication with and about the patient (n=384), and referral for escalation of care or specialist input (n=275) (see Table 18 for the frequencies of primary incident types).

Table 18 page 102: the severity and odds of harm associated with each primary incident type

Primary incident type	Severity of harm					Odds of harm	N primary incidents (% harmful)
	No harm	Low harm	Moderate harm	Severe harm	Death		
Medication	459	143	64	6	2	0.47	674 (31.9)
Dispensing	299	69	17	1	-	0.29	386 (22.5)
Administering	75	29	18	1	-	0.64	123 (39)
Prescribing	51	12	4	1	-	0.33	68 (25)
Clinical treatment decision	26	22	14	2	2	1.54	66 (60.6)
Other	8	11	11	1	-	2.88	31 9(74.2)
Diagnosis and assessment	344	50	37	9	9	0.31	449 (23.4)
Inadequate triaging	216	13	1	-	2	0.07	232 (6.9)
Delayed assessment	65	13	9	1		0.35	88 (26.1)
Diagnosis	9	14	14	6	2	4.00	45 (80)
Insufficient assessment (non-specific)	16	5	3	-	1	0.56	25 (36)
Inadequate discharge planning	10	3	5	1	1	1.00	20 (50)
Inadequate history taking	18	1	1	-	-	0.11	20 (10)
Failure to identify high risk children	4	-	1	-	2	0.75	7 (42.9)
Inadequate examination	3	1	2			1.00	6 (50)
Other	3	-	1	1	1	1.00	6 (50)
Administrative	179	27	13	3	0	0.24	222 (19.4)
Transfer of patient information	105	16	7	-	-	0.22	128 (18)
Access to care	56	7	5	3	-	0.27	71 (21.1)
Appointment management	13	2	1	-	-	0.23	16 (18.8)
Other	5	2	-	-	-	0.40	7 (28.6)
Referral and management	135	36	32	6	1	0.56	210 (35.7)
Delayed referral	79	17	15	4	-	0.46	115 (31.3)
Failure to refer when appropriate	22	6	11	2	1	0.91	42 (47.6)
Inappropriate/ incomplete referral	24	8	5	-	-	0.54	37 (35.1)
Referral administrative issues	9	5	1	-	-	0.67	15 (40)
Failure to arrange follow up	1					0.00	1 (0)
Communication	144	20	11	2	0	0.23	177 (18.6)
Communication - patients / caregivers	127	17	10	2	-	0.23	156 (18.6)
Communication between HCPs	17	3	1	-	-	0.24	21 (19)
Treatment and procedures	53	60	26	7	-	1.75	146 (63.7)
Equipment	71	13	5	-	-	0.25	89 (20.2)
Documentation	70	2	-	-	-	0.03	72 (2.8)
Other	21	19	18	-	-	1.76	58 (63.8)
Investigations	30	11	3	-	-	0.47	44 (31.8)
Transport/ transfer of patients	27	6	9	1	-	0.59	43 (37.2)
Total	1533	387	218	41	12	0.43	2191

3.2.1.5 Factors contributing to incidents involving ‘ unwell’ children

Of the 2191 incidents included, 1219 described at least one contributory factor and 1785 contributory factors were described in total (see Table 19 for definitions, and Appendix 3.4 for the frequency of each combination of contributory factors). Staff factors (n=722)[21] were the most frequently described contributory factors, which included failing to follow protocols (n=356)[22], mistakes (n=272)[23], and poor critical thinking (n=96). Organisational factors were also frequently described (n=463)[24], which included poor continuity of care (n=149)[25], inadequate working conditions (n=148)[26], and inadequate guidelines, protocols, and care plans (n=98). Other types of contributory factors described were patient (n=298)[27], equipment (n=78), and environmental (n=4) related. These will be discussed in further detail in relation to the incident types that they were associated with.

[21] In 113 cases more than one type of staff factor was described per report
[22] In one report failure to follow more than 1 protocol was described
[23] In five cases more than one type of mistake was described per report
[24] In 84 cases more than one type of organisational factor was described per report
[25] In one report more than one type of continuity of care factor was described
[26] In 28 cases more than one type of working condition-related factor was described
[27] In 22 cases more than one type of patient factors was described per report

Table 19 page 104: the contributory factors described in reports

(*some reports contained descriptions of >1 type of factor)

Contributory factors - *definition*	N codes
Staff factors	722*
Failure to follow protocol - *not adhering to organisational guidelines*	356*
Mistakes – *unintentional cognitive lapses*	272*
Critical thinking - *perception, learning, memory, concept formation, problem solving, and thinking*	96
Knowledge - *insufficient knowledge or inadequate application of knowledge*	94
Other	11
Organisational factors	463*
Continuity of care – *issues with the co-ordination of services*	149*
Working conditions – *factors relating to the work environment*	148*
Inadequate protocol/ guidelines/ care plan – *existing guidelines not fit for purpose*	98
Education and training – *insufficient education and training of staff*	74
Service availability - *service inaccessible to patients in a timely manner*	47
Non-specific	2
Patient factors	298*
Age – *child-specific factors e.g. weight-based dosing*	116
Behaviour – *the way in which patients or caregivers act or conduct themselves*	58
Health – *factors relating to the patient's physical and mental wellbeing*	55
Geography – *the area where patients live*	38
Knowledge – *insufficient knowledge or inadequate application of knowledge*	30
Language – *patient or caregiver unable to communicate in English*	14
Looked-after– *children not in the care of their parents e.g. in foster care*	8
Ethnicity – *the child belongs to a certain social group*	1
Equipment factors – *the equipment or medication is impractical, inadequate or faulty*	78
Environmental factors - *the physical environment is detrimental to healthcare*	4
Total	1785

3.2.1.6 The severity of harm resulting from safety incidents

Of the 2191 incidents described by 2178 reports, 30% (n=658) were harmful including 12 deaths, 41 cases of severe harm, 218 cases of moderate harm, and 387 cases of low harm. Reporters only classified 19% of these incidents as harmful, 308 incidents were upgraded in terms of harm severity (see blue cells in Table 20), 25 were downgraded (see green cells in Table 20.

Table 20 page 105: the severity of harm classified by reporters and the severity described in reports using WHO definitions (*four reports describing child deaths were upgraded from moderate and severe harms)

	Reporter-allocated harm severity					
Re-coded harm severity using WHO definitions	No Harm	Low harm	Moderate harm	Severe harm	Death	N codes
No harm	1521	10	1	-	1	1533
Low harm	195	181	10	1	-	387
Moderate harm	48	39	129	2	-	218
Severe harm	10	2	10	19	-	41
Death	-	-	1*	3	8	12
N codes	1774	232	151	25	9	2191

3.2.1.7 Outcomes of incidents involving 'unwell' children

Incident outcomes were described for 744 of the 2191 primary incidents; in total 1004 outcomes were described (Table 21). Patient inconvenience (n=411)[28] was the most frequently described outcome that included delays in management (n=261) and repeated visits to healthcare professionals (n=93). Clinical patient harm (n=316)[29] was also frequently described as an outcome of incidents; this included a wide range of outcomes such as harm necessitating a hospital visit (n=128), and general physical deterioration (n=101). Other types of outcomes described include psychological distress (n=59), organisational inconvenience (n=56)[30], patient injuries (n=26)[31], cardiorespiratory arrest (n=4), and death (n=12).[32]

[28] In 30 cases more than one type of patient inconvenience was described per report
[29] In 87 cases more than one type of clinical patient harm was described per report
[30] In one case more than one type of organisational inconvenience was described per report
[31] In two cases more than one type of patient injury was described per report
[32] In four reports death was described as a direct outcome of an incident but 12 patients who experienced incidents subsequently died

Table 21 page 107: the outcomes of incidents described in reports and their frequencies (N.B.*some reports include descriptions of multiple types of an outcome)

Outcomes	N codes
Patient inconvenience	411*
Delayed management	261
Repeated visits to healthcare providers	93
Additional treatment/ investigations	74
Unnecessary treatment	7
Other	6
Clinical patient harm	316*
Harm necessitating a hospital visit	128
General deterioration/ progression of condition	101
Discomfort/pain	27
Altered consciousness/ dizziness	25
Changes on physiological parameters	19
Nausea/ vomiting	18
Poor diabetic control	13
Seizures	12
Other	60
Psychological/ emotional distress	59
Organisational inconvenience	56*
Patient injuries	26*
Death	12
Cardio-respiratory arrest	4
Total	1004

3.2.2 Primary incident types

Almost 80% of incidents involved either medications (n=674)-, diagnosis and assessment (n=449)-, administrative(n=222)-, referral (n=210)-, or communication-related (n=177) issues. These will therefore be the focus of the exploratory quantitative analysis presented here (see Table 18 for a comprehensive breakdown of primary incident types and Table 22 for their respective contributory factors).

Table 22 page 109: the contributory factors described for each of the key primary incident types Note: *some primary incidents had multiple similar contributory factors

	Primary incident types				
Contributory factors	Medications	Diagnosis and assessment	Administrative	Referral	Communication
Staff factors	289*	205*	27*	80*	65*
Failure to follow protocol	63	140*	21	52	50
Mistakes	227*	7*	6	8	9
Critical thinking	0	63	2	21	7
Knowledge	32	23	1	15	10
Other	6	3	2	0	0
Organisational factors	148*	96*	71*	42*	27*
Continuity of care	24	25	54*	12	8
Working conditions	81*	20*	8*	9*	8
Inadequate protocols/ guidelines/ care plan	40	23	2	12	4
Education and training	17	21	3	11	6
Service availability	1	21	6	4	3
Non-specific	0	0	0	0	0
Patient factors	97*	68*	29*	28*	22*
Age	62	25	3	9	8
Behaviour	15	14	3	8	2
Health	7	15	6	4	6
Geography	5	7	14	2	2
Knowledge	15	4	1	2	4
Language	2	5	1	3	2
Looked-after	0	1	2	2	0
Ethnicity	0	0	0	1	0
Medication/ equipment factors	68	1	1	0	1
Environmental factors	0	1	0	0	0
Total number of contributory factor codes	690	423	138	177	129

3.2.2.1 Medication provision-related incidents

3.2.2.1.1 Characteristics of children experiencing medication-related incidents

The ages of children experiencing medication-related incidents crudely reflects that of the entire dataset i.e. those aged less than one year were most frequently involved in incidents, and the number of incidents per year of age plateaued between ages 2-18 years (Figure 19). Those less than 28 days old and between two to four years old had the highest odds of harm: 0.56 and 0.66 respectively; and neonates also had the highest odds of moderate harm, severe harm or death (0.27) compared to other age groups (Table 23).

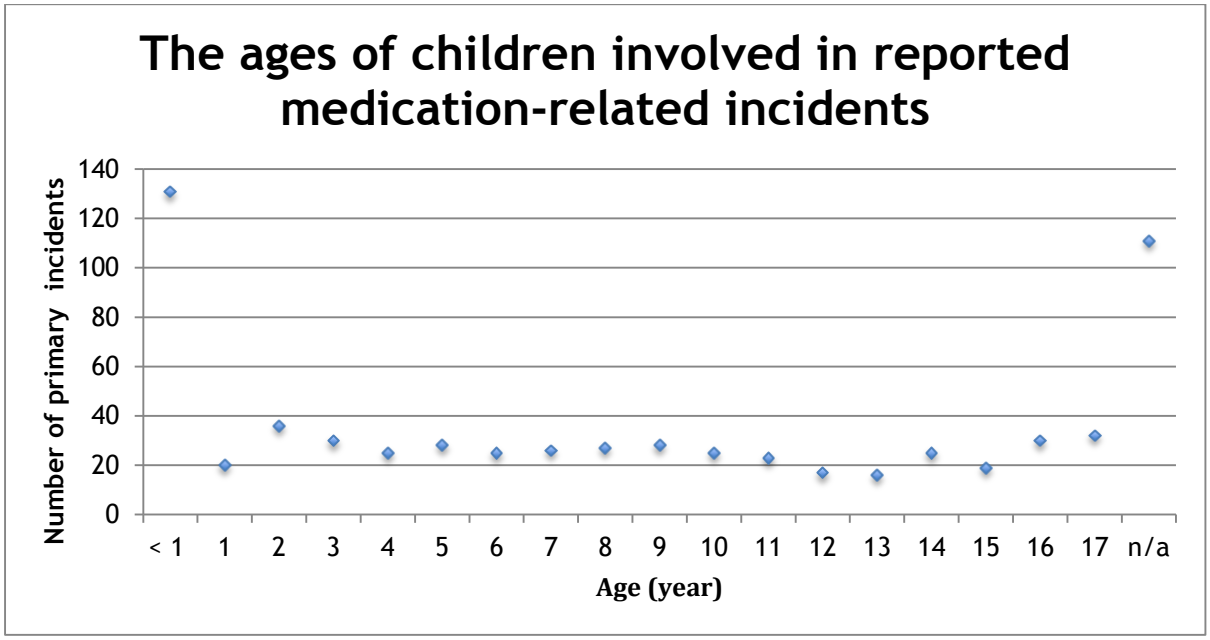


Figure 19 page 110: a scatter chart the frequency and ages of unwell children involved reported in medication-related incidents

Most (n=618) of the 674 medication-related reports described clinical conditions that necessitated treatment with medications (hence the medication-related incidents). These 618 reports described 657 diagnoses, signs or symptoms. Children with respiratory disorders (n=171) such as asthma (n=98); neurological and sensory disorders (n=113)[33] such as epilepsy (n=81); and infections necessitating antimicrobials (n=111) were most frequently involved in medication-related incidents.

[33] In one case a child had more than one type of neurological and sensory disorder

Table 23 page 111: a cross-tabulation demonstrating the relationship between age group and harm severity

Age	Severity of harm					Proportion of harm (%)	Odds of harm	Odds of moderate harm, severe harm, or death	N primary incidents
	No harm	Low harm	Moderate harm	Severe harm	Death				
Under 28 days	9	2	2	1	0	35.71	0.56	0.27	14
1 month to 1 year	90	20	12	2	0	27.42	0.38	0.13	124
2 to 4 years	80	36	16	1	0	39.85	0.66	0.15	133
5 to 11 years	159	49	20	1	1	30.87	0.45	0.11	230
12 to 17 years	121	36	14	1	1	30.06	0.43	0.10	173
Total	**459**	**143**	**64**	**6**	**2**	**31.90**	**0.47**	**0.12**	**674**

Most (n=618) of the 674 medication-related reports described clinical conditions that necessitated treatment with medications (hence the medication-related incidents). These 618 reports described 657 diagnoses, signs or symptoms. Children with respiratory disorders (n=171) such as asthma (n=98); neurological and sensory disorders (n=113)[34] such as epilepsy (n=81); and infections necessitating antimicrobials (n=111) were most frequently involved in medication-related incidents.

3.2.2.1.2 Primary medication-related incidents

Over 25% (n=674) of incidents were medication-related. These are broadly divided into medication dispensing- (n=386), administering- (n=123), prescribing- (n=68), and treatment decision-related incidents (n=66). (Table 18)

3.2.2.1.3 Contributory incidents

Of 674 medication-related incidents, 249 had contributory incidents and 312 contributory incidents were described in total (see Appendix 3.3 for the frequencies of each combination of incidents). The most frequent type of contributory incident was 'other medication incidents' (n=179) for example prescribing incidents often led to dispensing incidents. Other contributory incidents included communication incidents (n=39) such as giving incorrect advice to caregivers, and administrative incidents (n=30) such as inadequate transfer of patient information e.g. updated treatment plans between care settings.

3.2.2.1.4 Contributory factors

Most medication-related incidents (n=427) had contributory factors and 690 contributory factors were described in total. (Table 22 see Appendix 3.4 for the frequency of each combination of contributory factors)

3.2.2.1.5 Contributory staff factors

Staff factors (n=289)[35] were most frequently described. These included staff mistakes (n=227)[36] such as confusing similar medications (n=111), failing to follow protocols (n=63)

[34] In one case a child had more than one type of neurological and sensory disorder
[35] In 44 cases multiple staff factors contributed to medication incidents

such as double-checking procedures, and staff knowledge (n=32) for example, of certain medication contraindications particular to children.

3.2.2.1.6 Contributory organisational factors

Organisational-level contributory factors (n=148)[37] were also described by medication-related reports. These included inadequate working conditions (n=81)[38] such as inadequate staff levels and too high a workload; and inadequate guidelines protocols or care plans (40)- such as poor availability and awareness of epilepsy care plans.

3.2.2.1.7 Contributory caregiver or patient factors

Patient and caregiver level contributory factors were also frequently described (n=97)[39], most of these related to the patient's age (n=62) for example providing adult doses of medication, having difficulties calculating weight-based dosing, or providing medications contraindicated in certain age groups.

3.2.2.1.8 Medication or equipment-related factors

Medication and equipment-related factors were described as contributing to 68 incidents, for example storage of similar medications together resulting in the wrong medication being selected.

3.2.2.1.9 Harm and other outcomes associated with medication-related incidents

Almost a third of medication-related incidents (31.9%) were harmful, including two deaths, six cases of severe harm, 64 cases of moderate harm, and 143 cases of low harm (see Table 18). Outcomes were described for 211 incidents and 306 outcomes were described in total. These included clinical patient harm necessitating a hospital visit (n=49) (this included four children who were admitted to high dependency or intensive care); and deterioration in a child's condition (n=21). Other harmful outcomes included patient inconvenience (n=108), such as repeated visits to healthcare providers (n=52) and

[36] In 5 cases multiple types of mistakes contributed to medication incidents
[37] In 35 cases multiple organisational factors contributed to medication incidents
[38] In 20 cases multiple organisational factors contributed to medication incidents
[39] In 9 cases more than one patient/ parent factor contributed to medication incidents

delayed management of a condition (n=27); organisational inconvenience (n=19); and psychological harm (n=10).

3.2.2.1.10 Medication classes

Most medication-related incidents involved medications that target the central nervous system, the respiratory system, or infections (Table 24). Frequently reported medication types with the highest odds of harm were for: the cardiovascular system (0.75), eyes (0.63), gastrointestinal system (0.62), and infections (0.55). Medications affecting the central nervous system included anti-epileptics (n=94), anti psychotics (n=34), analgesia (n=31), and antidepressants (n=29). Respiratory medications included corticosteroids (n=89) and bronchodilators (=33). Beta lactam antibiotics (n=75) and macrolide antibiotics (n=24) were the medication types most frequently involved in infection-related medication incidents. These frequencies are likely a reflection of which medications are typically prescribed to children in primary care and their importance, and this in turn is influenced by which illnesses are frequent in childhood.

Table 24 page 115: the medications involved in medication-related incidents N.B. *some incidents involved multiple medications

Medication class	No harm	Low harm	Moderate harm	Severe harm	Death	Odds of harm	N primary incidents (% harmful)	N codes
Central nervous system	144*	38	29	3	1	0.49	215* (33)	227
Anti-epileptic	67	13	12	2	-	-	94	94
Anti-psychotic	21	4	8	1	-	-	34	34
Analgesic	21	5	5	-	-	-	31	31
Anti-depressant	19	8	2	-	-	-	29*	30
Other	15	5	2	-	1	-	23*	25
ADHD medication	12	3	-	-	-	-	15	15
Respiratory system	125*	20	12*	-	-	0.26	157* (20.4)	162
Inhaled corticosteroid	77	10	2	-	-	-	89	89
Bronchodilator	28	3	2	-	-	-	33	33
Antihistamine, immunotherapy, allergic emergencies	14	5	7	-	-	-	26	26
Other	10	2	2	-	-	-	14	14
Infections	97*	45*	7	1		0.55	150* (35.3)	157
Beta-lactam	57	18	-	-	-	-	75*	76
Non-specific antibiotic	10	11	4	-	-	-	25*	26
Macrolide	15	7	2	-	-	-	24	24
Antiviral	11	5	-	1	-	-	17	17
Other	6	8	1	-	-	-	15	15
Endocrine system	24	6	5	-	-	0.46	35 (31.4)	36
Gastro-intestinal system	13	6	2	-	-	0.62	21 (38.1)	21
Cardiovascular system	8	2	3	1	-	0.75	14 (42.9)	14
Ear, nose, and oropharynx	9	4	-	-	-	0.44	13 (30.8)	13
Eye	8	3	2	-	-	0.63	13 (38.5)	13
Skin	12	-	1	-	-	0.08	13 (7.7)	13
Musculoskeletal and joint diseases	8	2	-	-	-	0.25	10 (20)	10
Nutrition and blood	4	4	-	-	-	1.00	8 (50)	9
Anaesthesia	1	2	4	-	-	6.00	7 (85.7)	7
Obstetrics, gynaecology and urinary-tract disorders	3	-	-	-	-	0.00	3 (0)	3
Malignant disease and immunosuppression	-	2	-	-	-	1.00	2 (50)	2
Other	1	-	-	-	1	n/a	2 (100)	2
Number of incidents	451	133	59	5	2	0.44	650 (31.1)	689

Example medication-related incidents

Example 46: "Dispensing error - prescription for Erythromycin 250mg, dispensed chlorpromazine 50mg tablets. 16-year-old patient took wrong medicine for 3 days and suffered serious side effects including catatonic seizures. Pharmacist Action - Different brand of chlorpromazine to be kept in pharmacy PCT action - contacted manufacturer to request re - assessment of packaging Similarity of packaging led to error in tablet selection."

Example 47: "GP prescribed a 5year old child chlorphenamine (antihistamine) plus 3 other items. The pharmacist dispensed chlorpromazine (anti - psychotic) instead of chlorphenamine. Mother did not recognise name so phoned pharmacy to check if it was the same. A member of staff told her that it was the same. Mother gave 8year old (sibling) 5mls of 100mg chlorpromazine. Child became extremely drowsy and was admitted to high dependency unit for observations. Child has since recovered. Pharmacy is reviewing its dispensing procedures and putting these into a written format i.e. developing standard operating procedures. Poor dispensing procedures and very limited communisation between the pharmacist and the patients."

Example 48: "Child of 8 weeks was prescribed Ranitidine 75mg / 5ml. Dose prescribed was 2.5ml twice a day. Child weighed 3.75kg. The BNF for children 2013 indicates that dose should be calculated by weight and from this it was seen that the doctor had prescribed an overdose. The dose should have been 1mg / kg three times daily. GPs checking the dose in children by weight and weighing the child accurately."

Example 49: "Chlorampenicol eye drops 0.5% were prescribed but chloramphenicol ear drops 10% were dispensed from the fridge. This occurred because the medication was dispensed in a hurry and the pharmacist did not spot the error when the second check was made. When the patient used the drops she experienced a prolonged burning sensation and was taken to the hospital when the error was recognised. The different types of chloramphenicol drops had been separated in the past and placed on different shelves due to this error occurring previously. This will now be taken further so that the ear drops are kept in enclosed containers within the fridge and clearly marked on the outside as ear drops. Similar product name. Similar package."

Example 50: "The prescription read Risperidone 1m / ml dose: 0.25mg nocte. We supplied the correct product but it was labelled 2.5ml at night. Although this is a recognised dose for a child of this age it is 10x the prescribed dose. This was a labelling error of unknown cause. The pharmacist did not pick up the labelling error. Additional care needed at time of labelling and checking, especially with children's prescriptions for unusual medications. Causes: pressure - very busy, interruptions from phone and staff."

3.2.2.2 Characteristics of children experiencing diagnosis and assessment incidents

Over half of diagnosis and assessment incidents (n=234) in 'unwell' children were in children aged less than three years (mostly in those aged under one) (see Figure 20). Children aged 12-17 had the highest odds (0.19) of more serious harm (moderate harm, severe harm or death) compared to other age groups (Table 25). Most of these 'unwell' children had: injuries (n=117)[40] such as head injuries (n=58); general signs and symptoms (n=102)[41] such as fever (n=49) and altered consciousness (n=33); or skin and musculoskeletal conditions (n=87)[42] such as rashes (n=34) and skin discolouration (n=33).

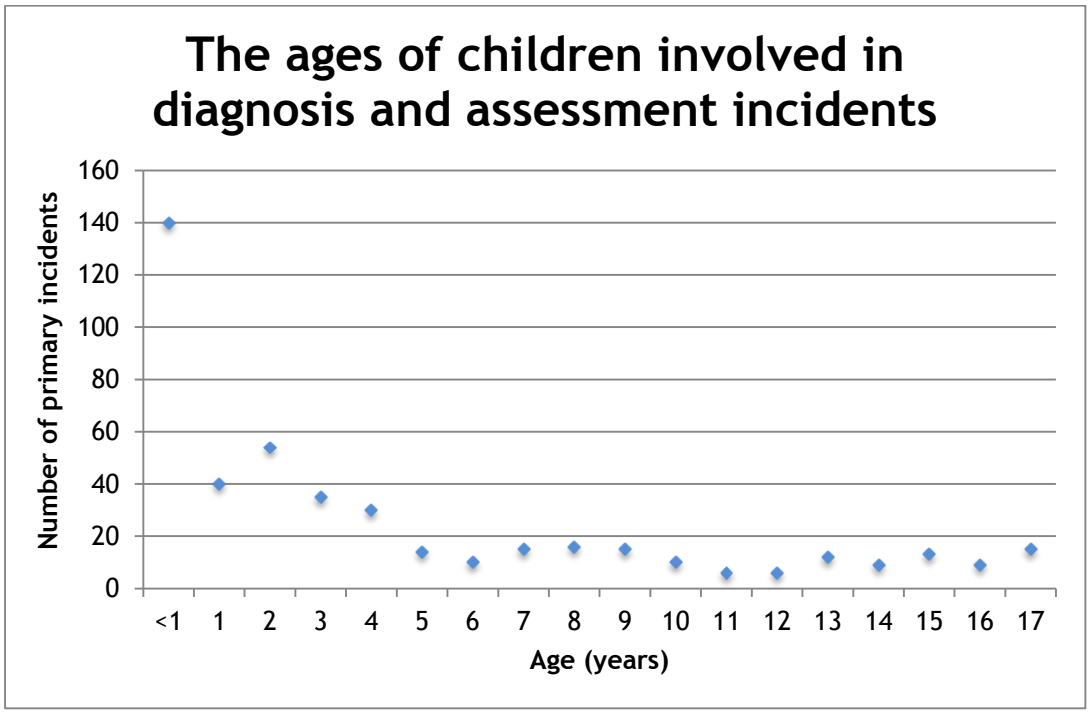


Figure 20 page 117: the frequency and ages of 'unwell' children involved in diagnosis and assessment incidents

[40] In one case multiple injuries were described
[41] In 23 cases multiple non-specific signs and symptoms were described
[42] In 12 cases multiple skin-related symptoms were described

Table 25 page 118: cross-tabulation of the relationship between age group and severity of harm

Age	Severity of harm					Odds of harm	Odds of moderate harm severe harm or death	N primary incidents (% harm)
	No harm	Low harm	Moderate harm	Severe harm	Death			
Under 28 days	6	5	1	0	0	1.00	0.09	12 (50)
1 month to 1 year	103	16	9	3	2	0.29	0.12	133 (23)
2 to 4 years	120	11	15	4	4	0.28	0.18	154 (22)
5 to 11 years	65	14	4	1	2	0.32	0.09	86 (24)
12 to 17 years	50	4	8	1	1	0.28	0.19	64 (22)
Total	**344**	**50**	**37**	**9**	**9**	0.31	0.14	**449(23)**

3.2.2.2.1 Primary diagnosis and assessment incidents

Diagnosis and assessment incidents included: insufficient assessment (n=315) (most of these (n=232) were related to inadequate patient triaging), delayed assessment (n=88), and inadequate diagnosis (n=45) i.e. delayed, missed, or wrong diagnosis.

3.2.2.2.2 Contributory incidents

Most diagnosis and assessment incidents (n=293) were preceded by other incidents: 403 contributory incidents were described in total and most were other diagnosis and assessment incidents (n=147) (see Appendix 3.3 for the frequencies of each combination of incidents). For example inadequate history taking (n=87) frequently contributed to the inadequate triaging of a child, as did failure to identify at risk and vulnerable children (n=29). Communication incidents (n=88)–particularly between healthcare professionals and caregivers (n=63)–frequently preceded incidents of inadequate diagnosis or assessment. For example, misunderstandings between triaging healthcare professionals and caregivers during telephone triaging often led to assessment issues.

3.2.2.2.3 Contributory factors

Most diagnosis and assessment incidents (n=302) had contributory factors and 423 were described in total (Table , see Appendix 3.4 for the frequency of each combination of contributory factors).

3.2.2.2.4 Contributory staff factors

Staff factors were most frequently described (n=205)[43]. Staff failures to follow protocols were often described (n=140)[44], which included following the wrong protocol (n=96), for example assessing a child using a 'wound' protocol rather than a head injury protocol. Inadequate critical thinking (n=63) such as advising caregivers not to attend emergency care apparently in-line with protocol, despite the child being severely ill, i.e. following the protocol blindly without question, was also frequently described as contributing to these incidents.

[43] In 33 cases multiple staff factors contributed to diagnosis and assessment incidents
[44] In one case failure to follow more than one type of protocol contributed to a diagnosis and assessment incident

3.2.2.2.5 Contributory organisational factors

Organisational factors (n=96)[45] contributing to these incidents include: poor continuity of care (n=25); inadequate guidelines, protocols, or care plans (n=23); poor working conditions (n=20)[46]; inadequate service provision (n=21); and insufficient education and training (n=21).

3.2.2.2.6 Contributory patient or caregiver factors

Patient factors (n=68)[47] contributing to these incidents included: age (n=25) such as assessing a child using an adult protocol, health (n=15) e.g. patients had pre-existing conditions that were not taken into consideration during diagnosis and assessment, and patient/ caregiver behaviour (n=14) such as non-disclosure of medical conditions.

3.2.2.2.7 Harm and other outcomes associated with diagnosis and assessment incidents

Only 23.4 % (n=105) of diagnosis and assessment incidents were harmful but they were the most harmful incident types in terms of harm severity: they resulted in 9 deaths, 9 cases of severe harm, and 37 cases of moderate harm (see Table 18). Patient inconvenience (n=104) was the most frequently described outcome type, largely because of delayed management of conditions (n=90). Other outcomes included clinical patient harm (n=54) necessitating hospital visit (n=26) and general deterioration of a child's condition (n=15).

[45] In 16 cases multiple organisational factors contributed to diagnosis and assessment incidents
[46] In two cases multiple types of working conditions contributed to diagnosis and assessment incidents
[47] In three cases multiple patient factors contributed to diagnosis and assessment incidents

Example diagnosis and assessment-reports

Example 51: "4-year-old girl was diagnosed with bilateral developmental dysplasia of the hip in a joint physiotherapy and orthopaedic clinic on. The child has been known to and seen by a number of health professionals since birth when she was diagnosed in the neonatal period as having a parietal lobe infarct with a possible risk of developing hemiplegia. There has been a significant delay in the diagnosis of this condition that may affect the outcome."

Example 52: "Patient was seen in urgent care centre with a history of passing blood in urine, treated as UTI. This was brought to my notice in the practice. I was concerned. Phoned school nurse and alerted members in practice to follow this patient. She was found to have a big tumour in her abdomen and was later diagnosed as Wilms tumour with metastasis."

Example 53: "Child with severe physical and learning disability noted to not be using her right arm in school from. She was seen in Casualty on by a Casualty Officer but not by a Paediatrician. The medical notes are not entirely legible but it appears that the examination findings showed a good range of movement in the right arm, but the impression was a pulled right elbow. Mum was told that there was a bruise on the bone and they were sent home. Child appeared to be in pain on moving the arm when visited that day. As child has complex neurodisability associated and is extremely petite on supplementary feeding but has very little subcutaneous fat my concerns were that she should have an X-ray to check for bone injury; she is also at risk of osteoporosis. I phoned the acute paediatrician; she was unaware of the child degree of disability from the casualty card but agreed for the child to attend the day unit to have a Paediatrician review and x-ray. The x-ray showed an impacted fracture at neck of humerus - child was admitted."

Example 54: "During consultation with this patient for developmental delay, I noted that patient has chest deformity. He was sent for chest X-ray. CXR report found abnormality of heart and abdominal organs- situs inversus / dextrocardia. During the second consultation I informed Dad the CXR Report and this warranted further investigations such as ultrasound of abdomen and cardiology referral for ECHO. The second line of investigation found no abnormality. Consultant radiologist advised repeat CXR. Parents were very upset on the erroneous information given to them from the CXR finding and the stress they were put through. They declined second CXR, clinic appointment and were upset with the radiographer as mother informed over the phone."

Example 55: "Patient presented to A &E with classical symptoms of new presentation of type 1 diabetes, parents concerned had presented to GP on Friday as concerned he had diabetes - GP recommended further test in 1 week later rather than immediate referral. Parents remained concerned bought blood glucose tester - sugar high. On presentation blood glucose high with 3.3 mmol / l of ketones - blood gas not acidotic. Local & national guidance of immediate referral of all suspected diabetes in children not followed."

3.2.2.3 Administrative-related incidents

3.2.2.3.1 Characteristics of children experiencing administrative-related incidents

The ages of children involved in administration-related incidents reflected that of the entire dataset, with the highest number of incidents (n=84) occurring in those aged less than 1 year (Figure 21). Most children suffering from these incidents had: general signs and symptoms (n=36)[48] such as fevers (n=13); mental and behaviour disorders (n=35)[49]; respiratory conditions (n=30); and injuries (n=29).

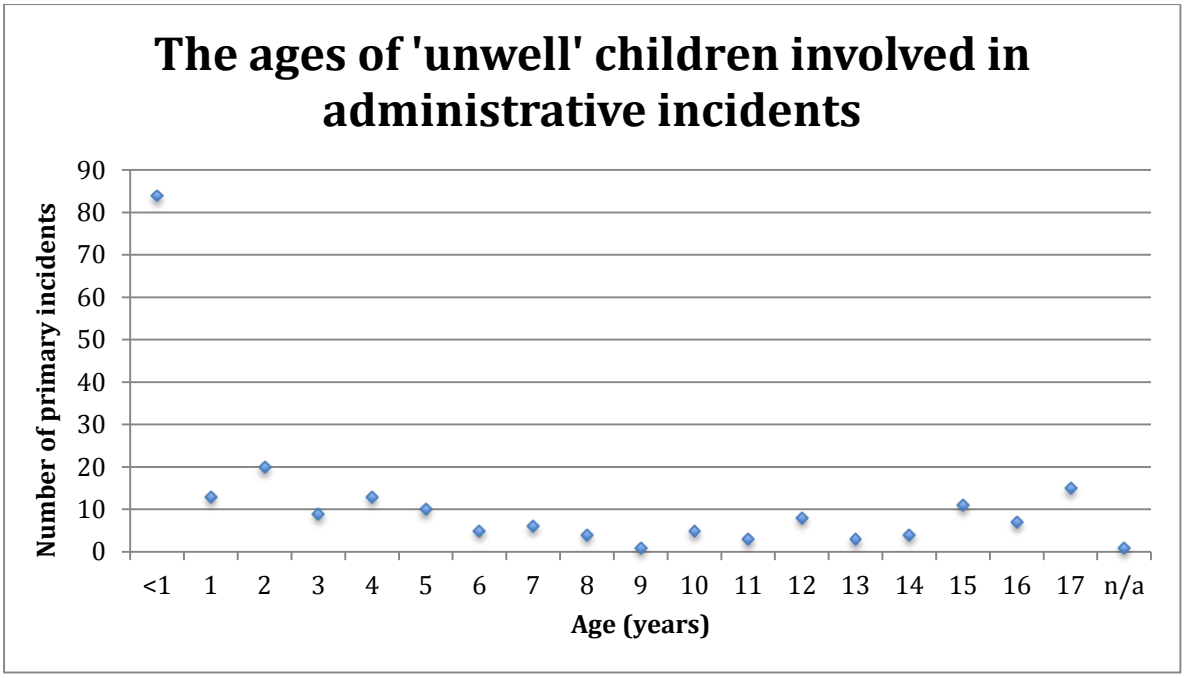


Figure 21 page 122: a scatter chart of the frequency and ages of 'unwell' children involved in administrative incidents

3.2.2.3.2 Contributory incidents

Only 100 administration-related incidents were preceded by other incidents, and these were mostly other administrative incidents (n=39) such as a patient not receiving a timely follow up phone call as a result of delays in transferring patient records; documentation failures (n=26) such as inaccurate patient records; and communication incidents (n=24) (see Appendix 3.3 for the frequencies of each combination of incidents).

[48] In seven cases multiple signs and symptoms were described
[49] In one case multiple mental and behavioural disorders were described

3.2.2.3.3 Contributory factors

Half of incidents (n=110) had contributory factors. These were mostly at the organisational level (n=71)[50], such as poor continuity of care (n=54)[51] (see Appendix 3.4 for the frequency of each combination of contributory factors).

3.2.2.3.4 Harm and other outcomes associated with administrative incidents

Of 222 administrative incidents 19.4% were harmful which included no deaths, 3 cases of severe harm, 13 cases of moderate harm, and 27 cases of low harm. Most incidents were related to transfers of patient information between care settings (n=128) such as midwives failing to inform a health visitors about a premature baby; and access to care (n=71) such as community nurses not following up children discharged from hospital. These incidents typically resulted in inconvenience to patients/ caregivers (n=26) through delays in management (n=19) and repeated visits to healthcare professionals (n=7), and/ or clinical patient harm (n=24) for example deterioration in the child's condition (n=10).

Example administrative incidents

Example 56: "Patient with Downs syndrome was under follow up with me. Last appointment booked was for Feb 2011. It appears that this appointment was cancelled by us but no appointment was remade. Patient therefore has not had any follow up, nor screening tests recommended for children with Downs syndrome on an annual / biannual basis. This was picked up because school rang to request a report and on investigating further it appears that this child should have been under follow up. Staff have not followed procedures."

Example 57: "Deaf patient needed to be seen by an out of hours (OOH) GP. BWIC Nurse called OOH profession line several times and no reply, also called clinical shift line which was dead. Patient could not wait and was not registered with a local GP. This is a recurring theme with the new OOH GP provider, resulting in timing out of calls, inappropriate referral to A&E as unable to get through for a GP appointment, having been assessed by Nurse Practitioners."

[50] In four cases multiple organisational factors contributed to administrative incidents
[51] In one case multiple continuity of care issues contributed to an administrative incident

3.2.2.4 Referral and management-related incidents

3.2.2.4.1 Characteristics of children experiencing referral-related incidents

Most referral-related incidents were described in children aged less than 4 years old (Figure 22). The 'unwell' children involved in referral-related incidents mostly had non-specific signs and symptoms (n=48)[52] including fever (n=18), altered cognition or behaviour (n=18), mental and behavioural disorders signs or symptoms (n=30) such as self-harming (n=10), and injuries (n=29), such as head injuries (n=26). Most of these children (n=165) presented acutely unwell (including 15 children with a chronic condition who presented acutely) however some referral incidents (n=19) were related to chronic condition management.

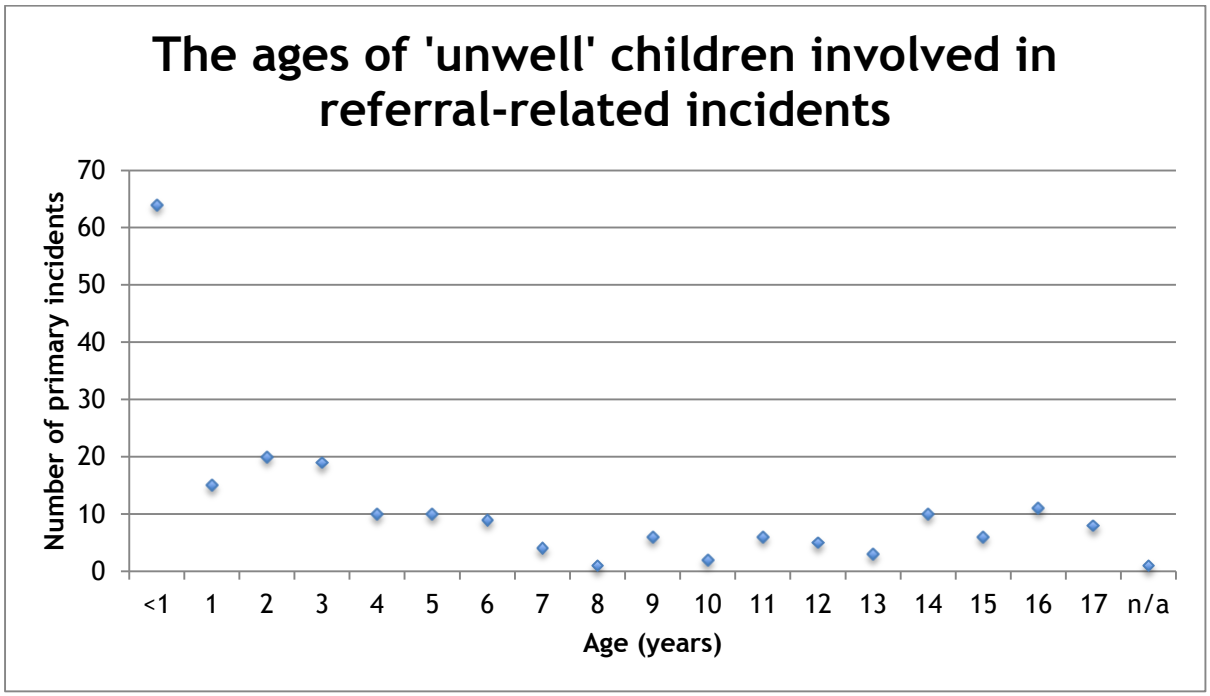


Figure 22 page 124: a scatter chart of the frequency and ages of children involved in referral-related incidents

[52] In 14 cases multiple non-specific signs and symptoms were described

3.2.2.4.2 Referral and management-related incident subtypes

Referral-related incidents included errors administrative referral errors such as referral paperwork getting lost or being sent to the wrong place, and errors in the referral decision-making process such as failing to refer when appropriate or making an inappropriate referral (such as referring a child with headaches to social services).

3.2.2.4.3 Contributory incidents

Most referral-related incidents (n=156) had contributory incidents and most of these were related to inadequate diagnosis and assessment (n=154) such as failing to refer a seriously unwell child as a result of not identifying the seriousness of the child's condition (see Appendix 3.3 for the frequencies of each combination of incidents). Communication-related incidents (n=30)–such as inadequate safety netting –also contributed to referral-related incidents.

3.2.2.4.4 Contributory factors

Contributory factors were described for 120 referral-related incidents (Table 22, see Appendix 3.4 for the frequency of each combination of contributory factors). Staff factors (n= 80)[53] included failing to follow protocols (n=52), inadequate critical thinking (n=21), and inadequate knowledge (n=50.) Organisational level factors (n=42)[54] included inadequate protocols, guidelines or care plans (n=12), poor continuity of care (n=12), inadequate working conditions (n=9)[55], and inadequate education and training (n=11).

3.2.2.4.5 Harm and other outcomes associated with referral-related incidents

Of the 210 referral-related incidents 35.7% were harmful, which included one death, six cases of severe harm, 32 cases of moderate harm, and 36 cases of low harm (Table 18). Incident outcomes were described by half (n=105) of these reports and 125 outcomes were described. Outcomes included: patient inconvenience (n=75) such as delayed management of a condition (n=67); and clinical patient harm (n=36) such as general deterioration (n=18), harm necessitating a hospital visit (n=10), or diabetic ketoacidosis (n=4).

[53] In 16 cases multiple staff factors contributed to referral-related incidents
[54] In eight cases multiple organisational factors contributed to referral-related incidents
[55] In two cases multiple types of working conditions contributed to referral-related incidents

3.2.2.4.6 Example referral and management-related incidents

Example 58: "Baby admitted to A and E as SUDI aged 2 months having died at home. Baby had been seen by GP on previous evening at with temperature of 38 degrees C and possible chest infection, prescribed amoxicillin. NICE guidance for fever states that fever ≥38 in child less than 3 months is a red flag and a child should be admitted to hospital. Preliminary results from post mortem suggesting that infection is likely cause of death.".

Example 59: "Mum attended with child alleged telephone call with health visitor at Medical Centre. Informed health visitor of non-blanching rash, glass test done and positive. Inappropriate referral to walk in centre, on arrival child referred to A&E via 999."

Example 60: "Child mother called requesting advice regarding a non-blanching rash to child upper leg also a 'little niggly' but otherwise well, no temperature, feeding well, no sickness, bowels / bladder normal, no GP in surgery therefore mother directed to walk in centre straight away for assessment. Baby should have been referred to A&E an antibiotic injection was administered before baby was taken to A&E baby admitted for three days for observation. A viral illness was diagnosed. Urgent management, same as one above."

Example 61: "Patient reported by relative that attended centre for management of burns. Dressing applied. No referral. Patient seen on 21 / 11 / 11 for a safeguarding medical, presented with full thickness burns severe enough to warrant urgent transfer and admission to a regional burns unit."

3.2.2.5 Communication incidents with or about the patient

3.2.2.5.1 Characteristics of children experiencing communication-related incidents

Communication-related incidents were most frequently reported in younger children (those aged less than three years old) (n=90) (see Figure 23). These incidents occurred in children with non-specific signs and symptoms (n=35)[56] such as fever (n=27) or failure to thrive (n=3); injuries (n=27)[57]; gastrointestinal or genitourinary symptoms such as vomiting (n=14) and abdominal pain (n=8).

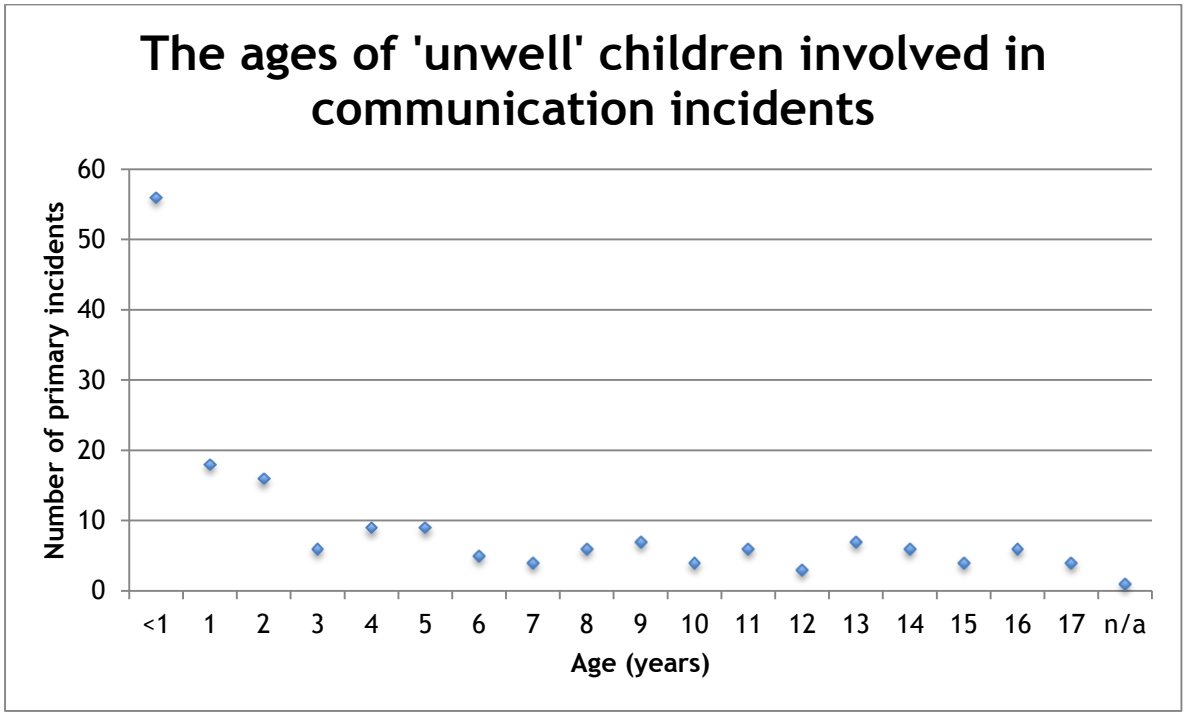


Figure 23 page 127: a scatter chart of the frequencies and ages of children involved in communication incidents

[56] In three cases multiple non-specific signs and symptoms were described
[57] In one case multiple injuries were described

3.2.2.5.2 Contributory incidents

Most communication-related incidents (n=98, 55%) were preceded by other incidents, particularly those relating to diagnosis and assessment (n=48) e.g. giving the wrong advice to a caregiver because of a missed diagnosis, administration failures (n=11), and documentation failures (n=10) (see Appendix 3.3 for the frequencies of each combination of incidents).

3.2.2.5.3 Contributory factors

Staff factors (n=65)[58] such as failing to follow protocols (n=50) (such as safety netting protocols) were the most frequent type of contributory factor described (Table 22, see Appendix 3.4 for the frequency of each combination of contributory factors).

3.2.2.5.4 Harm and other outcomes associated with communication-related incidents

Of the 177 communicated-related incidents, 18.6% were harmful which did not include any deaths but did include 2 cases of severe harm, 11 cases of moderate harm, and 20 cases of low harm (Table 18). Most communication incidents (n=156) were between healthcare professionals and caregivers, such as inadequate safety netting, providing the wrong advice or not clearly communicating the correct advice. Most communication-related incidents (n=143, 81%) did not describe outcomes.

[58] In 11 cases multiple staff factors contributed to communication incidents

3.2.2.5.5 Example communication incidents

Example 62: "Health Advisor sought advice on call relating to a 3 month old baby with a head injury after ending the call. Health Advisor was concerned mother would not take baby to A& E as advised. On attempting to call mother to offer nurse assessment phone was switched off. No home address details taken for caller."

Example 63: "Home visit to a child - mum very upset as she had received a letter from her child consultant detailing her most recent outpatient appointment with him. The letter stated patient condition as evolving cerebral palsy. Patient mother was extremely upset as she had never been told this as a diagnosis - it came as quite a shock to her. Patient mum has asked me to report this as an incident."

Example 64: "2nd call of the night for fever symptoms not reducing. On questioning the advice given for initial call contradicted advice to be given on return call. Relative informed that had been told to strip of clothing and tepid sponge, child was complaining of feeling cold and shivering fever remained 39.5 following medication. Concern because the same service providing contradictory advice for relief of fever symptoms. Call listened to. NA did not advise the caller to tepid sponge but did suggest that a cool flannel could be put on child's forehead but NA did advise that Ibuprofen and Paracetamol could be alternated. To be fed back to NA. Callers should not be advised to alternate Paracetamol and Ibuprofen."

Example 65: "10 year old with injury to arm, swollen and unable to move. Call was placed on queue as P3 for three hours. On attempting to call back no reply. Datix info not clear as to what the problem was with the call. HA dealt with call appropriately. The outcome was P3. The call reason was clearly documented within the call reason. The caller asked if she should take the child to A & E. The HA advised caller that she couldn't advise this but if the caller felt she wanted to then that was her choice. Caller decided to wait for a call back. Call back time was given to the caller but no worsening instructions were given. Critical thinking should have been used and clinical advice sought from the CTL on duty. HA has completed a call reflection and acknowledge she did not give worsening instructions. HA has been advised to be aware that the priority would have been higher if the this may be closer to communication category. call was triaged through limb injury."

3.2.2.6 Incidents affecting certain groups of children

The most commonly described medical conditions described in these reports will be discussed further here, including the types of incidents and harm affecting children with these conditions (see Tables 16-18).

3.2.2.6.1 Children presenting with fever

Of 133 primary incidents involving children with an unexplained fever, over 85% (n=94) were in children aged less than 5 years old. Children presenting with a fever in this dataset also had respiratory difficulty or cough (n=30), rashes (n=19), vomiting (n=19), skin discolouration (n=18), and altered consciousness or behaviour (n=14).
Most incidents in children presenting with a fever involved insufficient diagnosis and assessment (n=96) such as inadequate triaging (n=50) and history taking (n=19); and communication incidents (n=51) particularly with caregivers (n=47) such as giving the wrong advice about fever management and inadequate safety netting. Two of these children died, 11 suffered moderate harm, and 6 suffered low harm.

3.2.2.6.2 Children presenting with non-specific respiratory symptoms

Of 127 primary incidents involving children with respiratory difficulty (including coughs, dyspnoea, tachypnoea, wheezing, stridor *etc.*) almost 70% (n=88) involved children aged less than 3 years. As highlighted above 30 children with respiratory difficulty had a concurrent fever, in addition 29 had skin colour changes, 14 were vomiting, 13 presented with altered consciousness, 11 had cardiac disorders or symptoms, and 8 also had a rash. In total, 248 incidents were described in these children which included: diagnosis and assessment-related incidents (n=98) such as inadequate triaging (n=45); referral-related incidents (n=33) such as failing to refer to emergency care when appropriate (n=16); and communication incidents (n=32)-particularly with caregivers (n=24). Most of these incidents did not result in harm (n=99), however 3 children suffered severe harm (which includes one child who suffered a cardio-respiratory arrest); 15 suffered moderate harm and 10 suffered low harm.

3.2.2.6.3 Children with epilepsy

The ages of the 125 children with epilepsy included in this dataset was relatively constant, ranging from <1 to <18 years old. The most frequent incident type described in these children was medication incidents (n=114), particularly dispensing (n=65) and prescribing (n=24) incidents. Diagnosis and assessment incidents (n=29) were also described in these children. Of the 125 children described in these reports, 33 suffered harm including 3 cases of severe harm (two of these children were admitted to high dependency/ intensive care, and one suffered a cardio-respiratory arrest), 15 cases of moderate harm, and 15 cases of low harm.

3.2.2.6.4 Children with asthma

Children with asthma were described by 123 reports, 102 of these related to the management of chronic asthma, 19 children presented with acute exacerbations of chronic asthma, and 2 presented with first onset/ acute asthma. Of these children 24 suffered harm: 2 severe, 5 moderate and 17 low harm. Multiple incidents (n=172) were described in these children however medication incidents were the most frequent incident type described (n=117), particularly medication dispensing errors (n=93) such as dispensing the wrong doses of corticosteroids or bronchodilators.

3.2.2.6.5 Children with head injuries

Of the 123 children with head injuries suffering patient safety incidents, 37.8% were aged less than 1 year. Most incidents related to these children involved inadequate or delayed assessment (n=122), sub-standard triaging of these children was frequently described (n=69) in addition to poor history taking (n=32). Communication incidents (n=38) were described for this group of children, such as giving poor safety netting advice to caregivers and misunderstandings between caregivers and healthcare professionals during telephone triaging. Only 12.9% of these children experienced harm, which included one death, 6 cases of moderate harm, and 8 cases of low harm. Two children with head injuries died but only one death was described as the result of healthcare failings.

3.2.3 Thematic analysis of incident reports involving 'unwell' children

Three overarching themes were identified from included reports involving 'unwell' children:

- Inadequate provision of care in the community for chronically unwell children (i.e. those requiring on-going care and/ or follow up)

- The role of caregivers in mitigating and contributing to incidents

- Weaknesses in telephone-based assessments

These will be presented, described, and supported with illustrative free-text examples; the overlap and relationship of these themes with the previously presented quantitative findings will be discussed in the mixed methods section.

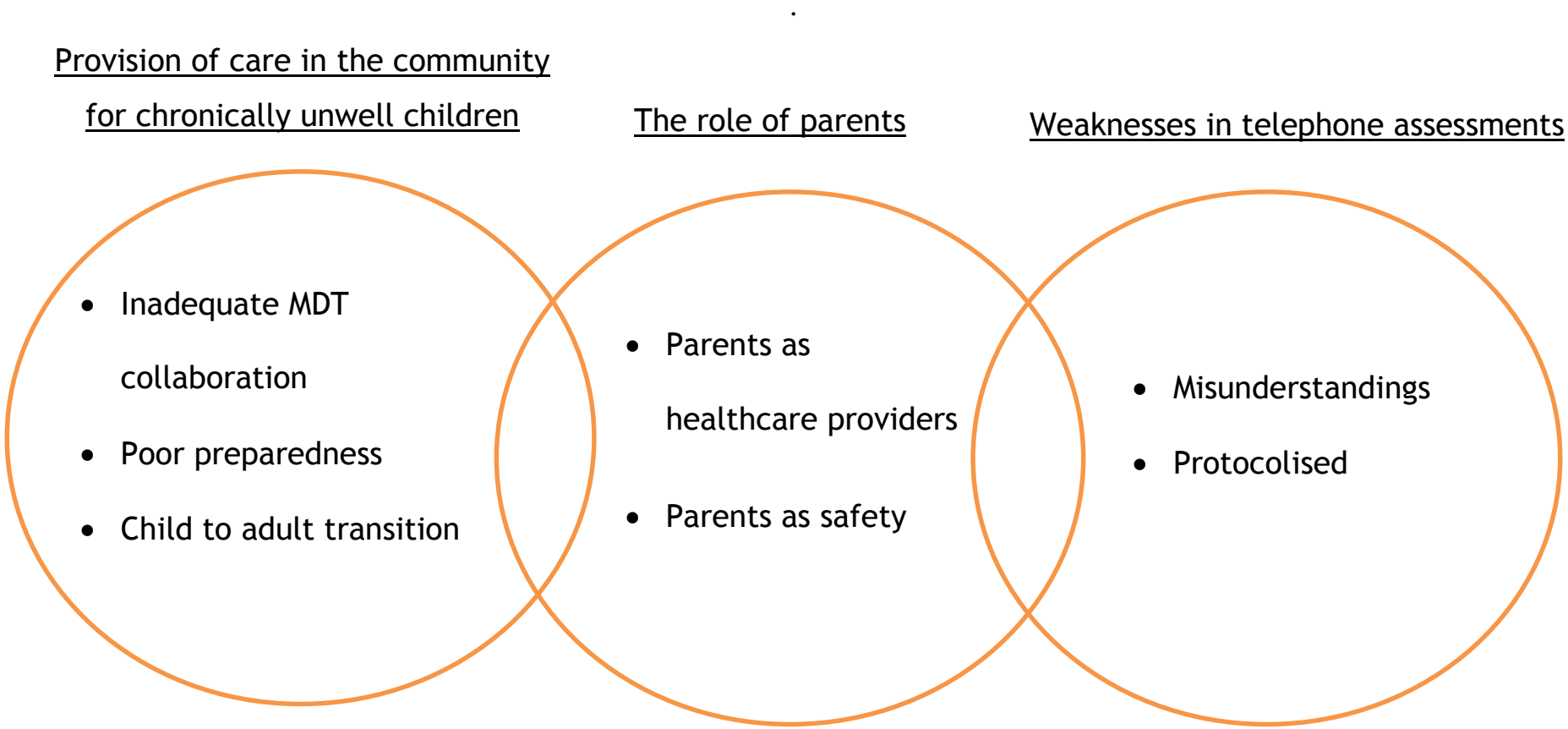


Figure 24 page 133: an illustration of the relationship between the three over-arching themes and their respective sub-themes

3.2.3.1 Provision of care in the community for complex/ chronically unwell children

3.2.3.1.1 Inadequate multidisciplinary collaboration

Poor collaboration between groups of professionals was described by reports that included health visitors, GPs, midwives, pharmacists, school nurses, social workers, and hospital clinicians. Inadequate collaboration was frequently described between healthcare professionals (hospitalists and midwives) with health visitors in the form of health visitors receiving inadequate handovers of care for neonates/ infants with jaundice, congenital disorders, birth complications, or not being updated about neonates admitted to Special Care Baby Units.

Examples

*Example 66: "The mother of a baby for whom I am the Named Health Visitor , attended Baby Clinic this afternoon and informed me that her baby had been admitted to *** Hospital several weeks ago with a severe illness (treated for meningitis) and was later transferred to *** Children's Hospital where she had bowel surgery and now has an ileostomy. No liaison has been received from either hospital however the mum had been told that the Health Visitor would be informed. As a result, I have been unaware of the baby's health problems and unable to offer mum any support at a very difficult stressful time."*

Example 67: "Primary visit allocated to me and I had a ' no access ' visit. I left a calling card with my contact detail asking family to phone me. On return to the office, we had received a discharge letter stating baby was in SCBU. I made the decision to liaise with the staff on SCBU / midwives during the next week. Mum informed me that the baby was " starved of oxygen at birth having complex medical needs. Because of this, the family were in "conversations with children services as to whether they felt they could manage to bring the baby home". Mum was uncertain what decision she was going to make. I believe that this should have been shared with me by the hospital, as clearly, this is a complex and uncertain situation."

School nurses were also frequently not kept up-to-date about their patients' conditions, needs, and treatment plans- an issue occasionally addressed by the caregivers themselves (the only constant between the various care settings).

Example

Example 68: "Pupil had been admitted to Paediatrics following concerns about her mental health. I (school nurse) had no knowledge of this even though I have been working with the family for some time. I am concerned that both CAMHS and the children's ward failed to communicate this admission to hospital. Mum had requested support and information as to why her child had been admitted to a specialist unit. As I had very little information I felt I was unable to support Mum to the best of my capabilities."

Children with chronic conditions such as epilepsy, who should have had formal care plans known to and accessible to all relevant healthcare professionals, often either did not have these written plans in place; or they were not accessible, known of, or followed. This was particularly apparent in the pharmacy and school setting- where a unified care plan-if followed- could have prevented substandard care. In addition GPs were not always kept up-to-date by hospitalists about developments in their patients' care plan.

Example

Example 69: "8 year old child who has epilepsy seen in clinic by Paediatrician on 14 / 5. He advised changes to medication in both formulation and dose. Letter was not dictated until 28 / 6. Letter only arrived in the GP practice 16 / 7. Seen by GP on 17 / 7. In the meantime an incorrect script was issued on 5 / 7 although the parent gave the correct dose as advised by the specialist. GP phoned to mother to clarify and explain on 17 / 7 and corrected the medication."

3.2.3.1.2 Poor preparedness for care in the community

Children requiring care in the community such as those with invasive devices were often described as having issues with equipment and therapeutic adjunct provision. For example, gastrostomy feeds were often delivered in insufficient quantities, out of date, or of the wrong brand or formulation. These issues were often compounded by inadequate therapeutic adjunct provision e.g. feeding tubes. Inadequate discharge of such patients accounts for some of these inadequacies i.e. not organising community nursing, social care and adequate equipment or therapeutic adjuncts on discharge.

Example

Example 70: "Carer called to inform us that delivery from Kangaroo was incorrect. Patient hadn't received enough feed. Patient had received either too many plastics or not enough."

Failing to ensure that relevant parties in the community had adequate training to care for such children was also described i.e. discharging high-risk children without providing life-support training to caregivers; or expecting school nurses to provide care for which they have receiving no training e.g. tracheostomy care.

Examples

*Example 71: "Patient is a 3 year old with cerebral palsy. She requires feeding by gastrostomy tube. She will commence school nursery on 22 / 09. It has been reported that *** is refusing to fund education / training of school staff."*

Example 72: "Potential incident as training not taken place. Mum trained but CCN to visit to reinforce training and liaise with school nurse regarding: school training. 2nd home visit to reinforce training and mum updated about format school training, message left for school nurse to contact me for Epipen training. Training still hasn't taken place and care plan for school / medication still at home."

Example 73: "A child that requires oral suction was taken to school on borough transport. The escort had been trained to give oral suction. Mum told the escort that the suction was not working properly. Once on the school bus the child was sick again. Escort went to give oral suction and the pump was not working. School nurse to organise training for escort on emergency procedures. To advised if equipment faulty not to take child to school on school transport."

3.2.3.1.3 Child to adult transition

Issues with adolescents transitioning from child to adult care were evident from reports. Due to a lack of a unified definition of when an adolescent is considered an adult by the NHS, occasionally children (between 16-18 years in particular) were unable to access care as they were not classed as children by the child health service or as adults by the adult service. These issues were described for mental health services, community nursing, and the outpatient setting.

Examples

Example 74: "Patient contacted the children's community nursing Team to ask if one of the nurses would go out and give an injection that was due today. She has been discharged home with no appropriate referral and follow up care and instructions. She has also been discharged home from Adult Care services and should receive appropriate follow up with adult services as she is no longer a paediatric patient. District nurses have refused to provide any follow up care until this young lady is 18. This is the second incident that has happened to this young lady who is very sick."

Example 75: "Young adults who have been discharged from paediatric services are not being ' picked up ' by adult District Nursing Services. Young adults 16 / 17 / 18yrs are therefore at risk of having unsupported care in community unless a more formal agreement is in place to support young adults with health needs at home. No apparent service / pathway for young adults in transition phase Young adults at risk of harm if better support is not provided."

3.2.3.2 The role of caregivers

3.2.3.2.1 Caregivers as healthcare providers

In the community setting caregivers often act as healthcare providers- this was a prevalent sub-theme. Caregivers are responsible for recognising when their child is ill and deteriorating; seeking help on behalf of their child; during out-of-hours, via telephone triaging, they are responsible for assessing and triaging their child (guided by the telephone service); and they are often responsible for providing care and treatment in the community -including administering medication. Parental error- described often and permitted by the systems in place- was a key contributor to substandard care in the community. Conversely, parents were also described as preventing errors from reaching their child - which will be discussed further in the next section.

Examples

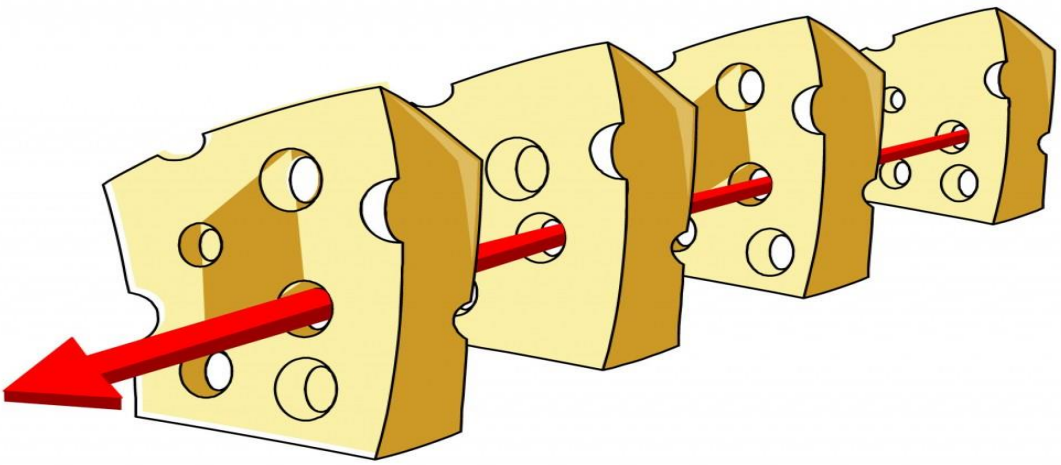
Example 76: "The parent took a copy of the prescription sheet to the GP who wrote out an FP10 prescription for the wrong dose. This was then taken to the local pharmacy and the medication was dispensed. It was the mother who noticed the error as the paediatrician had given her an instruction sheet detailing how much medication she should give."

Example 77: "Health Advisor answered ' no' to a rash that looked like bleeding or bruising when the child did have a mottled purple rash making the call a P3. HA read question addressing ' does she have a purple discolouration of the skin that looks like bruising or bleeding under the skin ' to which the mother responded 'no'."

Example 78: "After checking the patient record I labelled the prescription. I phoned the patient mother. She had removed the labels because they weren't right. She is a nurse and understands the dosage her daughter is taking. I re-dispensed the prescription and delivered the prescription."

3.2.3.2.2 Caregivers as safety nets

Several reports described parents as ‘error’ safety nets e.g. using Reason’s Swiss cheese model of harm, parents represented an additional layer of protection (or slice of cheese) (Reason J 1990;Walsh KE et al. 2005). Unwell children were in frequent contact with a variety of healthcare professionals responsible for different aspects of care; during and between these care encounters parents tended to be a constant presence i.e. the continuous and unifying factor (Berger Z et al. 2013).They are the expert with their own child, and engaged and informed parents were described as preventing incidents from reaching their child whereas less engaged more passive parents did not.



Examples

Example 79: "Patient had abdominal pain and vomiting, step - father went to see GP without patient for advice, GP then gave step - father prescription to collect. Prescription was for Propanolol reason not explained to step father mum read information leaflet and therefore did not give to her daughter. Felt to be an inappropriate prescription."

*Example 80: "*** is prescribed 1.5mg Risperidone at 18.00hrs. The dose and time for this medication is on her medication consent form and is signed by her mother. The nursing assistant practitioner commented that she thought *** was also being given Risperidone at school at 15.00hrs. *** is only supposed to have this medication 1 x daily. A phone call was made to the nursing team who confirmed that *** was having 1.5mg Risperidone at 15.00hrs whilst she was in school. Better communication needed between school nursing teams and community nursing team. Consent forms from parents must be continuously checked with them to ensure that children are receiving the correct medicines at the correct time. It needs to be reiterated to parents that they must inform community nursing staff of any changes to their child medication."*

3.2.3.3 Weaknesses in telephone-based assessments

3.2.3.3.1 Misunderstanding

Despite clear guidelines and protocols for telephone triaging of children, and robust training of healthcare professionals conducting these assessments, misunderstandings between caregivers and healthcare professionals via the telephone was a prevalent sub-theme. Healthcare professionals were described as misinterpreting the information provided by callers e.g. confusing medication enquiries and symptomatic calls which required triaging for referral. Similarly callers (typically parents) were described as misinterpreting assessment questions, providing incorrect answers to assessment questions, and generally misunderstanding advice provided by healthcare professionals over the telephone.

This partly overlaps with the previous theme (the role of caregivers) - this telephone-based system is dependent upon caregivers not only assessing their child but communicating that assessment effectively. Advice about fever management appeared particularly prone to miscommunication. Caregivers were reporting that healthcare professionals had provided inappropriate advice for fever management such as tepid sponging. On review some healthcare professionals were indeed providing this inappropriate advice-but some had provided appropriate advice that was misinterpreted.

Examples

Example 81: "Call placed in Health Information Queue as a medicines call which was a potential overdose of paracetamol."

Example 82: "I have listened to the call and it was correctly assessed by the Health Advisor. The call was a 999 after nurse assessment due to the fact that the child had a non - blanching rash. However, when asked by the health advisor if the child had a rash she was advised they didn't and therefore the call was correctly prioritised as a P3."

Example 83: "4 month old baby was feverish, had one pupil larger than the other and a hard fontanelle. Call was prioritised as a P2. There was approximately a 20 minute delay before the call was then assessed by a nurse. These symptoms were all potentially very serious so I called an ambulance without any further assessment. Health Advisor used 'generally unwell' protocol, and although he asked all the questions he did use any critical thinking when the mother commented that the child was " a little bit more dazed than usual "and" drowsy not with it " and therefore entered the incorrect answer to "are they able to respond normally to you now ". HA commented that he did not know that a hard fontanelle could be dangerous."

Example 84: "During assessment of call about child with ongoing fever and diarrhoea and vomiting, mother informed me that a nurse advisor had given advice yesterday to give ibuprofen and paracetamol at 2 hourly intervals for pain relief. Call listened to. The nurse advisor gave information regarding giving ibuprofen and paracetamol, but did not say to give them together at 2 hourly intervals. Advice given by the nurse was safe."

3.2.3.3.2 Protocolised medicine

The rigid protocols for healthcare providers conducting telephone assessment were themselves described as the source of some substandard care. Numerous reports described children who had been correctly triaged using the correct protocol but in whom the outcome was not adequate i.e. the algorithm advised self-care rather than attending emergency department. To prevent re-occurrence of these incidents callers were typically advised to use 'critical thinking' and to question the protocol outcome or seek advice when an outcome seems inappropriate. This is a flaw in the system which humans are expected to detect and compensate for. These health advisors were expected to know when to deviate from protocol.

Protocols were also described as the source of error when phone calls involved more than one child, were third party i.e. a neighbour phoning on behalf of a family without a phone, where symptoms were intermittent or not accounted for by a specific protocol, and where children had multiple issues and the health advisor was unclear which issue to use as the primary issue for triaging purposes. These often resulted in children not being triaged with the most appropriate protocol or being triaged incorrectly with the correct protocol.

Example 85: "Call concerning a baby under 2 months with worsening swelling in umbilical area - baby was crying and had been unwell all day. Nurse advisor used ' other symptoms ' algorithm instead of unwell baby under 3 month algorithm - she answered 2 questions and then downgraded the call from 'GP same day' to 'GP next working day'. The caller rang back a few hours later and swollen area was worsening, changing colour and baby still crying."

Example 86: "Mum reporting patient presenting with high temperature, fitting for 2 minutes and drowsiness. Patient has a history of fits. Inappropriate protocol chosen. Should have been assessed under 'fit' rather than 'fever' - as it would have covered all the correct questions and given correct end point."

3.2.4 Mixed methods synthesis of reported issues involving 'unwell children'

This section will discuss the relationship and links between the three overarching themes previously presented in section 3.2.3: provision of community care for complex patients; the role of caregivers; and weaknesses in the process of telephone assessment, and the quantitative findings reported in section 3.2.2.

3.2.4.1 Provision of care in the community and associated incidents

The sub-theme poor multidisciplinary collaboration was not associated with very harmful patient outcomes in terms of frequency or severity i.e. it was not implicated in any severe harms or deaths. Poor multidisciplinary collaboration was often associated with issues of transferring patient information between care settings (18% harmful) as well as documentation incidents e.g. medical records not being available (3% harmful). The main consequence described included fragmented knowledge about the patient between community team members. Communication incidents between healthcare professionals (19% harmful), such as inadequate handovers, were also implicated in poor multidisciplinary collaboration.

Poor preparedness for care in the community was associated with more harmful patient outcomes. This sub-theme included equipment-related incidents, which were 20% harmful though did not include any severe harms or deaths, e.g. not arranging appropriate care equipment for the home on discharge. Referral-related incidents, which were 35.7% harmful and included 7 severe harms and deaths, were associated with this sub-theme e.g. not referring to community nursing in a timely manner prior to discharge from hospital. In addition, incidents related to inadequate assessment for discharge, which were 50% harmful and included 2 severe harms and deaths, were associated with this sub-theme such as sending high-risk children home without providing caregivers with basic life support training or sending children home with an inadequate supply of medication.

This poor preparedness resulted in incidents related to treatment and procedures, which were 64% harmful and included 7 severe harms and deaths, e.g. children not receiving appropriate nursing care in the community; and medication incidents, which were 31.9% harmful including 8 severe harms and deaths, e.g. children being prescribed inadequate amounts of medications.

Issues related to transition from child to adult care was associated with several types of harmful incidents. This sub-theme was largely associated with administrative incidents such as inability to access services, which were 21% harmful. They were occasionally the result of referral incidents, which were 35.7% harmful such as adolescents being inappropriately referred to adult community nursing. However, at times they reflected a gap in services for this vulnerable age

group- this was described as resulting in treatment and procedure incidents (which were 64% harmful) e.g. not receiving necessary care.

3.2.4.2 The role of caregivers and associated incidents

This sub-theme was associated with several frequently and severely harmful incident types: diagnosis and assessment incidents (23.4% harmful which included 18 severe harms and deaths), communication with caregivers (19% harmful which included 2 severe harms), and medication incidents (31.9% harmful which included 8 severe harms and deaths).

The role of parents as healthcare providers was apparent in diagnosis and assessment incidents (particularly those related to inadequate triaging)- as they are responsible for providing accurate medical histories – and if assessment is telephone-based, parents are also responsible for assessing and examining their child.

Communication incidents between caregivers and healthcare professionals were also frequently associated with these incidents, as not only is the caregiver responsible for assessing their child, but they must also communicate that assessment, this child's history, and any concerns they may have effectively.

Parents were described as playing a prominent role in medication incidents either as partly being responsible for them, or mitigating them. In the community parents are frequently responsible for administering medications to their child- this was described as a source of error resulting in administration incidents- but it was also described as an opportunity where parents detected dispensing or prescribing errors – and therefore prevented them from reaching their child.

3.2.4.3 Weaknesses in the process of telephone-based assessment and associated incidents

Harmful incident types related to weaknesses in the process of telephone-based assessment included: diagnosis and assessment incidents which were 23.4% harmful and included 18 severe harms and deaths; and referral incidents which were 35.7% harmful and included 7 severe harms and deaths (Figure 25).

Diagnosis and assessment incidents (particularly those related to inadequate triaging and delayed assessment) were often the result of mismanaged telephone assessments. For example triaging an acutely unwell child with multiple symptoms using the wrong protocol (because the assessor is unsure which symptom to triage first e.g. fever or seizure) resulted in inadequate triaging. In addition inadequate triaging occasionally resulted in a child not being prioritised for further assessment, resulting in a delayed assessment. Referral incidents such as delayed referrals, failing to refer when appropriate and inappropriate referrals were described as the result of these assessment incidents. For example, as a result of inadequate triaging protocols, severely unwell children were referred to the out-of-hours GP service rather than the Emergency Department.

Communication incidents, particularly between callers (typically parents) and health care professionals, were prominently associated with this theme. Inadequate safety netting and failing to check callers' understanding were frequently described. Communication incidents resulted in some medication and treatment related incidents either because callers had received inappropriate treatment advice or had misunderstood appropriate advice resulting in them providing inappropriate treatment to their child-which was particularly noticeable for fever management.

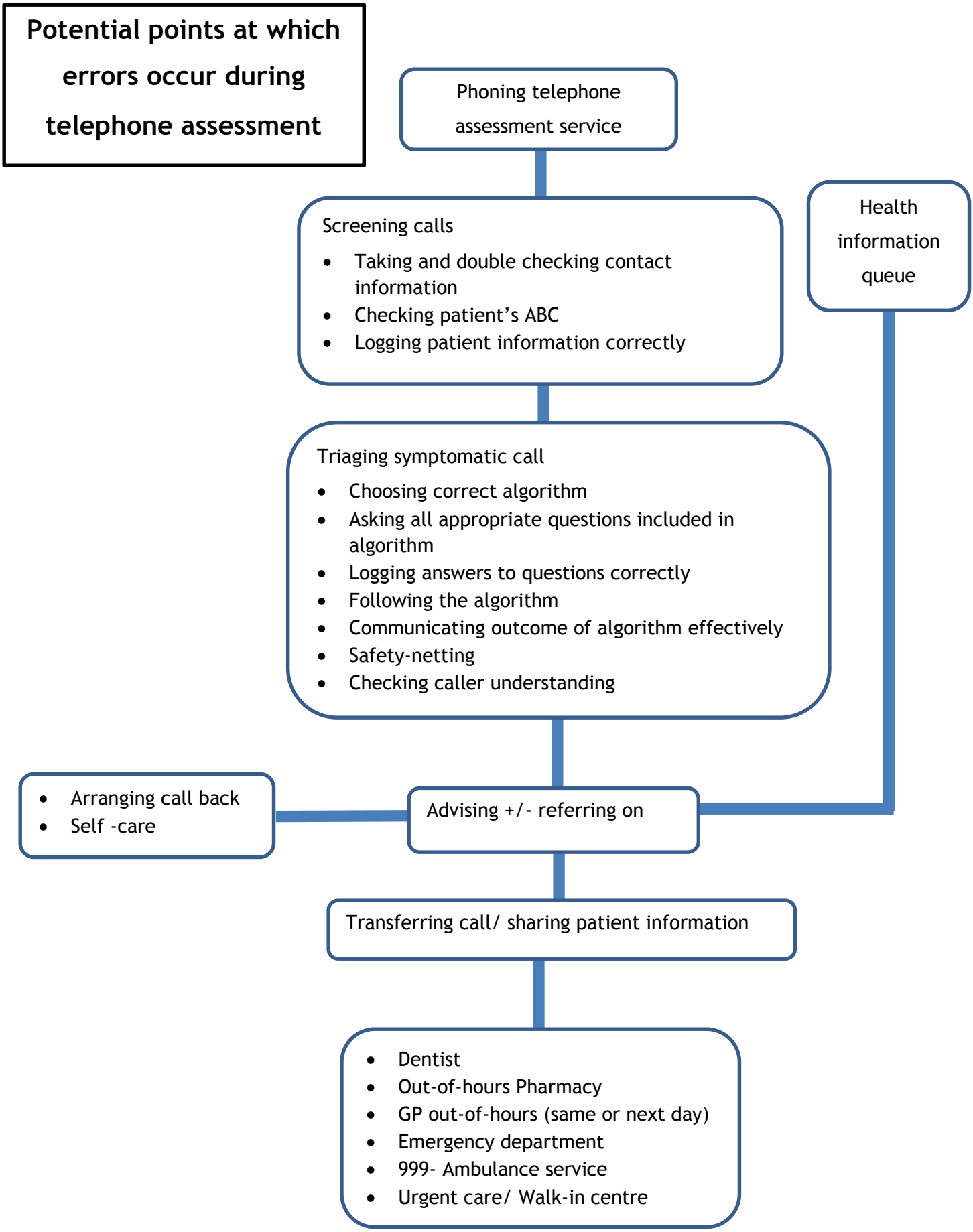


Figure 25 page 149: a visual model of the weakness in the telephone assessment system

3.2.5 Summary

Based on the burden (in terms of frequency and severity) and relative contribution of each incident type to subsequent incidents, the priority areas requiring improvement to reduce primary care-related harm to 'unwell' children include: medication-, diagnosis and assessment-, referral-, and communication-related incidents.

Children involved in medication-related incidents were largely less than one year old. These incidents were frequently related to medication dispensing, and the medications frequently involved included: anticonvulsants, bronchodilators or inhaled corticosteroids, or antimicrobials. These incidents were occasionally preceded by prescribing incidents, and were often the result of communication incidents and administrative issues. The most frequent contributory factors included staff mistakes and failure to follow protocols. These staff factors were often associated with inadequate working conditions and medication factors.

Most incidents related to diagnosis, assessment, referral, and communication were associated with telephone assessment issues, and were the result of similar contributory factors. Children involved in these incidents tended to be less than three years old, and had injuries, non-specific signs and symptoms such as fever, and skin conditions such as rashes.

A key theme, underlying many of the identified priority areas, was the contributory and sometimes protective role of parents. In the context of telephone assessments parents and caregivers were responsible for assessing the 'unwell' child and communicating their assessment effectively to the telephone advisor. Factors underlying these incidents were often related to issues with protocolised medicine including: failure to follow protocol (such as choosing the wrong assessment protocol) and failure to use critical thinking and challenge inappropriate protocol outcomes.

3.3 Literature review

The aim of this review is to identify potential and existing improvement interventions that may address the care quality issues identified in sections 3.1 and 3.2.

The research question addressed by this review is:

What improvement interventions have been proposed, tested, and/ or evaluated in primary or secondary care to address paediatric care quality issues in relation to:

3.3.2.2 Vaccination incidents
3.3.2.3 Medication incidents
3.3.2.4 Diagnosis and assessment incidents
3.3.2.5 Referral and management incidents
3.3.2.6 Communication incidents

3.3.1 Methods

3.3.1.1 Search strategy

A search strategy consisting of 33 keywords and Medical SubHeadings (MeSH) was designed in Medline Ovid and adapted for other databases. The search strategy was designed in three layers using terms for: the five priority areas (vaccination, mediation, diagnosis and assessment, referral, and communication) requiring improvement, child, and quality improvement (Appendix 3.3.1). The sensitivity of the search was limited to maximise specificity, for pragmatism. Searches of published literature were conducted across six databases: World of Knowledge, PsycINFO, HMIC (Health Management Information Consortium), EMBASE, Medline Ovid, and Medline in process and other non-indexed citations. Searches were limited to studies published after 2000 to ensure identified interventions were not out-dated. All references were exported to Endnote, where duplicates were removed.

3.3.1.2 Study selection

The titles and abstracts of all identified references were scanned for relevance and the full text of all those deemed potentially relevant was retrieved for further review. The student was the only reviewer involved in this process.

Studies of all designs were included: randomised controlled trials, cohort studies, cross-sectional studies, case control studies, interrupted time series, before and after studies, case series, and case reports (quality improvement reports and case studies). For inclusion: studies must have involved children aged less than 18 completed years, in primary or secondary care, and described an improvement intervention to address: vaccination-, medication-, diagnosis and assessment-, referral and management-, or communication-related incidents.

Due to the expected dearth of literature on quality improvement in primary care the student decided to include quality improvement literature from the hospital setting. Non-English studies were excluded, as well as abstracts, letters, and editorials. Studies related to increasing vaccine uptake; or to surgical, pathology or laboratory based diagnostic incidents were also excluded, as they are not relevant

to the priority areas identified as requiring improvement. Also studies from low-income countries, as defined by the World Bank in 2014, were excluded as they face different care quality challenges to the UK (World Bank 2014). Given that the purpose of this literature review was to identify improvement interventions regardless of the quality of evidence supporting them, studies were not excluded on the basis of methodological quality. However, the strength of interventions was appraised in terms of their potential to address conditions resulting in safety incidents. Strong interventions eliminate unsafe conditions by simplifying a process or removing unnecessary steps; intermediate interventions control unsafe conditions for example through developing checklists; and weak interventions accept unsafe conditions for example requiring medication double-checking.

The strength of interventions were graded using the U.S. Department of Veterans Affairs classification of strength of recommendations and these grades were corroborated by clinicians with human factors training (Morse RB and Pollack MM 2012).

3.3.1.3 Data extraction

Included studies were exported to a purpose built Microsoft Excel spread sheet, and the following variables extracted: author, year, title, study design, country, setting, priority area addressed, description of intervention(s) and the effectiveness of the intervention(s) if reported.

3.3.1.4 Data analysis

A narrative synthesis was undertaken of improvement interventions identified in relation to each of the five priority areas of interest.

3.3.2 Results

3.3.2.1 Overview of studies

Of 929 articles identified and scanned, 145 full text articles were reviewed, and 77 were included in the review (Figure 26; Appendix 3.3.3). Most were conducted in hospitals (n= 62); in the USA (n=43) or the UK (n=10); and were either interrupted time series (ITS) (n=46) or before and after studies (n=15). This review's findings are summarised by priority area in Table 26 and the characteristics of included studies are presented in Table 27.

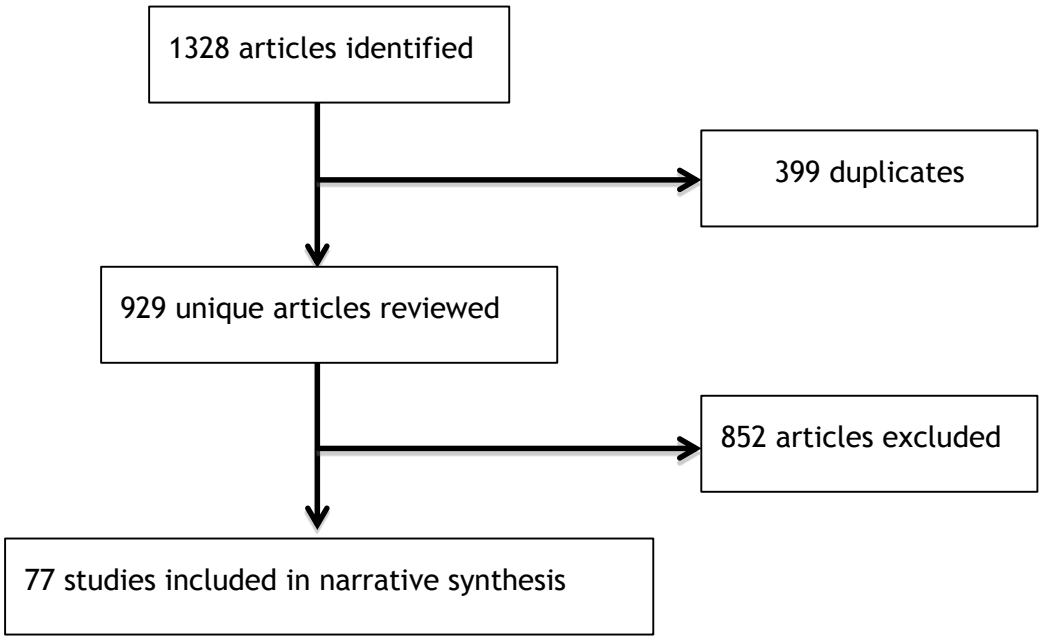


Figure 26 page 154: a flowchart demonstrating the literature review process.

Table 26 page 155: a summary of the interventions identified to address each priority area

Interventions and recommendations	Strength of intervention	References
Vaccines		
Electronic vaccine records	Strong/ intermediate	(Samuels RC et al. 2002)
Eliminate distractions (e.g. room re-arrangement)	Intermediate	(Neuspiel DR et al. 2011)
Designated person responsible for vaccination issues	Weak	(Samuels RC et al. 2002)
Co-location of pharmacists in vaccination clinics	Weak	(Haas-Gehres A et al. 2014)
Medications		
Computerised physician order entry +/- clinical decision support	Strong	(Abboud PA et al. 2006;Boling B et al. 2005;Brown CL et al. 2007;Cordero L et al. 2004;Di Pentima MC and Chan S 2010;Dinning C et al. 2005;Farrar K 2003;Fontan JE et al. 2003;Ginzburg R et al. 2009;Hain PD et al. 2007;Hilmas E et al. 2010;Holdsworth MT et al. 2007;Hyman D et al. 2012;Jani YH et al. 2010;Kadmon G et al. 2009;Kazemi A et al. 2011;Kim GR et al. 2006;Kirk RC et al. 2005;Lehmann CU et al. 2004;Lehmann CU et al. 2006;Lucas AJ 2004;Mullett CJ et al. 2001;Porter SC et al. 2008;Potts AL et al. 2004;Sard BE et al. 2008;Skouroliakou M et al. 2005;Sowan AK et al. 2010;Taylor JA et al. 2008;Walsh KE et al. 2008;Warrick C et al. 2011)
Bar-coding	Strong	(Morriss FH et al. 2009)
Pre-printed order sheets	Intermediate	(Alagha HZ et al. 2011;Broussard M et al. 2009;Burmester MK et al. 2008;Cimino MA et al. 2004;Cunningham S et al. 2008;Kozer E et al. 2005;Larose G et al. 2008;Robinson DL et al. 2006;Watts RG and Parsons K 2013)
Environmental changes (clear labelling/ storage to distinguish similar medications)	Intermediate	(Kaji AH et al. 2006;Sauberan JB et al. 2010;Sturgess E et al. 2011)
Education and training	Weak	(Abstoss KM et al. 2011;Alagha HZ et al.

		2011;Alemanni J et al. 2010;Bertsche T et al. 2010;Burmester MK et al. 2008;Campino A et al. 2009;Cimino MA et al. 2004;Davey AL et al. 2008;Eisenhut M et al. 2011;Kozer E et al. 2006;Leonard MS et al. 2006;Lope RJR et al. 2009;Pallás CR et al. 2007;Robinson DL et al. 2006;Sagy M 2009;Sullivan KM et al. 2013;Sullivan MM et al. 2010)
Increased pharmacist participation	Weak	(Condren M et al. 2014;Kalina M et al. 2009;Kaushal R et al. 2008;Otero P et al. 2008;Watts RG and Parsons K 2013)
Implementing protocols	Weak	(Sturgess E et al. 2011;Thomas C et al. 2011)
Publicising error rates	Weak	(Campino A et al. 2008;Sturgess E et al. 2011)
Verification procedures	Weak	(Watts RG and Parsons K 2013)
Diagnosis & assessment incidents		
Diagnostic decision support systems	Strong/ intermediate	(Ramnarayan P et al. 2006a;Ramnarayan P et al. 2004;Ramnarayan P et al. 2006b)
Use clinical guidelines/ algorithms/ diagnostic checklists	Intermediate	(Tabatabaei SA et al. 2012)
Point of care access to current evidence	Intermediate	(Ramnarayan P et al. 2006a;Ramnarayan P et al. 2004;Ramnarayan P et al. 2006b)
Referral		
Increased patient empowerment/ choice	Weak	(Messina FC et al. 2013)
Collaboration between referring and receiving clinicians	Weak	(Messina FC et al. 2013)
Communication		
Electronic handoffs linked to medical records	Strong	(Starmer AJ et al. 2013)
Standardised handoff templates/ tools/checklists	Intermediate	(Kim SW et al. 2012;Sahyoun C et al. 2013;Starmer AJ et al. 2013;Weingart C et al. 2013a)
Handoff mnemonic	Intermediate	(Starmer AJ et al. 2013)
Education and training	Weak	(Brock D et al. 2013;Hain PD et al. 2007;Starmer AJ et al. 2013;Weingart C et al. 2013a)
Huddles	Weak	(Kim SW et al. 2012)

Table 27 page 157: a summary of the key characteristics of included studies

First author	Year	Title	Study type	Hospital or primary care	Country	Priority area addressed	Interventions	Effectiveness
Abboud	2006	Impact of workflow-integrated corollary orders on aminoglycoside monitoring in children	ITS	Hospital	USA	Medication	CPOE with CDS	No (no significant difference)
Abstoss	2011	Increasing medication error reporting rates	Quality improvement report	Hospital	USA	Medication	1. A poster tracking 'days since last medication error resulting in harm', 2. A continuous slideshow showing performance metrics in the staff lounge 3. Multiple didactic curricula 4. Unit-wide e-mails summarising medication errors 5. CPOE 6. Unit-based pharmacy technicians for medication delivery 7. Patient safety report form streamlining	Yes (significant reduction in harmful medication errors (by 71% $p<0.01$)

Alagha	2011	Reducing prescribing errors in the paediatric intensive care unit: an experience from Egypt	ITS	Hospital	Egypt	Medication (prescribing)	1.Pre-printed order sheets 2.Education 3.Performance feedback	Yes (significant reduction in prescribing errors p<0.001)
Alemanni	2010	An assessment of drug administration compliance in a university hospital centre	ITS	Hospital	Canada	Medication (administering)	1.Education 2.Publicise error rates 3.Implement protocols	n/a

Bertsche	2010	Prospective pilot intervention study to prevent medication errors in drugs administered to children by mouth or gastric tube: a programme for nurses, physicians and parents	ITS	Hospital	Germany	Medication (administering)	Education programme for nurses and patients	Yes (significant reduction in administering errors ($p<0.001$)
Boling	2005	Effectiveness of computerized provider order entry with dose range checking on prescribing forms	ITS	Hospital	n/a	Medication (prescribing)	CPOE with CDS	No (non significant decrease in number of patients requiring antidotes for prescribed opioids benzodiazepines or potassium $p=0.17$)

Brock	2013	Inter-professional education in team communication	Before and after study (within subject)	Hospital	USA	Communication	Inter-professional communication training 1.Didactic teaching session 2.Simulated session where students observe, participate, and receive feedback on communication	It changed students' attitudes towards communication skills ($p<0.001$), their motivation to implement them ($p<0.001$), and self-efficacy ($p=0.005$). It also changed how they perceived the utility of these skills ($p<0.001$).
Broussard	2009	Pre-printed order sets as a safety intervention in pediatric sedation	ITS	Hospital	USA	Medication (prescribing)	Pre-printed order sheets	Yes (significant reduction in prescribing errors $p<0.05$)
Brown	2007	Error reduction when prescribing neonatal parenteral nutrition	ITS	Hospital	USA	Medication (prescribing)	CPOE	Yes (prescription errors significantly reduced $p=0.016$)
Burkhart	2005	An evaluation of children's metered-dose inhaler technique for asthma medications	ITS	Ambulatory care	n/a	Medication (administering)	Patient education on inhaler technique	Yes (significant reduction in administration errors $p<0.001$)

Burmester	2008	Interventions to reduce medication prescribing errors in a paediatric cardiac intensive care unit	ITS	Hospital	USA	Medication (prescribing)	1.Pre-printed order sheets 2.Physician education 3.Publicising error rates	Yes (significant reduction prescribing errors (p<0.001)
Campino	2009	Educational strategy to reduce medication errors in a neonatal intensive care unit	ITS	Hospital	Spain	Medication (prescribing)	1.Education 2.Standardised processes 3.Updated protocols	Yes (significant reduction in prescription errors p<0.001)
Campino	2008	Medication errors in a neonatal intensive care unit: influence of observation on the error rate	ITS	Hospital	Spain	Medication (prescribing and transcribing)	Reviewing data and registering error rates	Yes and no (significant reduction in prescribing errors p<0.001 and transcribing p=0.173)

Cimino	2004	Assessing medication prescribing errors in pediatric intensive care units	ITS	Hospital	USA	Medication (prescribing)	1.Pre-printed order sheets 2.Real-time feedback on errors 3.Education 4.Increased pharmacist staffing	Yes (significant reduction in prescribing errors p<0.001)
Condren	2014	Influence of a system based approach to prescribing errors in a pediatric resident clinic	Cross-sectional	Outpatients-clinic	USA	Medication (prescribing)	Pharmacist-led initiatives: 1. Daily prescription review 2. Provider feedback and education 3. EMR customisation: displayed weights in kg only; provided recommended doses; prepopulating instructions with dose frequency and quantity; prevented selection of certain formulations Other changes 4.Education sessions on drug dosing 5.Provided a dosing calculator to convert from mg per kg to ml (but the calculator was rounding up and down to nearest teaspoon)	Yes (the intervention clinic had an 11% error rate, and the comparison clinic had an error rate of 17.4% (P<.0012))

Cordero	2004	Impact of computerized physician order entry on clinical practice in a newborn intensive care unit	ITS	Hospital	USA	Medication (prescribing)	CPOE with CDS	n/a (no errors in intervention group 0/117 vs. 16/136 in comparison group)
Cunningham	2008	Effect of an integrated care pathway on acute asthma/wheeze in children attending hospital: cluster randomized trial	RCT	Hospital and ED	UK	Medication (prescribing)	1.Pre-printed order sheets 2.Integrated care-pathway	Yes (significant reduction in prescribing errors (p=0.002)
Davey	2008	Decreasing paediatric prescribing errors in a district general hospital	ITS	Hospital	UK	Medication (prescribing)	1.Education 2.Bedside prescribing guidelines	No reduction in prescribing errors

Di Pentima	2010	Impact of antimicrobial stewardship program on vancomycin use in a pediatric teaching hospital	ITS	Hospital	n/a	Medication (prescribing)	CPOE with CDS and real-time feedback	Yes (significantly reduced patient stay p<0.05)
Dinning	2005	Chemotherapy error reduction: a multidisciplinary approach to create templated order sets	Before and after	Hospital	USA	Medication (prescribing)	CPOE and pre-printed order sheets	Yes (prescription errors significantly reduced p<0.0001)
Eisenhut	2011	Reducing prescribing errors in paediatric patients by assessment and feedback targeted at prescribers	ITS	Hospital	UK	Medication (prescribing)	Education	N/a (prescribing errors in intervention group 120/588 vs. comparator group 188/421)

Farrar	2003	Use of structured paediatric prescribing screens to reduce the risk of medication errors in the care of children	ITS	n/a	n/a	Medication (prescribing)	CPOE with CDS	n/a (7 errors in intervention group 7/114 vs. 46/103 in comparator group)
Fontan	2003	Medication errors in hospitals: computerized unit dose drug dispensing system versus ward stock distribution system	Before and after	Hospital	France	Medication (prescribing and administering)	CPOE and unit dose drug distribution system	Yes (significant reduction in prescribing errors <0.0001, and administering errors (p<0.001)
Ginzburg	2009	Effect of a weight-based prescribing method within an electronic health record on prescribing errors	ITS	Ambulatory	USA	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in paracetamol or ibuprofen prescription errors p=0.002)

Gokmen-Ozel	2010	Errors in emergency feeds in inherited metabolic disorders: a randomised controlled trial of three preparation methods	RCT	Ambulatory	UK	Medication (dispensing)	Use pre-measured bags of glucose	Yes (significant reduction in dispensing errors (p=0.03)
Haas-Gehres	2003	Impact of pharmacist integration in a pediatric primary care clinic on vaccination errors	Cross-sectional	Primary care	USA	Vaccination	Pharmacist integration in clinic	Yes significant difference in vaccine error rates between clinics, and the intervention clinic had significantly lower rates of missed vaccination opportunities.(timeliness issues)

Hain	2007	Using risk management files to identify and address causative factors associated with adverse events in pediatrics	Cross-sectional	Paediatrics (inpatient and outpatient)	USA	Communication and Medication	1.Crew resource management to improve inter professional communication 2.CPOE 3.Targeted education and feedback to caregivers of high risk children	n/a
Hilmas	2010	Implementation and evaluation of a comprehensive system to deliver pediatric continuous infusion medications with standardized concentrations	ITS	Hospital	USA	Medication (prescribing)	1.CPOE with CDS 2.Standardised medication concentrations 3.Education	n/a (no errors in intervention group (0/200) vs. 98/200 errors in comparison group)

Holdsworth	2007	Impact of computerised prescriber order entry on the incidence of adverse drug events in pediatric inpatients	ITS	Hospital	USA	Medication	CPOE with CDS	Yes (significant reduction in total adverse drug events RR:0.64 (95%CI: 0.43-0.95))
Hyman	2012	The use of patient pictures and verification screens to reduce CPOE errors	Before and after	Hospital and primary care	USA	Medication	Order verification screen that includes patient photograph (to reduce CPOE errors)	Yes (25% reduction in patient ID errors from n=51 in 2010 to n=37 in 2011; and a 75% reduction in the number of ordering errors)
Jani	2010	Paediatric dosing errors before and after electronic prescribing	ITS	Hospital and ambulatory (outpatient clinics)	n/a	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in prescribing errors p=0.001)

Kadmon	2009	Computerized order entry with limited decision support to prevent prescription errors in a PICU	ITS	Hospital	Israel	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in prescribing errors p<0.001)
Kaji	2006	Emergency medical services system changes reduce pediatric epinephrine dosing errors in the prehospital setting	ITS	Ambulatory	USA	Medication (administering)	Colour coded tape for medications requiring weight-based dosing	Yes (significant reduction in administering errors 95% CI:1.4-6.6

Kalina	2009	A multidisciplinary approach to adverse drug events in pediatric trauma patients in an adult trauma center	ITS	Hospital and ED	USA	Medication (prescribing and administering)	MDT to care for paediatric patients	Yes (significant reduction in prescribing errors p=0.05 and administering errors p=0.05)
Kaushal	2008	Unit-based clinical pharmacists' prevention of serious medication errors in pediatric inpatients	Before and after	Hospital	USA	Medication	increased pharmacist involvement in drug therapy	n/a (errors in intervention group 25/3107 vs. 45/3331 in comparison group)

Kazemi	2011	The effect of computerized physician order entry and decision support system on medication errors in the neonatal ward: experiences from an Iranian teaching hospital	ITS	Hospital	Iran	Medication (prescribing and transcribing)	CPOE with CDS	Yes and no (significant reduction in prescribing errors $p<0.001$ but not transcribing errors)
Kim	2012	Interdisciplinary development and implementation of communication checklist for postoperative management of pediatric airway patients	Evaluation	Hospital	USA	Communication	Communication checklist and huddles	Yes- communication errors decreased significantly

Kim	2006	Error reduction in pediatric chemotherapy: computerized order entry and failure modes and effects analysis	ITS	Hospital	USA	Medication (prescribing)	CPOE with CDS	No (163/5918 errors in intervention group vs. 157/4978 in comparator group)
Kirk	2005	Computer calculated dose in paediatric prescribing	Before and after	Hospital ED and ambulatory	Singapore	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in prescribing errors (95% CI 0.34-0.52)
Kozer	2006	The effect of a short tutorial on the incidence of prescribing errors in pediatric emergency care	Before and after	ED	Canada	Medication (prescribing)	Education	No (no significant decrease in prescribing errors CI:0.66-1.7)

Kozer	2005	Using a preprinted order sheet to reduce prescription errors in a pediatric emergency department: a randomized controlled trial	RCT	ED	Canada	Medication (prescribing)	Pre-printed order sheets	Yes (significant reduction in prescribing errors CI:0.34-0.9)
Larose	2008	Quality of orders for medication in the resuscitation room of a pediatric emergency department	ITS	ED	n/a	Medication (prescribing and administering)	Pre-printed order sheets	Yes (significant reduction in prescribing errors 95% CI: 3-10% and administering errors 95% CI: 1-6%)
Lehmann	2004	Preventing provider errors: online total parenteral nutrition calculator	ITS	Hospital	USA	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in prescribing errors ($p<0.001$)

Lehmann	2006	Decreasing errors in pediatric continuous intravenous infusions	ITS	Hospital	USA	Medication (prescribing)	CPOE with CDS	n/a (prescribing errors in intervention group 8/142 vs. comparator group 35/129)
Leonard	2006	Risk reduction for adverse drug events through sequential implementation of patient safety initiatives in a children's hospital	ITS	Hospital	USA	Medication (prescribing)	1.Education 2.Zero tolerance policy 3.Prescriber feedback 4.Publicise error rates	Yes (significant reduction in prescribing errors p=0.001)
Lope	2009	A quality assurance study on the administration of medication by nurses in a neonatal intensive care unit	ITS	Hospital	Malaysia	Medication (administering)	Education	n/a

Lucas	2004	Improving medication safety in a neonatal intensive care unit	Evaluation	Hospital	USA	Medication	CPOE	n/a
MacDonald	2006	Home delivery of dietary products in inherited metabolic disorders reduces prescription and dispensing errors	Before and after	Ambulatory	UK	Medication (dispensing)	Home delivery of products	Yes (significant reduction in dispensing errors $p<0.05$)
Messina	2013	Improving specialty care follow-up after and ED visit using a unique referral system	Before and after	Hospital	USA	Referral	New referral mechanism: 1. ED physician telephones specialist to agree referral, accept specific treatment instructions, and agree on a referral time frame (i.e. urgency) 2. Referral request put into electronic medial record (includes time frame) 3. Patient chooses appointment time and date (of those available in an appropriate clinic within an appropriate time frame)	n/a (80% of those aged<18years kept their appointments)

Morriss	2009	Effectiveness of a barcode medication administration system in reducing preventable adverse drug events in a neonatal intensive care unit: a prospective cohort study	ITS	Hospital	USA	Medication	Barcode scanning	Yes (significant reduction in medication errors p<0.001)
Mullett	2001	Development and impact of a computerized pediatric anti-infective decision support program	ITS	Hospital	USA	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in prescription errors p<0.001)

Neuspiel	2011	Improving reporting of outpatient pediatric medical errors	ITS	Ambulatory care	USA	Vaccination	Eliminate distractions: 1.Use standing orders 2.Re-design room	n/a
Otero	2008	Medication errors in pediatric inpatients: prevalence and results of a prevention program	ITS	Hospital	Argentina	Medication (prescribing and administering)	1.Increased pharmacist participation in ordering 2.Education 3.Reduce interruptions	Yes (significant reduction in prescription errors p<0.05 and administering errors p<0.05)
Pallas	2007	Improving the quality of medical prescriptions in neonatal units	ITS	Hospital	Spain	Medication (prescribing)	1.Education 2.Dose calculation software	Yes (significant reduction in prescribing errors CI: 0.26-0.34)
Porter	2008	Impact of a patient-centered technology on medication errors during pediatric emergency care	Before and after	ED	USA	Medication	Parent-entered data given to provider with treatment recommendations	No (no significant reduction in medication errors p=0.42)

Potts	2004	Computerized physician order entry and medication errors in a pediatric critical care unit	ITS	Hospital	USA	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in prescription errors p<0.001)
Ramnarayan	2006	Assessment of the potential impact of a reminder system on the reduction of diagnostic errors: a quasi-experimental study	Quasi experimental	Hospital	UK	Diagnosis and assessment	Diagnostic reminder system- computerised decision support system (DSS)	Yes (significant decrease in diagnostic errors of omission p<0.001 (within person); and the mean diagnostic quality score increased (within person))
Ramnarayan	2004	ISABEL: a novel approach to the reduction of medical error	Description	Hospital	UK	Diagnosis and assessment	Computerised decision support system (DSS)- ISABEL contains: 1.A differential diagnosis tool 2.Clinical algorithms 3.MRCPCH exam guidance 4.A section to document lessons learned from clinical errors	n/a (it was 90% accurate on evaluation)

Ramnarayan	2006	Diagnostic omission errors in acute paediatric practice: impact of a reminder system on decision-making	Before and after study (within subject)	Hospital (paediatric ambulatory care)	UK	Diagnosis and assessment	Diagnostic reminders- computerised decision support system (DSS)	Yes (it significantly reduced the number of 'unsafe' workups p<0.001; and the number of 'unsafe' workups per case (p<0.001)
Robinson	2006	Using failure mode and effects analysis for safe administration of chemotherapy to hospitalized children with cancer	ITS	Hospital	n/a	Medication (prescribing)	1.Pre-printed order sheets 2.Education 3.Policy creation 4.Chemotherapy certification	n/a (prescribing errors in intervention group 31/221 vs. comparison group 77/331)
Sagy	2009	Optimizing patient care processes in a children's hospital using Six Sigma	ITS	Hospital	USA	Medication (prescribing)	Education	Yes (significant reduction in prescribing errors p<0.05)

Sahyoun	2013	Early identification of children at risk for critical care	Evaluation	Hospital	USA	Communication	Standard communication template	N/a- They looked at the tools sensitivity in detecting children requiring ICU not its affect on errors.
Samuels	2002	Improving accuracy in a computerized immunization registry	Before and after	Primary care	USA	Vaccination	1. A single person took responsibility for all vaccination-related issues 2. A clerk printed out each patients computerised immunisation record before scheduled visits and attached it to the chart (for use as a data entry form)- allowing them to ID mistakes and make corrections to the database	Yes- documentation errors significantly decreased
Sard	2008	Retrospective evaluation of a computerized physician order entry adaptation to prevent prescribing errors in a pediatric emergency department	ITS	ED	USA	Medication (prescribing)	CPOE with CDS	Yes (significant reduction prescribing errors $p<0.001$)

Sauberan	2010	Origins of and solutions for neonatal medication-dispensing errors	Case studies	Hospital	USA	Medication	1.Storage solutions e.g. store paediatric and adult formulations separately, do not store alphabetically 2.Colour labelling scheme-to distinguish medications with similar packaging	n/a
Skouroliakou	2005	Computer assisted total parenteral nutrition for pre-term and sick term neonates	Before and after	Hospital	Greece	Medication (prescribing)	CPOE with CDS	Yes (significant reduction in prescribing errors $p<0.0001$)
Sowan	2010	Computerized orders with standardized concentrations decrease dispensing errors of continuous infusion medications for pediatrics	Crossover	Hospital	USA	Medication	CPOE	Yes (significant reduction infusion order errors $p<0.03$)

Starmer	2013	Rates of medical errors and preventable adverse events among hospitalised children following implementation of a resident handoff bundle	Before and after	Hospital	USA	Communication	Handoff bundle 1.Communication skills training session (based on TEAM STEPPS) and interactive discussion session 2.Mnemonic (SIGNOUT?) 3.Restructured handoffs- integrated interns' and senior residents' handoffs, moved to quiet and private locations, and all handovers were overseen by chief resident or attending physician 4.Computerised handoff tool linked to the electronic medical records	Yes (significantly reduced medical errors ($p<0.001$) and preventable adverse events ($p=0.04$)
Sullivan	2013	Personalised performance feedback reduces narcotic prescription errors in a NICU	Quality improvement report	Hospital	USA	Medication	Personalised performance feedback	Yes (83% reduction in pharmacist intercepted narcotic prescribing errors)

Sullivan	2010	Impact of an interactive online nursing educational module on insulin errors in hospitalized pediatric patients	ITS	Hospital	USA	Medication (administering)	Education	Yes (significant reduction in administering errors p<0.001)
Tabatabaei	2012	Assessment of a new algorithm in the management of acute respiratory tract infections in children	Description	Hospital	Iran	Diagnosis and assessment; and Medication	Algorithm for diagnosing and treating children with respiratory symptoms	n/a

Taylor	2008	Medication administration variances before and after implementation of computerized physician order entry in a neonatal intensive care unit	ITS	Hospital	USA	Medication (administering)	CPOE with CDS	Yes (95%CI: 0.3-0.8)
Thomas	2011	The impact of the introduction of a gentamicin pathway	ITS	Hospital	UK	Medication (administering and monitoring)	Standardising processes and updating protocols	Yes (significant reduction in administering errors(p=0.02 and monitoring errors p=0.04)
Walsh	2008	Effect of computer order entry on prevention of serious medication errors in hospitalized children	ITS	Hospital	USA	Medication	CPOE with CDS	No (medication errors increased but not significantly)

Warrick	2011	A clinical information system reduces medication errors in paediatric intensive care	ITS	Hospital	UK	Medication (prescribing and administering)	CPOE	Yes and no (significant reduction in administering errors ($p<0.05$ but no prescribing errors 12/257 in intervention group vs. 14/159 in comparison group)
Watts	2013	Chemotherapy medication errors	Cohort	Hospital	USA	Medication	A multi-disciplinary pharmacy-associated error tracking system and chemotherapy safety initiative 1.Better formatted and colour coded outpatient order form 2.A mandatory therapy roadmap with all chemotherapy orders 3.Double-signature on every chemotherapy order 4.Pharmacist and nurse routinely check orders prior to administration 5.Pharmacy standardised drug dilutions 6.MDT review of therapy roadmaps 7.CPOE (proposed) 8.Provide individual feedback (proposed)	Yes (error rate fell by >50%)

Weingart	2013	Making good better	Before and after	Transport handoff to hospital	USA	Communication	Handoff bundle (education component and a standardised scripted handoff process)	Yes (measured provider satisfaction) $p<0.05$

3.3.2.2 Interventions for vaccination incidents

Childhood vaccination-related improvement was the focus of three included studies: these were all from primary care (Haas-Gehres A et al. 2014;Neuspiel DR et al. 2011;Samuels RC et al. 2002).

One article discussed improving the accuracy of vaccination-related documentation. Samuels RC et al. 2002 assessed the effectiveness of an intervention aimed at improving the accuracy of electronic vaccination records. In a before and after study they evaluated the effect of a two-pronged intervention. Firstly they allocated responsibility for all vaccination-related issues to one 'designated' person. Secondly they implemented a new process: all patients' computerised vaccination records were printed and attached to patients' charts before scheduled appointments, acting as data entry forms and allowing identification and correction of mistakes in the computerised database.

Neuspiel DR et al. 2011 propose elimination of distractions to reduce cognitive lapses i.e. mistakes which may result in vaccine administration errors. In addition Neuspiel DR et al. 2011 redesigned the vaccine room to facilitate access to the vaccination registry. .

Haas-Gehres A et al. 2014 compared the effect of pharmacist integration in a paediatric primary care clinic, with a clinic that had no pharmacy service, on vaccine errors and 'missed vaccination opportunities'. Pharmacists regularly reviewed all charts and educated healthcare professionals and parents on appropriate immunisation use. Co-location of pharmacists in this manner significantly reduced the number of vaccination errors in the intervention clinic $p=0.0021$), and significantly reduced the number of 'missed' vaccination opportunities ($p<0.001$)- increasing the timeliness of vaccination.

3.3.2.3 Interventions for medication incidents

Of 64 studies focusing on reducing medication incidents, 57 were in the hospital setting.

3.3.2.3.1 Computerised physician order entry (CPOE) with or without clinical decision support (CDS)

Of the 64 studies on medication incidents, 27 described CPOE. CPOE is a term used for a computerised system used by physicians to order medications. Compared to traditional manual ordering systems, electronic systems ensure that prescriptions are complete and legible with less reliance on accurate transcription (Kaushal R et al. 2001;Rinke ML et al. 2014). CPOE systems are often combined with clinical decision support (CDS) that assesses the safety of the prescribed medications (using various algorithms) in relation to the patient's age, weight, medical history, lab results, and other prescribed medications. The CDS alerts the physician to any potential safety concerns such as interactions between medications or contraindications (Kaushal R et al. 2001).

These systems can also include forcing functions that prevent certain safety alerts from being over-ridden by physicians and ordering of certain medications e.g. preventing certain chemotherapy medications from being ordered for intrathecal administration. However CPOE systems are not error proof. Hyman D et al. 2012 tested the effect of an order verification screen–that contained patient photographs–on medication errors by aiming to improve patient identification.

Studies comparing CPOE without CDS to manual order entry reported a 44-88% reduction in prescribing error rates (Brown CL et al. 2007;Dinning C et al. 2005;Fontan JE et al. 2003;Warrick C et al. 2011) and a 21-88% reduction in administration error rates (Fontan JE et al. 2003;Warrick C et al. 2011). Whereas those evaluating the effect of CPOE and CDS on all types of medication errors in inpatients saw between a 19% increase in errors (which was not statistically significant) and a 100% reduction (Abboud PA et al. 2006;Cordero L et al. 2004;Di Pentima MC and Chan S 2010;Hilmas E et al. 2010;Jani YH et al. 2010;Kadmon G et al. 2009;Kazemi A et al. 2011;Lehmann CU et al. 2004;Lehmann CU et al. 2006;Mullett CJ et al. 2001;Potts AL et al. 2004;Rinke ML et al. 2014;Skouroliakou

M et al. 2005;Walsh KE et al. 2008). This included studies analysing all prescribing errors in inpatients, those on PICU, and those related to parenteral nutrition, anti-infective medications, and continuous infusions. Studies comparing CPOE with CDS to CPOE without CDS reported a 36-87% reduction in all prescribing errors, and specifically a 59% reduction in paracetamol and ibuprofen prescribing errors in ambulatory care (Farrar K 2003;Ginzburg R et al. 2009;Kazemi A et al. 2011;Kirk RC et al. 2005;Rinke ML et al. 2014;Sard BE et al. 2008).

3.3.2.3.2 Educational interventions

Educational interventions aimed at parents, patients, nurses, residents, and office clerks to reduce prescribing, dispensing, and administering errors were described by 17 included studies. These took the form of online tutorials, educational websites, pharmacist-led tutorials, lectures, pamphlets, practical/ simulated training sessions, and tests/ competency exams with personalised feedback on correct and incorrect answers. Alagha HZ et al. 2011 and Davey AL et al. 2008 designed point of care prescribing guidelines, i.e. dosing sheets of the most commonly used intravenous, oral and inhaled medications were available at every patient bedside.

Studies which solely evaluated the effect of educational interventions, for over three months, found an 8-87% reduction in prescribing errors, a 14-81% reduction in administering and dispensing errors and a 49-87% reduction in any type of medication error (Alemanni J et al. 2010;Bertsche T et al. 2010;Burkhart PV et al. 2005;Campino A et al. 2009;Davey AL et al. 2008;Eisenhut M et al. 2011;Kozer E et al. 2006;Leonard MS et al. 2006;Lope RJR et al. 2009;Pallás CR et al. 2007;Rinke ML et al. 2014;Sagy M 2009;Sullivan MM et al. 2010).

3.3.2.3.3 Pre-printed order sheets

Pre-printed order sheets contain formatted and pre-allocated fields that aim to decrease medication errors by increasing the completeness of hand-written medication order forms. Included studies (n=9) used pre-printed order sheets for in-patient prescribing but also specifically in relation to intensive care patients, emergency department patients, and chemotherapy prescribing. They reported a reduction in prescribing errors of between 27-82% (Alagha HZ et al. 2011;Broussard

M et al. 2009;Burmester MK et al. 2008;Cimino MA et al. 2004;Cunningham S et al. 2008;Dinning C et al. 2005;Kozer E et al. 2005;Larose G et al. 2008;Rinke ML et al. 2014;Robinson DL et al. 2006).

3.3.2.3.4 Increased pharmacist participation

Several studies (n=5) proposed increasing pharmacist participation to reduce medication errors e.g. by having ward-based pharmacists who participate in physician ward rounds and monitor drug dispensing, storage and administering. Cimino MA et al. 2004, Kaushal R et al. 2008, and Otero P et al. 2008 reported a 17-50% reduction in medication errors.

3.3.2.3.5 Medication barcoding

Barcoding of medications has been described to reduce dispensing and administering errors (Kaushal R et al. 2001). Barcoding medications enables automation of the prescription filling process and facilitates staff to rapidly match the correct medication to the correct patient during administration. For example, on scanning the medication its name, dose, route, intended patient, and staff members involved in its prescription, dispensing and administration are immediately visible (Kaushal R et al. 2001). These interventions have largely been evaluated for adult patients, however Morriss et al. 2009 reported a significant reduction ($p<0.001$) in all types of medication errors (ordering, transcribing, dispensing, administering, and monitoring) in the intensive care setting after implementing barcode scanning for medication administration.

3.3.2.3.6 Other interventions

Additional interventions proposed or tested by studies include: environmental changes such as changing the storage of medications or using coloured tape to distinguish similar medications; publicising error rates – to improve and maintain awareness; implementing new protocols; and verification procedures i.e. double-checking (Gokmen-Ozel H et al. 2010;Kaji AH et al. 2006;MacDonald A et al. 2006;Sturgess E et al. 2011;Thomas C et al. 2011;Watts RG and Parsons K 2013).

3.3.2.4 Interventions for diagnosis and assessment incidents

All four studies focusing on diagnosis and assessment incidents were in the hospital setting. Interventions to reduce diagnostic and assessment errors were centred on 'getting help' (Graber ML et al. 2012).

Graber et al. 2012 described 'getting help' as key to reducing cognitive burden and improving decision-making. This included having point-of-care access to current evidence-based knowledge; and using decision aids such as diagnostic checklists, diagnostic decision support systems including computerised algorithms, and clinical guidelines..

3.3.2.5 Interventions for referral incidents

One study described an intervention to improve hospital referrals (Messina FC et al. 2013). They developed a new mechanism for emergency care providers to refer on to specialists. This involved the emergency physician agreeing upon a referral plan with the specialist before discharge, noting this conversation and referral in the patient's electronic medical record, and allowing the patient to select a convenient appointment (in the agreed clinic within the agreed time frame). The aim was to improve appointment compliance, and although no figures were provided for the compliance of patients aged < 18 years before this study, post-intervention compliance was high at 80%.

3.3.2.6 Interventions for communication incidents

All seven studies proposing or evaluating interventions to improve communication focused on improving inter-professional communication (Brock D et al. 2013;Gronczewski CA 2005;Hain PD et al. 2007;Kim SW et al. 2012;Sahyoun C et al. 2013;Starmer AJ et al. 2013;Weingart C et al. 2013b). Most were hospital based (n=4) or involved the primary-hospital care interface (n=2); and most studies tested or evaluated interventions (n=6).
Educational interventions were described by Brock D et al. 2013, Starmer AJ et al. 2013 and Weingart C et al. 2013. The educational sessions implemented by Brock et al. 2013 and Starmer AJ et al. 2013 were based on the programme developed by

the Agency for Healthcare Research and Quality and the USA Department of Defence: Team Strategies, and Tools to Enhance Performance and Patient Safety (TeamSTEPPS). This approach stemmed from airlines that use crew resource management, which Hain PD et al. 2007 also implemented with an aim of reducing inter-professional communication errors (although its effect was not evaluated).

Brock et al. D 2013 evaluated the impact of a multidisciplinary educational intervention where students observed, practiced and received feedback on communication in a simulated environment, evaluating effects on student attitudes, motivation and self-efficacy towards communication skills. However Starmer AJ et al. 2013 and Weingart C et al. 2013 implemented educational interventions as part of handoff 'bundles' i.e. they tested the intervention in clinical practice rather than a simulated environment. Interventions are typically combined in a 'bundle' where it is believed that they complement each other and will be more effective together than individually.

Several studies standardised communication templates to address handoff communication errors (Kim SW et al. 2012;Sahyoun C et al. 2013;Starmer AJ et al. 2013;Weingart C et al. 2013a). Kim SW et al. 2012 implemented team 'huddles' in conjunction with a handoff checklist to ensure that patient care was handed over to the receiving team rather than from one professional to another. They saw a significant decrease in communication errors, although no specific figures were available to support this statement. Handing over to the multi-disciplinary team provided the team with an opportunity to summarise what they had understood from the handover, challenge any ambiguities, and plan for any potential patient deterioration.

Starmer AJ et al. 2013 described the most effective and comprehensive handoff bundle. It consisted of three key components: a communication training session; introduction of a handoff mnemonic (SIGNOUT?)[59] to standardise handoffs; and restructured verbal handoffs–interns and senior residents conducted handoffs together somewhere quiet, private and supervised by a chief resident or attending physician. Also, one unit linked electronic handoff documents to patient medial records. This handoff bundle significantly reduced medical errors ($p<0.001$) and

[59] SIGNOUT? Sick or not for resuscitation, Identifying patient information, General hospital course, New events today, Overall health status, Upcoming possibilities, Tasks for completion, Any Questions.

preventable adverse events (p=0.04); in addition to increasing the time spent by physicians at the patient's bedside.

3.3.3 Discussion

3.3.3.1 Summary of findings

This review identified 77 studies, which described, tested, and / or evaluated a wide range of interventions to reduce: vaccination-; medication-; diagnosis and assessment-; referral-; and communication-related safety incidents.

Two studies reported a reduction in vaccination incidents by co-locating pharmacists in vaccination clinics, use of electronic vaccine records, and having a designated person responsible for vaccination issues.

Several studies reported a reduction in medication errors in response to using: CPOE and CDS; increasing pharmacist participation in medication ordering and ward rounds; pre-printed medication order sheets; and barcoding of medications to reduce medication errors.

Four studies focusing on diagnosis and assessment incidents tested or evaluated interventions such as diagnostic decision support tools. Few interventions were identified to reduce referral incidents. There was considerable support for various interventions to reduce communication errors such as: education and training, standardised handoff templates tools or checklists, and handoff mnemonics that were incorporated into a handoff bundle.

3.3.3.2 Strengths and limitations

The purpose of the literature review was to identify potential interventions that could address the priority areas requiring improvement, rather than to formally evaluate the improvement literature. Therefore, despite conducting this literature review systematically and rigorously it cannot be considered a 'systematic review'. The student was the only reviewer of identified articles and the only data extractor. In addition, the search strategy was not designed for maximal recall: its sensitivity was limited to maximise precision.

Evaluations of improvement interventions are often not to the standard of traditional effectiveness studies. In addition, as a result of broad inclusion criteria, included studies were heterogeneous in terms of their design, population, and aims.

The implications of this review's findings in relation to creating recommendations for practice and further research will be discussed in Chapter 5.

Chapter 4: Discussion of methods

4.1 Summary

Broadly this study aimed to address two questions:

- What paediatric safety incidents in primary care, involving vaccination, and the management of 'unwell' children, are occurring in practice and are reported to the NRLS?

- How can safety problems involving paediatric vaccination and the management of 'unwell' children be addressed?

The student sought to address these questions by analysing incident report data. This involved designing a search strategy for maximum recall of relevant reports; systematically capturing the content described within the free-text elements of reports; capturing the nuanced and context-specific issues present but not explicitly described within reports; and subsequently analysing this large 'processed' data set to identify learning.

4.2 Searching the NRLS data

The search strategy was dependent on reports specifying a patient age of <18 years and containing at least one key word permutation. The list of key words was developed to be as sensitive as possible but within practical limits for numbers identified. Searches were conducted in Microsoft Excel, however the specificity of searches could have been enhanced if software permitting the use of search strings containing Boolean operators had been available. Unfortunately, a notable number of reports (n=139,847; 51.2%) some of which likely involved children, did not specify patient age, and therefore would not have been retrieved for free-text searching. In hindsight the number of paediatric-related reports identified for free-text searching could have been increased with free-text searches to identify child-specific characteristics, and through using manual filters to identify additional reports in child-specific locations such as schools.

4.3 Data processing

During the student's previous pilot work with the NRLS dataset it became apparent that existing taxonomies used for classifying patient safety incidents were inadequate (Rees P et al. 2015). The level of detail of other taxonomies was insufficient and they were not grounded in UK primary care data, which limited their utility. The student therefore developed three taxonomies to describe incident types, contributory factors, and incident outcomes.

These taxonomies were developed iteratively: they were regularly amended and updated as more reports were read and different learning emerged, and are therefore grounded in UK paediatric-related primary care data. However, existing taxonomies, such as Learning from International Networks about Errors and Understanding Safety in Primary Care (LINNEAUS Euro-PC) and the WHO International Classification for Patient Safety, did at a high level, inform the taxonomies used in this study (World Health Organisation 2009). For example, the student used the "five rights" of medication administration: right medication, right patient, right dose, right route, and right time, but supplemented it with more detailed codes such as right formulation and right number of doses (Kron T 1962). This similarity will facilitate comparisons between previous and future studies in this area.

To structure the application of codes from the taxonomies, the student used the Recursive Model of Incident Analysis developed by the Australian Patient Safety Foundation (Hibbert PD et al. 2007). This allows the incident, the factors leading to the incident (i.e. other incidents and contributory factors), and the outcomes of the incident to be captured systematically, by coding these factors in chronological order. Following training, this model ensures reproducibility between coders and allows the rich detailed descriptions to be coded, rather than reduced and summarised. This model permits detailed data processing, unlike other models of incident analysis that traditionally find one 'best fit' category in which to place the incident, even if multiple incidents are described. Also, other models tend not to clearly distinguish between contributory factors and incidents (Hibbert PD et al. 2007).

During data processing the student noted all medications involved in incidents and where applicable the signs, symptoms or diagnoses present in children involved in

safety incidents. Capturing this supplemental information provided additional structured variable data, for a more in-depth analysis of the data than previous studies of this nature: as the pre-allocated medication fields are often incomplete, and signs, symptoms, and diagnoses, are not routinely captured by incident reporting systems. Using ICD-10 to classify the 'types of illness' present in children involved in incidents will also permit corroboration of this study's findings with future primary care case note reviews (the funding for which has recently been secured by the Division of Population Medicine, Cardiff University, in collaboration with Nottingham University et al.).

The NRLS does not collect information on patient disease; this information is therefore only present if reporters include it in the free-text descriptions of incidents. Therefore, the reports included in this study may not be a true reflection of all reported incidents involving 'unwell' children in primary care. Additionally this likely compromised the comprehensiveness and accuracy at which illnesses described by included reports could be classified using ICD-10. This may also be responsible for the notably high number of included incidents involving acutely unwell children. The student hypothesises that incidents involving acutely unwell children may be more likely to contain descriptions of 'illness', permitting detection during free-text searches and classification with ICD-10, than incidents involving children with chronic conditions.

4.4 Data analysis

Using the Recursive Model of Incident Analysis resulted in a complex and in-depth characterisation of reports. This allowed modelling of the complex sequence of events leading to and resulting from an incident. In turn this allowed me to examine the sequences of 'codes' and the relationships between variables using frequency distributions and cross-tabulations. To the student's knowledge few studies have analysed the events described within incident report data in this level of detail. This exploratory approach to quantitative analysis is arguably a more flexible and comprehensive approach to analysing incident report data, allowing hypotheses to be generated, rather than rigidly testing pre-formed hypotheses as done in other studies (Alexander DC et al. 2009;Bundy DG et al. 2008;Bundy DG et al. 2009;Rinke ML et al. 2010).

4.5 Thematic analysis

Supplementing quantitative analysis with thematic analysis of a purposive sample of reports provided greater insight than data processing could have alone. It enabled examination of contextual insights that would otherwise have gone un-noted. However, in retrospect it was possible to capture most of the information contained within reports using the structured coding frameworks.

In previous work with NRLS data the student had not systematically captured variables such as 'medications involved in incidents' and 'diagnoses'. Thematic analysis (aimed at examining factors not detected by the frameworks) was a useful method of exploring and not overlooking these important factors. However during this study, the scope of thematic analysis to identify 'new' contextual insights was limited as the quantitative analysis was very detailed.

4.6 Reflection on alternative approaches and methods

If the student were to do the study again, she would have done it in three parts: a case note review, incident report data analysis, and supplementary root cause analysis.

Analysis of incident report data provided in-depth learning about the nature of unsafe care in practice sufficient to address the research question. However, this study's findings are unlikely to be representative of what occurs in practice, hence the need for a case note review.

To conduct a case note review, the student would first (through consensus methods) have piloted a UK-specific paediatric trigger tool for primary care. A case note review would allow me to gain a handle on the true priority areas in primary care requiring improvement, as the findings would be representative of what occurs in practice and would also therefore be generalisable. More in-depth information could be retrieved using this method, permitting more reliable, comprehensive, and accurate classification of patient outcomes including harm severity, and patient characteristics including social status, presentation, and pre-existing diagnoses. This approach would permit identification of the most harmful incidents in primary care (in terms of frequency and severity). Also, this approach

would enable risk modelling, whereby the association between patient characteristics and safety incidents or healthcare harm could be analysed. Case note reviews have well-publicised attributes – they provide generalisable and comprehensive information about 'what' occurs in practice. However, they are unable to provide in-depth information on contributory factors, 'why' safety incidents are occurring in practice, hence the need for incident report analysis. Analysis of incident report data, as done in this study, would be necessary, to address the priority areas identified through case note review and to design interventions to mitigate particularly harmful safety incidents.

A key and unique attribute of incident report data is its ability to provide vast quantities of comprehensive and relatively detailed information on the contributory factors pre-disposing to safety incidents, as perceived by reporters. Analysing incident report data allows identification of patterns of incidents and contributory factors underlying safety incidents, which can be targeted by improvement interventions.

Unfortunately reporters do not routinely receive human factors or root cause analysis training. Therefore they are unlikely to comprehensively detect and report the system factors and root causes of incidents, they are more likely to report human-factors that are more readily apparent to them. To overcome this selective deposit bias and to supplement the information gained from incident report data, the student would conduct a root cause analysis of a sample of the most complex and harmful safety incidents. This would ensure that system issues underlying safety incidents are not overlooked and are adequately targeted by interventions.

Chapter 5: Discussion of findings

This chapter will summarise and discuss key findings related to: vaccination failures presented in section 3.1, and diagnosis, assessment, referral, and communication failures involving 'unwell' children presented in section 3.2, in the context of current literature. Recommendations for improvement in these areas, informed by the interventions identified in section 3.3, will be presented. This chapter will conclude with recommendations for future research to improve understanding of the problems identified by this study, and to further inform changes to policy and practice to improve primary care for children.

5.1 Discussion of vaccination-related findings

5.1.1 Summary

Most reported vaccination-related incidents were in younger children especially those aged less than one year old. The most frequently reported vaccination incidents were related to administration, including the wrong number of doses, wrong timing, and wrong vaccine. Other frequently reported incidents involved adverse reactions to vaccines and communication failures with parents and caregivers. The reported reasons for these incidents included documentation failures, appointment management problems, staff mistakes such as confusing similar vaccines, staff failing to follow protocols such as preparing more than one vaccine concurrently, and patient/ caregiver factors such as inappropriate behaviour and ill-health. Parents and caregivers played an important role in contributing to and preventing vaccination-related incidents, and vulnerable children such those in care (without parents to advocate for them) appeared disproportionately vulnerable to vaccination-related incidents.

5.1.2 Context of current literature

The frequency of reports describing administration of the wrong number of doses is unsurprising, because they are errors of commission i.e. as a result of actions taken, and are therefore typically apparent to the healthcare professionals involved, and therefore likely to be reported (World Health Organisation 2009). This finding also mirrors the literature, which highlights that receiving additional vaccines is a prevalent issue and often the result of inadequate documentation (Bundy DG et al. 2009;Feikema SM et al. 2000;Weltermann BM et al. 2014). A study conducted by Feikema SM et al. 2000, highlights that 20% of children in the USA receive unnecessary duplicate vaccinations.

The study contained numerous reports of delayed vaccination or receipt of vaccines out-of-sync with the national vaccination schedule. The consequences of delayed vaccination are well acknowledged in the literature, a Confidential Enquiry of child deaths related to primary care identified vaccination timeliness as a priority area requiring improvement (Derrough TF and Kitchin NR 2002;Harnden A et al. 2009;Vivier PM et al. 1999). Errors of omission, as result of actions not taken, are more difficult to detect and less likely to be reported, therefore the three child deaths detected in the study may represent a much larger body of children

who have not received vaccinations and thus vulnerable to life-threatening diseases (World Health Organisation 2009). The potentially harmful consequences of deviating from the national vaccination schedule, which is specifically developed by experts to afford children maximum protection and to minimise the risk of vaccine interactions, are unclear (Bundy DG et al. 2009;Derrough TF and Kitchin NR 2002;Vivier PM et al. 1999).

Administration of the wrong vaccine is a widespread and well-recognised problem (Bundy DG et al. 2009;National Patient Safety Agency 2004;National Patient Safety Agency 2008;Weltermann BM et al. 2014). Other studies in this area report staff confusing vaccines with similar names or packaging, as an important cause of these errors, which mirrors this study's findings (Bundy DG et al. 2009;Makeham MAB et al. 2004;National Patient Safety Agency 2004). Fortunately in the student's study no cases of severe harm or death were described as a result of administration of the wrong vaccine. However these data potentially reflect the tip of the iceberg, and of note, WHO guidelines have highlighted several case reports of severe harm or death in children who received the wrong vaccination (World Health Organisation 2014). Of concern, are children who are under-protected and whose inadequate immunity is also unrecognised, for example they received the wrong vaccine but the error went undetected.

Other studies highlight the potentially severe consequences of vaccination incidents involving live vaccines and medically vulnerable children, such as those present in the student's study. For example, a 2007 case report describes an immunocompromised child who develops severe varicella after receiving a live varicella vaccine (which was contraindicated) (Jean-Philippe P et al. 2007).

Socially vulnerable children appeared disproportionately prone to reported vaccination-related incidents, implying that the inverse care law, where those most in need of high quality care are the least likely to receive it, may be an existing problem in this context (Hart JT 1971). Vaccination uptake in socially vulnerable children is well described as sub-optimal in the literature (Barnes P et al. 2005;Webb E et al. 2001;Williams J et al. 2001). However the vulnerability of these children to vaccination-related incidents, such as receiving the wrong vaccine, is not well-publicised, this may partly be due to the difficult nature of conducting research in marginalised populations (Webb E 2004).

5.1.3 Recommendations for improvement

Recommendations to improve vaccination in children are centred on four underlying and contributory weaknesses: reducing staff mistakes; minimising documentation and appointment failures; improving caregiver knowledge; and improving staff knowledge.

Manufacturing-targeted recommendations include encouraging manufacturers to create vaccines with different packaging and names, or at least to continue using tall man lettering with the aim of reducing staff mistakes (Filik R et al. 2006;Levine SR et al. 2001).

At a policy level, electronic red books that are accessible to caregivers and staff could reduce documentation discrepancies by eliminating the current system, where three types of vaccination records exist, and staff would not be dependent on caregivers to bring red books to appointments. This could prove particularly beneficial to looked-after children who were frequently without red books in this study. CDS software could be incorporated into these electronic books, whereby warnings about vaccines contraindicated for each child appear on the screen acting as a reminder for healthcare professionals and caregivers.

Education-level recommendations to reduce incidents in medically vulnerable children include providing staff with feedback on the learning generated from vaccination-related reports raised locally, and educating caregivers and staff about vaccine contraindications and the potentially fatal consequences of receiving contraindicated vaccines. Additionally, encouraging caregiver involvement, and creating a culture where caregivers feel comfortable challenging healthcare professionals, could prevent safety incidents. At a practice level, to reduce staff mistakes, staff must adhere to verification and standardised preparation procedures.

5.2 Discussion of medication-related findings

5.2.1 Summary

Children aged less than one year typically experienced medication incidents. These children were being treated for epilepsy, asthma, and various infections. Most incidents were related to dispensing or administering of medications, and prescribing incidents often preceded them. Reasons for these incidents included communication failures between staff or with patients or caregivers, and administrative (paper-work) issues. Underlying staff factors included failure to follow protocols, mistakes, and inadequate knowledge. Patient and caregiver factors included age-specific factors (such as weight-based dosing), poor knowledge, and inappropriate behaviour. These were often compounded by medication factors such as adjacent storage of similar medications, and organisational factors such as busy working conditions or inadequate care plans for treatment of chronic conditions.

5.2.2 Context of current literature

Medication errors are believed to be the most common type of medical error in children and adults (Department of Health 2000;Department of Health 2001;Kohn LT et al. 1999;Wong IC et al. 2009). Avery AJ et al. 2013 report that children under 15 years old have an 87% excess risk of a prescribing error in UK general practice, compared to those aged 15-64, and others report that medication errors are three times more prevalent in children than adults (Kaushal R et al. 2001;Wong IC et al. 2009). Therefore this study's finding, that medication incidents are the most frequent type of reported safety incident involving 'unwell' children, is in keeping with the literature.

The ages of children involved in reported medication incidents was as expected, as similar trends are reported in the literature where younger children are more prone to medication errors (Koren G et al. 1986;Koren G and Haslam RH 1994;Smith MD et al. 2014;Wong IC et al. 2009). A national study of medication errors in young children in the USA reports that children aged <1 year are responsible for 25.2% of reported incidents in those aged less than six years (Smith MD et al. 2014). In addition, Smith MD et al. 2014 report that these younger children are also more likely to suffer severe harm from medication incidents, which is reflective of this study's findings. They hypothesise that younger children's limited ability to communicate may account for the inverse association between error rate and age.

This study's findings partially reflect those reported by Smith MD et al. 2014 where reported out-of-hospital medication errors in children aged < 6 years in the USA most frequently involved analgesics, cough and cold medications, antihistamines, and antimicrobials. However, anti-epileptic and asthma medications were the most frequent types of medications involved in medication errors in this study. Differences could be the result of international variation, differences in study populations, or unsystematic reporting bias present in both studies. Antimicrobials are one the most frequently reported class of medications responsible for adverse reactions resulting in hospital admission, and are reported as the class of medications most frequently involved in medication errors (Ghaleb MA et al. 2006;Smyth RM et al. 2012). This may be partly due to how frequently they are prescribed in practice (Ghaleb MA et al. 2006).

A recent study of medication prescribing errors in UK general practice report considerably different findings in terms of the risk of error associated with medication class (Avery AJ et al. 2013). Avery et al. 2013 report that patients (children and adults) were most at risk of error if they were prescribed musculoskeletal, malignancy, immunology/ vaccines, or skin medications. Medications were classified using the British National Formulary (as done for the student's study) however their population included adults and children, which, in conjunction with reporting bias, may explain the differences in the medication types involved in incidents (Avery AJ et al. 2013). In addition Avery AJ et al. 2013 had a narrower focus, prescribing errors in general practice, compared to this study, which focused on all medication errors reported in primary care.

The high frequency of asthma-related medication incidents was anticipated since asthma is the most common chronic condition of childhood in the UK, and a recent report highlights severe failures in the management of childhood asthma in the community (Asthma UK 2015). Asthma UK estimate that approximately 12,000 children with asthma experienced a prescribing incident between 2010-2013, and that approximately 2000 children have been prescribed long acting beta agonists alone (without inhaled steroids) putting them at risk of a severe asthma attack. Whilst the student's study's findings reflect some of these widely reported issues, it also highlights the importance of dispensing errors, which are less widely reported in this group of children.

Several studies highlight the importance of clear communication with caregivers and patients to prevent medication errors (Stebbing C et al. 2007;Wong IC et al. 2006;Wong IC et al. 2009). Walsh KE et al. 2013 highlight the contribution of communication failures with parents to home-based medication errors. In the community setting, where parents are responsible for understanding their child's treatment plan and administering the correct medication, at the correct dose, via the correct route, and at the correct time, suboptimal communication about this process increases vulnerability to medication errors (Walsh KE et al. 2011;Walsh KE et al. 2013).

A UK epilepsy review found that poor communication with parents and caregivers prompted numerous medication administration errors (Royal College of Paediatrics and Child Health 2013). Typical examples include dosing errors as a result of: confusing mg and ml and confusing different formulations of buccal midazolam (Royal College of Paediatrics and Child Health 2013). Other examples in the literature of communication failures resulting in medication errors include: failing to explain treatment plan changes and to provide written management plans for caregivers, resulting in them continuing to administer medications according to an old treatment regime. In addition, failure to communicate the importance of regularly checking expiry dates of infrequently used *pro re nata* (PRN) medications, is described as resulting in administration of expired medications (Walsh KE et al. 2011).

The national epilepsy review found that only 77% of children with epilepsy had an emergency plan for seizure management, and only 26% had a school health plan (Royal College of Paediatrics and Child Health 2013). Failing to provide a written management plan also predisposes to communication errors between caregivers, which have been reported as resulting in medication administration errors (Walsh KE et al. 2011).

The UK epilepsy review also highlights a lack of evidence of collaboration with young patients in current practice (Royal College of Paediatrics and Child Health 2013). This study highlights the importance of involving caregivers and patients in discussions about their treatment plan, and supports the model put forward by Walsh KE et al. 2011 that describes parents and caregivers as a final layer of

protection for children from medication errors. However, there is a paucity of literature on the role of parents in preventing or contributing to medical errors (Walsh KE et al. 2011).

Avery AJ et al. 2013 report that many inter-related contributory factors underpin prescribing errors in UK general practice including: prescriber training, knowledge and experience of specific medications and patients, risk perception, patient characteristics, team collaboration, GPs signing nurse generated prescriptions without seeing the patient, poor working conditions including time pressures and interruptions, and computer-related issues. Several of these factors were also present in the student's study. Poor working conditions were an important reported factor, not only in general practice but also in community pharmacies, other important reported factors include inadequate staff knowledge about certain medications and patient characteristics such as age.

Staff failure to follow protocol was common described as contributing to medication incidents, and although failure to follow National Institute of Health and Care Excellence or Scottish Intercollegiate Guidelines Network (SIGN) epilepsy treatment protocols was uncommon in the national epilepsy review, compliance was noted as sub-optimal.

5.2.3 Recommendations for improvement

The electronic prescription service (a form of CPOE) was rolled out in UK General Practice in 2005 and is now widely used. Introduction of such technology may have reduced certain types of medical error, as it did in the paediatric in-patient setting, but its impact on safety must be regularly evaluated, as it may predispose to IT-related medical errors at the human-machine interface (Conroy S et al. 2007;Walsh KE et al. 2005;Wong IC et al. 2009). The electronic prescription service could be improved with better linkage to patient records, enabling more sensitive detection of medication contraindications specific to each patient, and by incorporating more rigid forcing functions into it e.g. to stop prescribers ignoring or overriding certain high-risk safety alerts (Kaushal R et al. 2001).

Although prescribing errors often preceded reported dispensing errors, errors at the prescribing-dispensing interface were more frequent i.e. the prescription was correct but a dispensing error occurred. Electronic transmission of prescriptions

from the prescriber to the dispensing community pharmacy has been proposed to address errors at the prescribing-dispensing interface. However, if not implemented correctly medication errors could increase, as highlighted by a recent review of this technology in UK primary care (Franklin BD et al. 2014).

Education and training of all pharmacy staff, in human factors for example, would facilitate staff to recognise error prone-areas of their practice, and to strengthen those areas (Campino A et al. 2009;Kaji AH et al. 2006;Leonard MS et al. 2006;Levine SR et al. 2001;Sturgess E et al. 2011;Sullivan MM et al. 2010). Providing staff with the tools to address safety problems themselves is a more effective and flexible way to address problems that may be specific to their pharmacy.
Implementation of a barcoding system for all dispensed medication could reduce the potential for human error, by acting as an additional safety check prior to giving the patient their medication (Kaushal R et al. 2001;Morriss FH et al. 2009;Poon EG et al. 2010).

Publicising community pharmacy error rates could also facilitate medication error reduction, as transparency incentivises improvement (Sturgess E et al. 2011). This form of feedback could encourage competition between pharmacies and help to create a culture of openness and shared learning where the more error-prone pharmacies learn from the 'safer' pharmacies (Eisenhut M et al. 2011;Leonard MS et al. 2006).

Children with chronic conditions requiring regular treatment, such as those with epilepsy, should have written management plans that are accessible to all relevant parties. The RCPCH have since launched an epilepsy passport to improve clarity about epilepsy management, including any changes to the treatment plan, to improve continuity of care for children seeing multiple professionals.

5.3 Discussion of diagnosis-, assessment-, referral-, and communication-related findings

5.3.1 Summary

A considerable proportion of diagnosis and assessment-, referral-, and communication-related incidents were associated with telephone assessments, and underpinned by similar factors requiring attention. Therefore, in this section, these incidents will be considered together in the context of current literature and recommendations for improvement.

Diagnosis, assessment, referral, and communication incidents were most commonly reported in younger children (less than three years old), presenting acutely with injuries, non-specific signs and symptoms such as fever and altered consciousness, and skin conditions such as rashes and discolouration.

These 'unwell' children frequently experienced inadequate telephone triaging, and delays in assessment and referral. Incidents underpinning diagnosis, assessment and referral failures included: communication incidents and other assessment failures, particularly inadequate history taking. Communication incidents (primary incidents and those contributing to diagnosis, assessment and subsequent referral incidents) were related to inadequate safety netting, and provision of the wrong advice to caregivers during telephone assessment.

Caregivers were described as playing an important role in incidents related to telephone assessment. They contributed to incidents through poor interpretation of their child's conditions, and subsequent communication of that inappropriate interpretation to the telephone assessor. However they also prevented incidents by challenging the management decisions of staff. Other factors contributing to telephone assessment failures were related to issues with protocolised medicine, including failing to follow protocols such as those related to safety netting, failures of the protocols themselves, and poor staff critical thinking whilst using the protocols.

5.3.2 Context of current literature

5.3.2.1 Telephone assessment

The finding that younger children were more prone to reported failures involving diagnosis, assessment, referral, and communication is not unexpected and likely reflects: differences in physiological reserve and speed of deterioration, differences in disease epidemiology, communication difficulties, and dependency of younger children on caregivers to recognise illness (Walsh KE et al. 2014;Wolfe I et al. 2011). In addition, considering the high proportion of incidents involving telephone assessment and that those under-5 years old are the highest users of NHS direct (contributing to 25% of all calls), it is unsurprising that most diagnosis, assessment, referral, and communication incidents in this study involved younger children (Cook EJ et al. 2013).

Problems with telephone assessment (which occasionally resulted in referral incidents) were prevalent in this dataset, and concerns about the safety of telephone triaging are echoed in the literature (Derkx HP et al. 2008;Giesen P et al. 2007;Huibers L et al. 2011;McLellan N 1999;McLellan N 2004;O'Cathain A et al. 2003;Smits M et al. 2010;Stewart B et al. 2006). Given the focus of this study, 'unwell' children in primary care, and considering that NHS direct handles over 500,000 calls a month with up to 40% involving children, numerous reports of telephone assessment problems were anticipated (McLellan N 2004;Stewart B et al. 2006).

Safe telephone assessment involves correctly determining the urgency of the child's condition, and subsequently giving appropriate management advice, which may involve referral to emergency services. A systematic review of telephone triaging conducted by Huibers L et al. 2011, highlights that approximately 10% of calls are unsafe, and that patients presenting with highly urgent symptoms may be particularly vulnerable to unsafe care. Triaging incidents in the student's study included both under and overestimation of urgency. Derkx HP et al. 2008 highlight similar issues with telephone triaging, and that in 41% of calls urgency is underestimated, and that in 1% urgency is overestimated. Overestimating the urgency of a child's condition is also a safety concern as it may result in unnecessary referrals and further investigations (Cook R et al. 2010).

The high number of incidents involving young children with injuries, non-specific signs and symptoms, and skin conditions described in this dataset, is in keeping with the literature (Cook EJ et al. 2015;Cook EJ et al. 2013). Cook EJ et al. 2013 highlight that most NHS direct calls involving children are for: crying (1.01 calls/100 population per annum), skin hand or nail conditions (0.9 calls/ 100 population per annum), cold flu or sickness (0.77 calls/100 population per annum), and wounds and injuries (0.67 calls/ 100 population per annum).

Paediatricians have expressed concern about the use of telephone assessment for children due to the non-specific nature of many childhood illnesses, in addition to dependency on caregivers to observe their child and most importantly to interpret their observations and communicate those interpretations effectively (McLellan N 1999;McLellan N 2004;Stewart B et al. 2006). The student's study supports these concerns, because misunderstandings between caregivers and professionals over the telephone, such as misunderstanding fever management advice or the difference between a blanching and non-blanching rash, were frequent.

Many highlight issues with the CDS used by NHS direct, particularly in relation to assessing the urgency of children's conditions (McLellan N 1999;McLellan N 2004;Stewart B et al. 2006). CDS software is designed to minimise risk by improving the consistency of assessment and decision making during telephone triaging, but they also reduce professional autonomy, a factor underlying many incidents in this study (McLellan N 2004;O'Cathain A et al. 2003). However, the trade-off between their sensitivity to urgent presentations requiring emergency management, and their specificity (to exclude non urgent cases from referral to emergency services), and their responsiveness to contextual information, is contentious and dependant on the CDS software used. Many argue that it is unclear whether CDS can compensate for inadequate knowledge and clinical paediatric experience (Doctor K et al. 2014;Leprohon J and Patel VL 1995;McLellan N 1999;McLellan N 2004;Monaghan R et al. 2003;O'Cathain A et al. 2003).

Staff are able to submit suggested improvements to the CDS software and calls are regularly audited against minimum quality standards. However, without evaluating, on a large scale, the outcomes of children triaged via this process, it is unclear whether auditors can reliably detect inadequacies in the CDS software.

Huibers L et al. 2011 highlight the importance of good quality history taking to inform triaging decisions, a factor which commonly contributed to triaging incidents in this study. Healthcare professionals' ability to assess and manage 'unwell' children is influenced by their experience and professional background. Monaghan R et al. 2003 highlight differences in triaging practices between general nurses and children's nurses (Pettinari CJ and Jessopp L 2001;Smith S 2010). Despite this, only 1% of professionals employed by NHS direct have a background in paediatrics (McLellan N 2004). It is therefore unsurprising that in relation to paediatric triaging, nurses are reluctant to deviate from and challenge the triaging protocols and algorithms. This was reflected by the high number of reports describing poor staff critical thinking as contributing to diagnosis, assessment, and referral incidents. Smith S 2010 also reiterates that clinical reasoning (i.e. critical thinking and adherence to guidelines and protocols) frequently underpins safety failures related to triaging, diagnosis and treatment in primary care out-of-hours.

5.3.2.2 Safety netting

Communication incidents involving caregivers were frequently related to: misunderstandings between caregivers (callers) and professionals, the use of inappropriate triaging protocols, or not following protocols or safety netting guidelines. Derkx HP et al. 2008 also report problems with misinterpretation of callers' responses to triaging questions leading to assessment incidents. Despite communication incidents being highlighted as a priority area requiring improvement in primary care, there is a paucity of literature on the topic, particularly in relation to telephone triaging-related communication errors involving caregivers (Cresswell KM et al. 2013;Rees P et al. 2015). However, NHS direct safety netting has been described as generic and not specific to the child or family (Roland D et al. 2014).

5.3.2.3 Role of caregivers

The role of patients and caregivers in preventing safety incidents, although not a new concept in healthcare quality and safety, has been relatively underexplored in the literature (Berger Z et al. 2013;Walsh KE et al. 2005). Roland D et al. 2014 theorise that, providing comprehensive safety netting advice, that includes

information on diagnostic probabilities and uncertainties, could empower patients and caregivers to challenge the diagnostic process as they feel is necessary. They believe that educating patients in this manner will improve their understanding of the process, and additionally encourage them to provide pertinent information, for example about the history of their presentation, which may otherwise have been overlooked. Educating caregivers in this manner is supported by a randomised controlled trial, which reports improved identification of serious symptoms in educated patients (McCarthy PL et al. 1990).

Parents are often disempowered by healthcare, despite having the potential to be a valuable asset in their child's care(Graedon J and Graedon T 2006;Neill SJ 2010;Titcombe J 2015). Parents are a reasonably constant presence in their child's life, they know their child's normal behaviour and temperament, and are particularly astute observers when their child is unwell (Brady PW et al. 2014;Graedon J and Graedon T 2006). Titcombe J 2015 argues that parents will "always have continuity and context on their side", we must therefore not overlook their opinion. They are important allies. The role of caregivers is being increasingly valued in healthcare: many paediatric early warning scores take into account parental concern as an indicator of the severity of a child's illness, and Birmingham Children's Hospital permit parents to write in the child's medical notes (Roland D 2015;Roland D et al. 2013;Sen AI et al. 2013;Titcombe J 2015).

Brady PW et al. 2014 demonstrate the value of involving parents in the hospital care process by allowing them to directly activate the rapid response team. They report that families use the system responsibly, there are few unnecessary activations, 24% of activations result in intensive care transfers, and fewer cardiorespiratory arrests occur.

5.3.4 Recommendations to improve telephone assessment

5.3.4.1 Education and training

Mandatory paediatric training for all trainee GPs, to increase their tacit knowledge through experiential learning, is imperative to improve the detection of seriously unwell children presenting in person or via the telephone to general practice (Rees P et al. 2015;Wolfe I et al. 2011). All healthcare professionals in contact with children should be familiar with the 'spotting the sick child' website, and complete the online modules as part of their continuing professional development. NHS direct (now NHS 111) calls are regularly audited and the results of that audit are fed back to staff, peer-review rather than senior-review of calls could help reviewers and those being reviewed to maintain high standards and prevent them from developing poor habits over time (Graber ML et al. 2012;Singh H et al. 2010;Thammasitboon S and Cutrer WB 2013).

All healthcare professionals, whether GPs or telephone assessment staff, should be made aware of error-prone areas of practice, such as triaging the wrong symptom in a child with multiple symptoms over the telephone (Graber ML et al. 2012;Singh H et al. 2010;Thammasitboon S and Cutrer WB 2013).

5.3.4.2 Teamwork/ collaboration

This study supports re-organisation of general practice for children into child health hubs, which is currently being piloted in some parts of the UK (Wolfe I et al. 2011). This involves co-locating paediatricians, GPs with an interest in paediatrics, and other members of the multi-disciplinary team, enabling integrated care and increasing the support and expertise readily available to professionals caring for children in the community, in and out of hours.

5.3.4.3 Amend protocols

Telephone assessment protocols should be regularly reviewed and updated. It is insufficient to depend on professionals to detect and report inadequacies in the CDS software, particularly when they are unaware of patient outcomes. The outcomes of children assessed via the telephone should be regularly reviewed

(rather than simply auditing the calls themselves) to assess the adequacy of protocols. The sensitivity of protocols for certain groups of patients could then be improved through amending the CDS software (Graber ML et al. 2012;Ramnarayan P et al. 2006a;Ramnarayan P et al. 2004;Ramnarayan P et al. 2006b;Singh H et al. 2012). Regular reviews of calls to measure error rates would allow feedback to professionals, but also, when analysed in conjunction with outcome data, would enable assessment of whether changes such as updates in CDS protocols actually improve patient safety (Ramnarayan P et al. 2006a;Ramnarayan P et al. 2004;Ramnarayan P et al. 2006b;Singh H et al. 2012).

Certain error-prone presentations may benefit from mandatory senior assessment. Also CDS could be strengthened to improve error-prone areas of practice, for example by inserting reminders when triaging head wounds to double check the absence of a head injury (which would require triaging with a different protocol) (Graber ML et al. 2012;Ramnarayan P et al. 2006a;Ramnarayan P et al. 2004;Ramnarayan P et al. 2006b;Singh H et al. 2012).

5.3.4.4 Patient/ caregiver empowerment

The utility of caregivers must not be under-estimated, they should be directed to evidence-based resources to get further information about their child's condition and when it is and is not appropriate to present to healthcare professionals (Singh H et al. 2010).

5.3.4.5 Better safety netting

This study points to a clear need for improved safety netting via the telephone. Parents and caregivers should receive oral and written safety netting information (perhaps via e-mail, text messages, or smart phone applications) (Roland D et al. 2014). The content of safety net advice must be reviewed in this setting, to ensure it is individually tailored and comprehensive to include: diagnostic probabilities, warning signs to be aware of, a likely time frame for illness recovery, and advice on the most appropriate way to access healthcare if there is no improvement or the child deteriorates (O'Cathain A et al. 2003). Safety netting protocol adherence could be improved through using mnemonics or checklists (Kim SW et al. 2012;Sahyoun C et al. 2013;Starmer AJ et al. 2013;Weingart C et al. 2013a).

5.4 Recommendations for future research

This study has highlighted priority areas requiring improvement using incident report data, however estimates of the burden of unsafe primary care for children would be beneficial. Mangione-Smith R et al. 2007 in the USA were the first to measure ambulatory care quality for children; this study is now being repeated in Australia (Hibbert PD et al. 2015). The UK would also benefit from a comprehensive and generalisable case note review, to determine which areas of primary care are most harmful and costly to child health, in order to target improvement interventions efficiently to those areas most in need of improvement (Hibbert PD et al. 2015;Mangione-Smith R et al. 2007a).

With the emergence of large datasets such as those managed by the Health and Social Care Information Centre (HSCIC) and the Secure Anonymised Information Linkage (SAIL) databank, that can be linked to provide epidemiological data on care quality, there is considerable scope for future studies to evaluate the epidemiology of healthcare harm in children (Dattani N et al. 2013;Hardelid P et al. 2013;Hardelid P and Gilbert R 2013). Future research could utilise such resources to model the risk of substandard care given certain characteristics such as age, location, past medical history, treatment history, family history, and social factors including family socioeconomic status.

The role of caregivers in contributing to, and mitigating, substandard care was a prominent theme in this dataset. Future work should consider the benefit of parental involvement in quality improvement projects. The role of caregivers as potential 'error safety nets' should be explored, particularly in the context of them having access to their children's medical records, which is anticipated imminently (Woodman J et al. 2015).

Finally, this study hypothesises that socially vulnerable children are disproportionately vulnerable to unsafe and poor quality care. This hypothesis should be investigated in future research, to include an in-depth exploration of the reasons for such a potential pre-disposition, and piloting interventions targeted to improve the safety of care for this vulnerable population of children, by addressing contributory factors specific to this group.

Chapter 6: Conclusions

This thesis explores the quality and safety of primary care for children by identifying key reported safety issues related to childhood vaccination and the provision of care to 'unwell' children.

Priority areas related to vaccination requiring improvement include administration of: the wrong number of doses, vaccines at the wrong time, and the wrong vaccine. Weaknesses underlying these incidents include documentation failures, appointment management problems, staff mistakes, and failure to follow vaccination protocols. Certain groups of children such as looked-after children appeared disproportionately vulnerable to these failures. Recommendations to potentially address these issues include: building IT infrastructure to mitigate vaccination-related documentation weaknesses such as implementing electronic 'red' books; and encouraging better communication and shared decision making between healthcare professionals and caregivers.

Key primary care-related safety incidents involving 'unwell' children were related to medication provision; and diagnosis, assessment, referral, and communication failures with regards to telephone assessment.

Medication-related incidents were underpinned by: staff factors such as mistakes and failing to follow protocols; organisational factors such as poor working conditions and inadequate care plans and protocols; patient factors such as age; and medication factors such as adjacent storage of similar medications. Recommendations to mitigate these incidents include: improving linkage between electronic prescription services and patient records, routine electronic transmission of prescriptions to dispensing pharmacies, barcoding of all medications to act as a double-check prior to dispensing, and providing human factors training to all pharmacy staff.

Telephone assessment failures were the result of assessors choosing the wrong assessment protocols, not utilising the protocols correctly, or not using critical thinking to challenge inappropriate protocol outcomes. Inadequate safety netting was also described in this context. Given the nature of these incidents, parents and

caregivers played an important role in ensuring their children received appropriate telephone assessments.
Recommendations for improving telephone assessment of 'unwell' children include: reviewing and amending CDS software and telephone assessment protocols, to ensure that they are comprehensive, sensitive, user-friendly, and suitable for use on children. The quality of safety netting protocols should also be reviewed and adherence to them should be improved, perhaps through the use of a mnemonic.

Further studies are required to assess the burden of unsafe primary care in children; and to test the hypotheses generated from this study with regards to the nature of unsafe primary care, the causative factors underlying this unsafe care, and the recommendations for improvement.

References

e redbook: your baby's digital health record [*online*]. Available at: http://www.eredbook.org.uk [Accessed 1st Jul 2015].

Learning from International Networks about Errors and Understanding Safety in Primary Care (LINNEAUS Euro-PC) [*online*]. Available at: http://www.linneaus-pc.eu [Accessed 1st Jul 2015].

Abboud PA, et al. (2006). Impact of workflow-integrated corollary orders on aminoglycoside monitoring in children. *Health Informatics J* 12(3) 187-198.

Abstoss KM, et al. (2011). Increasing medication error reporting rates while reducing harm through simultaneous cultural and system-level interventions in an intensive care unit. *BMJ Qual Saf* 20(11) 914-922.

Adamson P (2012). Measuring child poverty. New league tables of child poverty in the world's rich countries. Italy, UNICEF.

Agarwal S, et al. (2010). Prevalence of adverse events in pediatric intensive care units in the United States. *Pediatr Crit Care Med* 11(5) 568-578.

Agerbo E, Nordentoft M and Mortensen PB (2002). [Suicide among young people--familial, psychiatric and socioeconomic risk factors. A nested case-control study]. *Ugeskrift for laeger* 164(49) 5786-5790.

Ahgren, B. (2003). Chain of care development in Sweden: results of a national study. *Int J Integr Care* 3 e01.

Alagha HZ, et al. (2011). Reducing prescribing errors in the paediatric intensive care unit: an experience from Egypt. *Acta Paediatr* 100(10) e169-e174.

Alemanni J, et al. (2010). An assessment of drug administration compliance in a university hospital centre. *J Eval Clin Pract* 16(5) 920-926.

Alexander DC, et al. (2009). Cardiovascular medication errors in children. *Pediatrics* 124(1) 324-332.

Alio AP, et al. (2010). An ecological approach to understanding black-white disparities in perinatal mortality. *Matern Child Health J* 14(4) 557-566.

Anachebe NF (2006). Racial and ethnic disparities in infant and maternal mortality. *Ethn Dis* 16(2 Suppl 3) S3-71-76.

Arntzen A and Nybo-Andersen AM (2004). Social determinants for infant mortality in the Nordic countries, 1980-2001. *Scand J Public Health* 32(5) 381-389.

Asthma UK (2007). The asthma divide: inequalities in emergency care for people with asthma in England.

Asthma UK (2015). Patient safety failures in asthma care: the scale of unsafe prescribing in the UK.

Avery AJ, et al. (2013). The prevalence and nature of prescribing and monitoring errors in English general practice: a retrospective case note review. *Br J Gen Pract* 63(613) e543-553.

Barnes P, et al. (2005). Immunisation status in the public care system: a comparative study. *Vaccine* 23(21) 2820-2823.

Bazeley P (2007). *Qualitative data analysis with NVivo*. London: Sage Publications.

Berger Z, et al. (2013). Promoting engagement by patients and families to reduce adverse events in acute care settings: a systematic review. *BMJ Qual Saf* bmjqs-2012-001769.

Bertsche T, et al. (2010). Prospective pilot intervention study to prevent medication errors in drugs administered to children by mouth or gastric tube: a programme for nurses, physicians and parents. *Qual Saf Health Care* 19(5) 1-5.

Blakely T, et al. (2003). Child mortality, socioeconomic position, and one-parent families: independent associations and variation by age and cause of death. *Int J Epidemiol* 32(3) 410-418.

Boling B, et al. (2005). Effectiveness of computerized provider order entry with dose range checking on prescribing errors. *J Patient Saf* 1(4) 190-194.

Bourgeault I, Dingwall R and DeVries R (2010). *The SAGE handbook of qualitative methods in health research*: Sage.

Brady PW, et al. (2014). Developing and evaluating the success of a family activated medical emergency team: a quality improvement report. *BMJ Qual Saf* bmjqs-2014-003001.

Braun V and Clarke V (2006). Using thematic analysis in psychology. *Qualitative research in psychology* 3(2) 77-101.

Brennan TA, et al. (1991). Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 324(6) 370-376.

Brennan TA, et al. (2004). Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. 1991. *Qual Saf Health Care* 13(2) 145-151; discussion 151-142.

Brock D, et al. (2013). Interprofessional education in team communication: working together to improve patient safety.[Reprint in Postgrad Med J. 2013 Nov;89(1057):642-51; PMID: 24129031]. *BMJ Qual Saf* 22(5) 414-423.

Broussard M, et al. (2009). Preprinted order sets as a safety intervention in pediatric sedation. *J Pediatr* 154(6) 865-868.

Brown CL, Garrison NA and Hutchison AA (2007). Error reduction when prescribing neonatal parenteral nutrition. *Am J Perinatol* 24(7) 417-427.

Bryce J, et al. (2003). Reducing child mortality: can public health deliver? *Lancet* 362(9378) 159-164.

Bryce J, Victora CG and Black RE (2013). The unfinished agenda in child survival. *Lancet* 382(9897) 1049-1059.

Bryman A (2012). *Social research methods*. Oxford: Oxford university press.

Bundy DG, et al. (2008). Medication errors in the ambulatory treatment of pediatric attention deficit hyperactivity disorder. *Jt Comm J Qual Patient Saf* 34(9) 552-559, 497.

Bundy DG, et al. (2009). Pediatric vaccination errors: Application of the "5 Rights" framework to a national error reporting database. *Vaccine* 27(29) 3890-3896.

Burkhart PV, Rayens MK and Bowman RK (2005). An evaluation of children's metered-dose inhaler technique for asthma medications. *Nurs Clin North Am* 40(1) 167-182.

Burmester MK, et al. (2008). Interventions to reduce medication prescribing errors in a paediatric cardiac intensive care unit. *Intensive Care Med* 34(6) 1083-1090.

Campino A, et al. (2008). Medication errors in a neonatal intensive care unit. Influence of observation on the error rate. *Acta Paediatr* 97(11) 1591-1594.

Campino A, et al. (2009). Educational strategy to reduce medication errors in a neonatal intensive care unit. *Acta paediatrica* 98(5) 782-785.

Carson-Stevens A, et al. (2015). Reducing the burden of iatrogenic harm in children. *Lancet* 385(9978) 1593-1594.

Chapman SM, et al. (2014). Prevalence and severity of patient harm in a sample of UK-hospitalised children detected by the Paediatric Trigger Tool. *BMJ Open* 4(7) e005066.

Cimino MA, et al. (2004). Assessing medication prescribing errors in pediatric intensive care units*. *Pediatr Crit Care Medi* 5(2) 124-132.

Classen DC, et al. (2011). 'Global trigger tool'shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs* 30(4) 581-589.

Collison D, et al. (2007). Income inequality and child mortality in wealthy nations. *J Public Health (Oxf)* 29 114-117.

Committee on Quality of Health Care in America Institute of Medicine (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*: National Academies Press.

Computer Sciences Corporation. (2015). *AIMS Incident Management System* [*online*]. Available at: http://www.isofthealth.com/en/Solutions/HospitalsandClinics/AIMS.aspx [Accessed 31 May 2015].

Condren M, et al. (2014). Influence of a systems-based approach to prescribing errors in a pediatric resident clinic. *Acad Pediatr* 14(5) 485-490.

Conroy S, et al. (2007). Interventions to reduce dosing errors in children: a systematic review of the literature. *Drug Saf* 30(12) 1111-1125.

Cook EJ, et al. (2015). A study of urgent and emergency referrals from NHS Direct within England. *BMJ Open* 5(5) e007533.

Cook EJ, et al. (2013). Young people's use of NHS Direct: a national study of symptoms and outcome of calls for children aged 0–15. *BMJ Open* 3(12) e004106.

Cook R, et al. (2010). To ED or not to ED: NHS 24 referrals to the emergency department. *Emerg Med J* 27(3) 213-215.

Cordero L, et al. (2004). Impact of computerized physician order entry on clinical practice in a newborn intensive care unit. *J Perinatol* 24(2) 88-93.

Cresswell KM, et al. (2013). Global research priorities to better understand the burden of iatrogenic harm in primary care: an international delphi exercise. *PLoS Med* 10(11) e1001554.

Cresswell KM and Sheikh A (2008). Information technology-based approaches to reducing repeat drug exposure in patients with known drug allergies. *J Allergy Clin Immunol* 121(5) 1112-1117 e1117.

Creswell JW (2013). *Research design: qualitative, quantitative, and mixed methods approaches*: Sage publications.

Creswell JW and Clark VLP (2007). Designing and conducting mixed methods research.

Cunningham S, et al. (2008). Effect of an integrated care pathway on acute asthma/wheeze in children attending hospital: cluster randomized trial. *J Pediatr* 152(3) 315-320. e312.

Dattani N, et al. (2013). Accessing electronic administrative health data for research takes time. *Arch Dis Child* 98(5) 391-392.

Davey AL, Britland A and Naylor RJ (2008). Decreasing paediatric prescribing errors in a district general hospital. *Quali Saf Health Care* 17(2) 146-149.

Denzin NK and Lincoln YS (2011). *The SAGE handbook of qualitative research*. London: SAGE publications.

Department of Health (2000). An organisation with a memory. London, Stationary Office.

Department of Health (2001). Building a safer NHS for patients. Implementing an organisation with a memory. London, Stationary Office.

Department of Health (2013). A promise to learn - a commitment to act: improving the safety of patients in England.

Derkx HP, et al. (2008). Quality of clinical aspects of call handling at Dutch out of hours centres: cross sectional national study. *BMJ* 337.

Derrough TF and Kitchin NR (2002). Occurrence of adverse events following inadvertent administration of childhood vaccines. *Vaccine* 21(1-2) 53-59.

Di Pentima MC and Chan S (2010). Impact of antimicrobial stewardship program on vancomycin use in a pediatric teaching hospital. *Pediatr Infect Dis J* 29(8) 707-711.

Dinning C, et al. (2005). Chemotherapy error reduction: a multidisciplinary approach to create templated order sets. *J Pediatr Oncol Nur* 22(1) 20-30.

Doctor K, Correa K and Olympia RP (2014). Evaluation of an after-hours call center: are pediatric patients appropriately referred to the emergency department? *Pediatr Emerg Care* 30(11) 798-804.

Doherty C and Mc Donnell C (2012). Tenfold medication errors: 5 years' experience at a university-affiliated pediatric hospital. *Pediatrics* 129(5) 916-924.

Donaldson LJ, Panesar SS and Darzi A (2014). Patient-safety-related hospital deaths in England: thematic analysis of incidents reported to a national database, 2010-2012. *PLoS Med* 11(6) e1001667.

Dovey SM, et al. (2002). A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 11(3) 233-238.

Dyer C (1999). Doctors cleared of manslaughter. *BMJ* 318(7177) 148.

Edwards P, et al. (2006). Deaths from injury in children and employment status in family: analysis of trends in class specific death rates. *BMJ* 333(7559) 119.

Eisenhut M, Sun B and Skinner S (2011). Reducing prescribing errors in paediatric patients by assessment and feedback targeted at prescribers. *International Scholarly Research Notices* 2011.

Farrar K (2003). Use of structured paediatric-prescribing screens to reduce the risk of medication errors in the care of children. *British Journal of Healthcare Computing and Information Management* 20(4) 25-27.

Feikema SM, et al. (2000). Extraimmunization among US children. *JAMA* 283(10) 1311-1317.

Filik R, et al. (2006). Labeling of medicines and patient safety: evaluating methods of reducing drug name confusion. *Hum Factors* 48(1) 39-47.

Fontan JE, et al. (2003). Medication errors in hospital: computerized unit dose drug dispensing system versus ward stock distribution system. *Pharm World Sci* 25(3) 112-117.

Francis R (2013). Report of the Mid Staffordshire NHS foundation trust public inquiry *In* Department of Health ed. London, The Stationary Office.

Franklin BD, et al. (2014). The effect of the electronic transmission of prescriptions on dispensing errors and prescription enhancements made in English community pharmacies: a naturalistic stepped wedge study. *BMJ Qual Saf* 23(8) 629-638.

Fraser J, et al. (2014). Learning from child death review in the USA, England, Australia, and New Zealand. *Lancet* 384(9946) 894-903.

Freemantle N, et al. (2009). What factors predict differences in infant and perinatal mortality in primary care trusts in England? A prognostic model. *BMJ* 339.

Gakidou E, et al. (2010). Increased educational attainment and its effect on child mortality in 175 countries between 1970 and 2009: a systematic analysis. *Lancet* 376(9745) 959-974.

Ghaleb MA, et al. (2006). Systematic review of medication errors in pediatric patients. *Ann Pharmacother* 40(10) 1766-1776.

Giesen P, et al. (2007). Safety of telephone triage in general practitioner cooperatives: do triage nurses correctly estimate urgency? *Quali Saf Health Care* 16(3) 181-184.

Gill PJ, et al. (2011). The evidence base for interventions delivered to children in primary care: an overview of cochrane systematic reviews. *PLoS ONE* 6(8) e23051.

Ginzburg R, et al. (2009). Effect of a weight-based prescribing method within an electronic health record on prescribing errors. *Am J Health Syst Pharm* 66(22) 2037-2041.

Glaser BG and Strauss AL (2009). *The discovery of grounded theory: Strategies for qualitative research*: Transaction Publishers.

Glik DC, et al. (1986). Integrating Qualitative and Quantitative Survey Techniques' *International Quarterly of Community Health Education* 7(3) 181-200.

Gokmen-Ozel H, et al. (2010). Errors in emergency feeds in inherited metabolic disorders: a randomised controlled trial of three preparation methods. *Arch Dis Child* 95(10) 776-780.

Graber ML, et al. (2012). Cognitive interventions to reduce diagnostic error: a narrative review. *BMJ Qual Saf* bmjqs-2011-000149.

Graedon J and Graedon T (2006). Enlisting families as patient safety allies. *Clinical Pediatric Emergency Medicine* 7(4) 265-267.

Greaves F and Donaldson L (2013). Measles in the UK: a test of public health competency in a crisis. *BMJ* 346.

Green J and Thorogood N (2009). *Qualitative methods for health research*. 2nd ed: SAGE.

Griffin FA and Classen DC (2008). Detection of adverse events in surgical patients using the Trigger Tool approach. *Qual Saf Health Care* 17(4) 253-258.

Griffin FA and Resar RK (2009). IHI Global Trigger Tool for measuring adverse events. . *IHI innovation series white paper*.

Gronczewski CA (2005). The lost endotracheal tube: An unreported complication of prehospital intubation. *Pediatr Emerg Care* 21(5) 318-321.

Haas-Gehres A, Sebastian S and Lamberjack K (2014). Impact of pharmacist integration in a pediatric primary care clinic on vaccination errors: a retrospective review. *J Am Pharm Assoc* 54(4) 415-418.

Hain PD, et al. (2007). Using risk management files to identify and address causative factors associated with adverse events in pediatrics. *Ther Clin Risk Manag* 3(4) 625-631.

Hardelid P, et al. (2013). Child Health Reviews-UK: overview of child deaths in the four UK countries. London, Royal College of Paediatrics and Child Health.

Hardelid P and Gilbert R (2013). Investing in national primary care data is way forward in time of care. data. *BMJ* 347.

Harnden A, et al. (2009). Child deaths: confidential enquiry into the role and quality of UK primary care. *Br J Gen Pract* 59(568) 819-824.

Hart JT (1971). The inverse care law. *Lancet* 1(7696) 405-412.

Healthcare Commission (2007). Improving services for children in hospital.

Hibbert PD, et al. (2015). CareTrack Kids—part 3. Adverse events in children's healthcare in Australia: study protocol for a retrospective medical record review. *BMJ Open* 5(4) e007750.

Hibbert PD, et al. (2007). A Recursive Model of Incident Analysis. Australian Patient Safety Foundation.

Hilmas E, et al. (2010). Implementation and evaluation of a comprehensive system to deliver pediatric continuous infusion medications with standardized concentrations. *Am J Health Syst Pharm* 67(1) 58-69.

Hippisley-Cox J, Fenty J and Heaps M (2007). Trends in consultation rates in general practice 1995 to 2006: analysis of the QRESEARCH database.

Holdsworth MT, et al. (2007). Impact of computerized prescriber order entry on the incidence of adverse drug events in pediatric inpatients. *Pediatrics* 120(5) 1058-1066.

Holloway I and Todres L (2003). The status of method: flexibility, consistency and coherence. *Qualitative research* 3(3) 345-357.

Huibers L, et al. (2011). Safety of telephone triage in out-of-hours care: a systematic review. *Scandinavian journal of primary health care* 29(4) 198-209.

Hyman D, et al. (2012). The use of patient pictures and verification screens to reduce computerized provider order entry errors. *Pediatrics* 130(1) E211-E219.

Institute for Health Metrics and Evaluation. (2010). *Global Burden of Disease Study 2010—western Europe results by cause 1990-2010* [*online*]. Available at: http://www.healthdata.org/gbd/data [Accessed 5th Oct 2015].

Institute of Medicine (1996). *Primary care: America's health in a new era*. Washington DC: National Academy Press.

Jacobs S, et al. (2007). Errors and adverse events in family medicine: developing and validating a Canadian taxonomy of errors. *Can Fam Physician* 53(2) 271-276, 270.

Jani YH, Barber N and Wong ICK (2010). Paediatric dosing errors before and after electronic prescribing. *Qual Saf Health Care* 19(4) 337-340.

Jean-Philippe P, et al. (2007). Severe varicella caused by varicella-vaccine strain in a child with significant T-cell dysfunction. *Pediatrics* 120(5) e1345-1349.

Johnston BD (2014). Why is UK performance in child and youth mortality so poor? *The Lancet* 384(9946) 837-838.

Joint Commission Resources (2005). *Hospital Accreditation Standards*. Oakbrook Terrace: Joint Commission on Accreditation on Healthcare Organizations.

Kadmon G, et al. (2009). Computerized order entry with limited decision support to prevent prescription errors in a PICU. *Pediatrics* 124(3) 935-940.

Kaji AH, et al. (2006). Emergency medical services system changes reduce pediatric epinephrine dosing errors in the prehospital setting. *Pediatrics* 118(4) 1493-1500.

Kalina M, et al. (2009). A multidisciplinary approach to adverse drug events in pediatric trauma patients in an adult trauma center. *Pediatr Emerg Care* 25(7) 444-446.

Kaushal R, Barker KN and Bates DW (2001). How can information technology improve patient safety and reduce medication errors in children's health care? *Arch Pediatr Adolesc Med* 155(9) 1002-1007.

Kaushal R, et al. (2008). Unit-based clinical pharmacists' prevention of serious medication errors in pediatric inpatients. *Am J Health Syst Pharm* 65(13) 1254-1260.

Kazemi A, et al. (2011). The effect of Computerized Physician Order Entry and decision support system on medication errors in the neonatal ward: experiences from an Iranian teaching hospital. *J Med Syst* 35(1) 25-37.

Kennedy I (2001). The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: learning from Bristol.

Kim GR, et al. (2006). Error reduction in pediatric chemotherapy: computerized order entry and failure modes and effects analysis. *Arch Pediatr Adolesc Med* 160(5) 495-498.

Kim SW, et al. (2012). Interdisciplinary development and implementation of communication checklist for postoperative management of pediatric airway patients. *Otolaryngol Head Neck Surg* 146(1) 129-134.

Kirk RC, et al. (2005). Computer calculated dose in paediatric prescribing. *Drug Saf* 28(9) 817-824.

Kohn LT, et al. (1999). To err is human: building a safer health system. Washington DC, National Academies Press.

Kong KA, et al. (2010). Childhood cancer mortality and socioeconomic position in South Korea: a national population-based birth cohort study. *Cancer Causes Control* 21(10) 1559-1567.

Koren G, Barzilay Z and Greenwald M (1986). Tenfold errors in administration of drug doses: a neglected iatrogenic disease in pediatrics. *Pediatrics* 77(6) 848-849.

Koren G and Haslam RH (1994). Pediatric medication errors: predicting and preventing tenfold disasters. *J Clin Pharmacol* 34(11) 1043-1045.

Kostopoulou O and Delaney B (2007). Confidential reporting of patient safety events in primary care: results from a multilevel classification of cognitive and system factors. *Qual Saf Health Care* 16(2) 95-100.

Kozer E, et al. (2005). Using a preprinted order sheet to reduce prescription errors in a pediatric emergency department: a randomized, controlled trial. *Pediatrics* 116(6) 1299-1302.

Kozer E, et al. (2006). The effect of a short tutorial on the incidence of prescribing errors in pediatric emergency care. *Can J Clin Pharmacol*. 13(3) e285-291.

Kron T (1962). Stepping beyond the 5 rights of administering drugs. *Am J Nurs* 62 62-63.

Lacey A and Luff D (2001). *Qualitative data analysis: trent focus for research and development in primary health care*: Trent focus.

Lamont T, et al. (2011a). Safer insertion of suprapubic catheters: summary of a safety report from the National Patient Safety Agency. *BMJ* 342 d924.

Lamont T, et al. (2011b). Early detection of complications after laparoscopic surgery: summary of a safety report from the National Patient Safety Agency. *BMJ* 342 c7221.

Lamont T, et al. (2010). Reducing risks of tourniquets left on after finger and toe surgery: summary of a safety report from the National Patient Safety Agency. *BMJ* 340 c1981.

Lamont, T., et al. (2011c). Checking placement of nasogastric feeding tubes in adults (interpretation of x ray images): summary of a safety report from the National Patient Safety Agency. *BMJ* 342 d2586.

Landrigan CP, et al. (2010). Temporal trends in rates of patient harm resulting from medical care. *N Eng J Med* 363(22) 2124-2134.

Larose G, Bailey B and Lebel D (2008). Quality of orders for medication in the resuscitation room of a pediatric emergency department. *Pediatr Emerg Care* 24(9) 609-614.

Larsen GY, et al. (2007). Preventable harm occurring to critically ill children. *Pediatr Crit Care Med* 8(4) 331-336.

Lehmann CU, Conner KG and Cox JM (2004). Preventing provider errors: online total parenteral nutrition calculator. *Pediatrics* 113(4) 748-753.

Lehmann CU, et al. (2006). Decreasing errors in pediatric continuous intravenous infusions. *Pediatr Crit Care Med* 7(3) 225-230.

Leonard MS, et al. (2006). Risk reduction for adverse drug events through sequential implementation of patient safety initiatives in a children's hospital. *Pediatrics* 118(4) e1124-e1129.

Leprohon J and Patel VL (1995). Decision-making strategies for telephone triage in emergency medical services. *Med Decis Making* 15(3) 240-253.

Levine SR, Cohen MR and Blanchard N (2001). Guidelines for preventing medication errors in pediatrics. *J Pediatr Pharmacol Ther* 6 426-442.

Lightfoot TJ, et al. (2012). Survival from childhood acute lymphoblastic leukaemia: the impact of social inequality in the United Kingdom. *Eur J Cancer* 48(2) 263-269.

Ligi I, et al. (2008). Iatrogenic events in admitted neonates: a prospective cohort study. *Lancet* 371(9610) 404-410.

Liu L, et al. (2012). Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. *Lancet* 379(9832) 2151-2161.

Lope RJR, et al. (2009). A quality assurance study on the administration of medication by nurses in a neonatal intensive care unit. *Singapore Med J*(50) 68-72.

Lucas AJ (2004). Improving medication safety in a neonatal intensive care unit. *Am J Health Syst Pharm* 61(1) 33-37.

MacDonald A, et al. (2006). Home delivery of dietary products in inherited metabolic disorders reduces prescription and dispensing errors. *J Hum Nutr Diet* 19(5) 375-381.

Mackenbach JP, et al. (2008). Socioeconomic inequalities in health in 22 European countries. *N Engl J Med* 358(23) 2468-2481.

Magrabi F, et al. (2011). Patient safety problems associated with heathcare information technology: an analysis of adverse events reported to the US Food and Drug Administration. AMIA Annual Symposium Proceedings, American Medical Informatics Association.

Makeham MA, et al. (2002). An international taxonomy for errors in general practice: a pilot study. *Med J Aust* 177(2) 68-72.

Makeham MA, et al. (2008). Patient safety events reported in general practice: a taxonomy. *Qual Saf Health Care* 17(1) 53-57.

Makeham MAB, et al. (2004). Letter to the editor: meningococcal vaccine. *Aust Fam Physician* 33(9) 679.

Mangione-Smith R, et al. (2007a). The quality of ambulatory care delivered to children in the United States. *N Engl J Med* 357(15) 1515-1523.

Mangione-Smith R, et al. (2007b). The quality of ambulatory care delivered to children in the United States. *N Eng J Med* 357(15) 1515-1523.

Marmot M, et al. (2012). WHO European review of social determinants of health and the health divide. *Lancet* 380 1011-1029.

Martijn LLM, et al. (2013). Patient safety in midwifery-led care in the Netherlands. *Midwifery* 29(1) 60-66.

Matlow AG, et al. (2011). Description of the development and validation of the Canadian Paediatric Trigger Tool. *BMJ Qual Saf* 20(5) 416-423.

McCarthy PL, et al. (1990). Mothers' clinical judgment: a randomized trial of the Acute Illness Observation Scales. *J Pediatr* 116(2) 200-206.

McLellan, N. (1999). NHS Direct: here and now. *Arch Dis Child* 81(5) 376-378.

McLellan, N. (2004). NHS Direct: virtually engaged. *Arch Dis Child* 89(1) 57-59.

Messina FC, et al. (2013). Improving specialty care follow-up after an ED visit using a unique referral system. *Am J Emerg Med* 31(10) 1495-1500.

Miles MB and Huberman AM (1994). *Qualitative data analysis: an expanded sourcebook*. 2nd ed. Thousand Oaks: Sage.

Milne C, Forrest L and Charles T (2010). Learning from analysis of general practitioner referrals to a general paediatric department. *Arch Dis Child* 96(1) A71.

Monaghan R, Clifford C and McDonald P (2003). Seeking advice from NHS direct on common childhood complaints: does it matter who answers the phone? *J Adv Nurs* 42(2) 209-216.

Morriss FH, et al. (2009). Effectiveness of a barcode medication administration system in reducing preventable adverse drug events in a neonatal intensive care unit: a prospective cohort study. *J Pediatr* 154(3) 363-368.

Morse, J. M. (2003). Principles of mixed methods and multimethod research design. *Handbook of mixed methods in social and behavioral research* 189-208.

Morse RB and Pollack MM (2012). Root cause analyses performed in a children's hospital: events, action plan strength, and implementation rates. *J Healthc Qual* 34(1) 55-61.

Muething, S. E., et al. (2010). Identifying causes of adverse events detected by an automated trigger tool through in-depth analysis. *Qual Saf Health Care* 19(5) 435-439.

Mullett CJ, et al. (2001). Development and impact of a computerized pediatric antiinfective decision support program. *Pediatrics* 108(4) e75-e75.

National Diabetes Audit (2008). Key findings about the quality of care for children and young people with diabetes in England and Wales 2007-2008.

National Patient Safety Agency. *Root Cause Analysis Investigation Tools* [*online*]. Available at: http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60180 [Accessed 1st Jul 2015].

National Patient Safety Agency. (2004). *Ensuring safer practice with Repevax and Revaxis vaccines* [*online*]. Available at:

http://www.nrls.npsa.nhs.uk/alerts/?entryid45=59795&p=4 [Accessed 1st Jul 2015].

National Patient Safety Agency. (2008). *Quarterly data summary issue 10: learning from reporting - vaccination incidents involving children* [*online*]. Available at: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59857 [Accessed 1st Jul 2015].

National Reporting and Learning System. *Organisation patient safety incident reports* [*online*]. London: NHS. Available at: http://www.nrls.npsa.nhs.uk/news-cp/organisation-patient-safety-incident-reports-september-2012/ [Accessed 1st Jul 2015].

Neill, S. J. (2010). Containing acute childhood illness within family life: a substantive grounded theory. *Journal of Child Health Care* 14(4) 327-344.

Neuspiel DR, Stubbs EH and Liggin L (2011). Improving reporting of outpatient pediatric medical errors. *Pediatrics* 128(6) E1608-E1613.

New South Wales Government. (2005). *Severity Assessment Code (SAC) Matrix* [*online*]. Available at: http://www0.health.nsw.gov.au/pubs/2005/sac_matrix.html [Accessed 1st Jul 2015].

NHS Scotland. (2015). *Pareto Chart* [*online*]. Available at: http://www.qihub.scot.nhs.uk/knowledge-centre/quality-improvement-tools/pareto-chart.aspx [Accessed 3rd Oct 2015].

Nolte E and McKee M (2008). *Caring for people with chronic conditions: a health system perspective: a health system perspective*. Oxford: McGraw-Hill International.

O'Cathain A (2013). Mixed methods involving qualitative research. *In* Bourgeault I, Dingwall R and DeVries R eds. *The SAGE handbook of qualitative methods health research*. London, SAGE Publications.

O'Cathain A, Murphy E and Nicholl J (2007). Why, and how, mixed methods research is undertaken in health services research: a mixed methods study. *BMC Health Services Research* 7 85.

O'Cathain A, et al. (2003). NHS Direct: consistency of triage outcomes. *Emerg Med J* 20(3) 289-292.

Otero P, et al. (2008). Medication errors in pediatric inpatients: prevalence and results of a prevention program. *Pediatrics* 122(3) e737-e743.

Padley M and Hirsch D (2014). Households below a minimum income standard 2008-9 to 2011-12. Loughborough, University of Loughborough.

Paediatric Formulary Committee (2013). BNF for children (online). London, BMJ group, Pharmaceutical press, and RCPCH Publications.

Pallás CR, et al. (2007). Improving the quality of medical prescriptions in neonatal units. *Neonatology* 93(4) 251-256.

Panesar SS, et al. (2013a). Patient safety in orthopedic surgery: prioritizing key areas of iatrogenic harm through an analysis of 48,095 incidents reported to a national database of errors. *Drug Healthc Patient Saf* 5 57-65.

Panesar SS, Cleary K and Sheikh A (2009a). Reflections on the National Patient Safety Agency's database of medical errors. *J R Soc Med* 102(7) 256-258.

Panesar SS, et al. (2009b). To cement or not in hip fracture surgery? *Lancet* 374(9695) 1047-1049.

Panesar SS, et al. (2013b). The orthopaedic error index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach. *BMJ Open* 3(11) e003448.

Parry G, Cline A and Goldmann D (2012). Deciphering harm measurement. *JAMA* 307(20) 2155-2156.

Pearson G (2008). Why children die: a pilot study 2006 England (south west, north east and west midlands), Wales and Northern Ireland. Confidential Enquiry into Maternal and Child Health.

Petrou S, Fraser J and Sidebotham P (2014). Child death in high-income countries. *Lancet* 384(9946) 831-833.

Pettinari CJ and Jessopp L (2001). 'Your ears become your eyes': managing the absence of visibility in NHS Direct. *J Adv Nurs* 36(5) 668-675.

Pickett KE and Wilkinson RG (2007). Child wellbeing and income inequality in rich societies: ecological cross sectional study. *BMJ* 335(7629) 1080.

Poon EG, et al. (2010). Effect of bar-code technology on the safety of medication administration. *N Engl J Med* 362(18) 1698-1707.

Pope C and Mays N (1995). Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *BMJ* 311(6996) 42.

Pope C, Ziebland S and Mays N (2000). Qualitative research in health care: analysing qualitative data. *BMJ* 320(7227) 114.

Porter SC, et al. (2008). Impact of a patient-centered technology on medication errors during pediatric emergency care. *Ambul Pediatr* 8(5) 329-335.

Potts AL, et al. (2004). Computerized physician order entry and medication errors in a pediatric critical care unit. *Pediatrics* 113(1) 59-63.

Pritchard C and Williams R (2011). Poverty and child (0–14 years) mortality in the USA and other western countries as an indicator of "how well a country meets the needs of its children" (UNICEF). *Int J Adolesc Med Health* 23 251-255.

Ramnarayan P, et al. (2006a). Assessment of the potential impact of a reminder system on the reduction of diagnostic errors: a quasi-experimental study. *BMC Med Inform Decis Mak* 6 22.

Ramnarayan P, Steel E and Britto JF (2004). ISABEL: A novel approach to the reduction of medical error. *Clinical Risk* 10(1) 9-11.

Ramnarayan P, et al. (2006b). Diagnostic omission errors in acute paediatric practice: impact of a reminder system on decision-making. *BMC Med Inform Decis Mak* 6 37.

Reason, J. (1990). *Human error*: Cambridge university press.

Rees P, et al. (2014). Quality improvement informed by a reporting and learning system. *Arch Dis Child* 99(7) 702-703.

Rees P, et al. (2015). Safety incidents in the primary care office setting. *Pediatrics* 35(6) 1027-1035.

Resar RK, et al. (2006). A trigger tool to identify adverse events in the intensive care unit. *Jt Comm J Qual Patient Saf* 32(10) 585-590.

Rinke ML, et al. (2010). Pediatric antidepressant medication errors in a national error reporting database. *J Dev Behav Pediatr* 31(2) 129-136.

Rinke ML, et al. (2014). Interventions to reduce pediatric medication errors: a systematic review. *Pediatrics* 134(2) 338-360.

Robinson DL, Heigham M and Clark J (2006). Using failure mode and effects analysis for safe administration of chemotherapy to hospitalized children with cancer. *Jt Comm J Qual Patient Saf* 32(3) 161-166.

Rodwin VG and Neuberg LG (2005). Infant mortality and income in 4 world cities: New York, London, Paris, and Tokyo. *Am J Public Health* 95(1) 86-90.

Roland D (2015). But I told you she was ill! The role of families in preventing avoidable harm in children. *BMJ Qual Saf* bmjqs-2015-003950.

Roland D, et al. (2014). Safety netting in healthcare settings: what it means, and for whom? *Arch Dis Child Educ Pract Ed* 99(2) 48-53.

Roland D, et al. (2013). Use of paediatric early warning systems in Great Britain: has there been a change of practice in the last 7 years? *Arch Dis Child* 99(1) 26-29.

Rosser W, et al. (2005). Medical errors in primary care: results of an international study of family practice. *Can Fam Physician* 51(3) 386-387.

Royal College of General Practitioners (2008). Weekly returns service annual prevalence report 2007. *Birmingham Research Unit* 1-89.

Royal College of Paediatrics and Child Health (2008). Developing the workforce for children RCPCH medical workforce census 2007. London, RCPCH.

Royal College of Paediatrics and Child Health (2012). Epilepsy 12 National Report: United Kingdom collaborative clinical audit of healthcare for children and young people with suspected epileptic seizures. London, RCPCH.

Royal College of Paediatrics and Child Health (2013). Coordinating Epilepsy Care: a UK-wide review of healthcare in cases of mortality and prolonged seizures in children and young people with epilepsies.

Rubin G, et al. (2003). Errors in general practice: development of an error classification and pilot study of a method for detecting errors. *Qual Saf Health Care* 12(6) 443-447.

Sagy M (2009). Optimizing patient care processes in a children's hospital using Six Sigma. *JCOM* 16(9).

Sahyoun C, et al. (2013). Early identification of children at risk for critical care standardizing communication for inter-emergency department transfers. *Pediatr Emerg Care* 29(4) 419-424.

Samuels RC, et al. (2002). Improving accuracy in a computerized immunization registry. *Ambul Pediatr* 2(3) 187-192.

Sandelowski, M. (1993). Rigor or rigor mortis: the problem of rigor in qualitative research revisited. *Adv Nurs Sci* 16(2) 1-8.

Sard BE, et al. (2008). Retrospective evaluation of a computerized physician order entry adaptation to prevent prescribing errors in a pediatric emergency department. *Pediatrics* 122(4) 782-787.

Sari ABA, et al. (2007). Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ* 334(7584) 79.

Sauberan JB, et al. (2010). Origins of and solutions for neonatal medication-dispensing errors. *Am J Health Syst Pharm* 67(1) 49-57.

Saxena S, et al. (2009). Increasing short-stay unplanned hospital admissions among children in England; time trends analysis '97-'06. *PLoS ONE* 4(10) 7484.

Schäfer W, et al. (2009). The Netherlands: health system review. *Health systems in transition* 12(1) 1-228.

Sen AI, Morgan RW and Morris MC (2013). Variability in the implementation of rapid response teams at academic American pediatric hospitals. *J Pediatr* 163(6) 1772-1774.

Sharek PJ, et al. (2006). Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to identify harm in North American NICUs. *Pediatrics* 118(4) 1332-1340.

Sidebotham P, et al. (2014a). Understanding why children die in high-income countries. *Lancet* 384(9946) 915-927.

Sidebotham P, et al. (2014b). Patterns of child death in England and Wales. *Lancet* 384(9946) 904-914.

Singh H, et al. (2012). System-related interventions to reduce diagnostic errors: a narrative review. *BMJ Qual Saf* 21(2) 160-170.

Singh H, et al. (2010). Errors of diagnosis in pediatric practice: A multisite survey. *Pediatrics* 126(1) 70-79.

Singh R, et al. (2009). Experience with a trigger tool for identifying adverse drug events among older adults in ambulatory primary care. *Qual Saf Health Care* 18(3) 199-204.

Skouroliakou M, et al. (2005). Computer assisted total parenteral nutrition for pre-term and sick term neonates. *Pharm World Sci* 27(4) 305-310.

Smith GD (2000). Learning to live with complexity: ethnicity, socioeconomic position, and health in Britain and the United States. *Am J Public Health* 90(11) 1694-1698.

Smith MD, et al. (2014). Out-of-hospital medication errors among young children in the United States, 2002-2012. *Pediatrics* 134(5) 867-876.

Smith S (2010). Helping parents cope with crying babies: decision – making and interaction at NHS Direct. *J Adv Nurs* 66(2) 381-391.

Smits M, et al. (2010). Patient safety in out-of-hours primary care: a review of patient records. *BMC Health Services Research* 10(1) 335.

Smyth RM, et al. (2012). Adverse drug reactions in children-a systematic review. *PLoS ONE* 7(3) e24061.

Sokol DK (2013). "First do no harm" revisited. *BMJ* 347.

Sowan AK, et al. (2010). Computerized orders with standardized concentrations decrease dispensing errors of continuous infusion medications for pediatrics. *J Pediatr Pharmacol Ther* 15(3) 189-202.

Spencer, N. (2004). The effect of income inequality and macro-level social policy on infant mortality and low birthweight in developed countries - a preliminary systematic review. *Child Care Health Dev* 30(6) 699-709.

Starfield, B. (1991). Primary care and health: a cross-national comparison. *JAMA* 266(16) 2268-2271.

Starfield, B. (1994). Is primary care essential? *Lancet* 344(8930) 1129-1133.

Starfield B, Shi L and Macinko J (2005). Contribution of primary care to health systems and health. *Milbank quarterly* 83(3) 457-502.

Starmer AJ, et al. (2013). Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle. *JAMA* 310(21) 2262-2270.

Stebbing C, et al. (2007). The role of communication in paediatric drug safety. *Arch Dis Child* 92(5) 440-445.

Stewart B, et al. (2006). Review of calls to NHS Direct related to attendance in the paediatric emergency department. *Emerg Med J* 23(12) 911-914.

Sturgess E, et al. (2011). Reduction in prescription errors on paediatric intensive care with 'zero tolerance prescription'.

Sullivan KM, et al. (2013). Personalised performance feedback reduces narcotic prescription errors in a NICU. *BMJ Qual Saf* 22(3) 256-262.

Sullivan MM, et al. (2010). Impact of an interactive online nursing educational module on insulin errors in hospitalized pediatric patients. *Diabetes care* 33(8) 1744-1746.

Suresh G, et al. (2004). Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pediatrics* 113(6) 1609-1618.

Tabatabaei SA, et al. (2012). Assessment of a new algorithm in the management of acute respiratory tract infections in children. *J Res Med Sci* 17(2) 182-185.

Takata GS, et al. (2008). Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. *Pediatrics* 121(4) 927-935.

Taylor JA, et al. (2008). Medication administration variances before and after implementation of computerized physician order entry in a neonatal intensive care unit. *Pediatrics* 121(1) 123-128.

Thammasitboon S and Cutrer WB (2013). Diagnostic decision-making and strategies to improve diagnosis. *Curr Probl Pediatr Adolesc Health Care* 43(9) 232-241.

The Netherlands: Eindhoven University of Technology The Eindhoven Classification Model for System Failure (ECM) and The Prevention and Recovery Information System for Monitoring and Analysis – Medical (PRISMA)

Thomas C, Kamalanathan AN and Subhedar NÛ (2011). The impact of the introduction of a gentamicin pathway. *Arch Dis Child Fetal Neonatal Ed* 96(1) S50-51.

Thomas EJ and Petersen LA (2003). Measuring errors and adverse events in health care. *J Gen Intern Med* 18(1) 61-67.

Titcombe J (2015). Parent-activated medical emergency teams: a parent's perspective. *BMJ Qual Saf* 24(3) 182-183.

Vincent, C. (2007). Incident reporting and patient safety. *BMJ* 334(7584) 51.

Vincent C, et al. (2008). Is health care getting safer? *BMJ* 337 a2426.

Vincent C, Burnett S and Carthey J (2013). *The Measurement and monitoring of safety*. London: Health Foundation.

Vincent C, Neale G and Woloshynowych M (2001). Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 322(7285) 517-519.

Vincent CA (2004). Analysis of clinical incidents: a window on the system not a search for root causes. *Qual Saf Health Care* 13(4) 242-243.

Viner RM, et al. (2014). Deaths in young people aged 0-24 years in the UK compared with the EU15+ countries, 1970-2008: analysis of the WHO Mortality Database. *Lancet* 384(9946) 880-892.

Vivier PM, et al. (1999). Immunization status of children enrolled in a hospital-based medicaid managed care practice: the importance of the timing of vaccine administration. *Pediatr Infect Dis J* 18(9) 783-788.

Walsh KE, Bundy DG and Landrigan CP (2014). Preventing health care-associated harm in children. *JAMA* 311(17) 1731-1732.

Walsh KE, Kaushal R and Chessare JB (2005). How to avoid paediatric medication errors: a user's guide to the literature. *Arch Dis Child* 90(7) 698-702.

Walsh KE, et al. (2008). Effect of computer order entry on prevention of serious medication errors in hospitalized children. *Pediatrics* 121(3) e421-e427.

Walsh KE, et al. (2011). Medication errors in the homes of children with chronic conditions. *Arch Dis Child* 96(6) 581-586.

Walsh KE, et al. (2013). Medication errors in the home: a multisite study of children with cancer. *Pediatrics* 131(5) e1405-1414.

Wang H, et al. (2014). Global, regional, and national levels of neonatal, infant, and under-5 mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*.

Wang, H., et al. (2012). Age-specific and sex-specific mortality in 187 countries, 1970-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 380(9859) 2071-2094.

Warrick C, et al. (2011). A clinical information system reduces medication errors in paediatric intensive care. *Intensive Care Med* 37(4) 691-694.

Watts RG and Parsons K (2013). Chemotherapy medication errors in a pediatric cancer treatment center: prospective characterization of error types and frequency and development of a quality improvement initiative to lower the error rate. *Pediatr Blood Cancer* 60(8) 1320-1324.

Webb E (1998). Children and the inverse care law. *BMJ* 316(7144) 1588-1591.

Webb E (2004). Discrimination against children. *Arch Dis Child* 89(9) 804-808.

Webb E, et al. (2001). The health of children in refuges for women victims of domestic violence: cross sectional descriptive survey. *BMJ* 323(7306) 210-213.

Weingart C, et al. (2013a). Making good better: implementing a standardized handoff in pediatric transport. *Air Med J* 32(1) 40-46.

Weingart, C., et al. (2013b). Making good better: Implementing a standardized handoff in pediatric transport. *Air Medical Journal* 32(1) 40-46.

Weltermann BM, et al. (2014). Vaccination management and vaccination errors: a representative online-survey among primary care physicians. *PLoS ONE* 9(8) e105119.

West D, et al. (2005). Using reported primary care errors to develop and implement patient safety interventions: a report from the ASIPS Collaborative. *Advances in patient safety: from research to implementation*. Rockville (MD), Agency for Healthcare Research and Quality (US).

Williams J, et al. (2001). Case–control study of the health of those looked after by local authorities. *Arch Dis Child* 85(4) 280-285.

Wolfe I, et al. (2011). Improving child health services in the UK: insights from Europe and their implications for the NHS reforms. *BMJ* 342 d1277.

Wolfe I, et al. (2015). UK child survival in a European context: recommendations for a national Countdown Collaboration. *Arch Dis Child*.

Wolfe I, et al. (2014). Why children die: death in infants, children and young people in the UK. London, Royal College of Paediatrics and Child Health.

Wolfe I, et al. (2013). Health services for children in western Europe. *Lancet* 381(9873) 1224-1234.

Wong IC, et al. (2006). Supply problems of unlicensed and off-label medicines after discharge. *Arch Dis Child* 91(8) 686-688.

Wong IC, Wong LY and Cranswick NE (2009). Minimising medication errors in children. *Arch Dis Child* 94(2) 161-164.

Wood AM, et al. (2012). Trends in socioeconomic inequalities in risk of sudden infant death syndrome, other causes of infant mortality, and stillbirth in Scotland: population based study. *BMJ* 344 e1552.

Woodman J, et al. (2015). Online access to medical records: finding ways to minimise harms. *Br J Gen Pract* 65(635) 280-281.

Woolf SH, et al. (2004). A string of mistakes: the importance of cascade analysis in describing, counting, and preventing medical errors. *Ann Fam Med* 2(4) 317-326.

World Alliance for Patient Safety (2005). WHO draft guidelines for adverse event reporting and learning systems. From information to action. Geneva, World Health Organisation.

World Bank. (2014). *Country and lending groups data* [*online*]. Available at: http://data.worldbank.org/about/country-and-lending-groups [Accessed 5th Oct 2015].

World Health Organisation. *European health for all database 2010* [*online*]. Available at: http://data.euro.who.int/hfadb/. [Accessed 1st Jul 2015].

World Health Organisation. *Information model for patient safety (IMPS)*. [*online*]. Available at: http://www.who.int/patientsafety/implementation/information_model/en/. [Accessed 1st Jul 2015].

World Health Organisation (2009). The conceptual framework for the international classification for patient safety.

World Health Organisation (2010). ICD 10. International statistical classification of diseases and related health problems.

World Health Organisation (2014). Global manual on surveillance of adverse events following immunisation. Geneva, World Health Organisation.

World Health Organisation Commission on Social Determinants of Health (2008). Closing the gap in a generation: health equity through action on the social determinants of health: Commission on Social Determinants of Health final report. *In* W. H. Organisation ed. Geneva.

World Health Organisation Regional Office for Europe. (2012). *European detailed mortality database* [*online*]. Available at: http://data.euro.who.int/dmdb/ [Accessed 1st Jul 2015].

Appendices

Appendix 1 – Published manuscripts 241
1.1 BMJ letter (contraindicated BCG vaccination) 241
1.2 Archives of disease in childhood letter (socially deprived children) 243
1.3 Lancet letter (UK child mortality) 245
1.4 Pediatrics manuscript (safety incidents in general practice) 247
1.5 Lancet commentary (iatrogenic harm in children) 257
1.6 Vaccine manuscript (vaccination errors in primary care) 260
Appendix 2 268
2.1 Search terms used to retrieve vaccination-related reports 268
2.2 Search terms used to retrieve reports involving 'unwell' children 269
2.3 Incident descriptors framework 274
2.4 Contributory factors framework 282
2.5 Incident outcomes framework 285
Appendix 3 287
3.1 The frequencies of combinations of incident types described by included vaccination-related reports 287
3.2 The frequencies of combinations of contributory factors for the primary incident types related to vaccination 299
3.3 The frequency of each combination of incidents involving 'unwell' children 314
3.4 The frequency of combinations of contributory factors for each primary incident type involving 'unwell' children 344
3.5 Medline ovid search strategy for literature review 381

Appendix 1 – Published manuscripts

1.1 BMJ letter (contraindicated BCG vaccination)

Rees P, Evans H, Panesar S, Llewelyn M, Edwards A, Carson-Stevens A. Contraindicated BCG vaccination in "at risk" infants. BMJ. 2014 Sep 9;349:g5388. doi: 10.1136/bmj.g5388

BMJ 2014;349:g5388 doi: 10.1136/bmj.g5388 (Published 9 September 2014)

LETTERS

BCG VACCINATION AND TB IN CHILDREN

Contraindicated BCG vaccination in "at risk" infants

Philippa Rees *intercalated MPhil medical student*[1], Huw Evans *academic foundation year 2 doctor*[1], Sukhmeet Panesar *honorary fellow*[2], Meirion Llewelyn *consultant in infectious diseases*[3], Adrian Edwards *professor of general practice and institute director*[1], Andrew Carson-Stevens *clinical lecturer in healthcare improvement*[1]

[1]Cochrane Institute of Primary Care and Public Health, School of Medicine, Cardiff University, Cardiff CF14 4YS, UK; [2]Centre for Population and Health Sciences, University of Edinburgh, Edinburgh, UK; [3]Royal Gwent Hospital, Newport, UK

Roy and colleagues highlight the effectiveness of the BCG vaccine in preventing tuberculosis in immunocompetent children.[1] However, those responsible for prescribing and administering BCG vaccinations must be mindful of the contraindications for immunocompromised children.[2]

Our study of primary care related paediatric safety incidents from the England and Wales National Reporting and Learning System identified 1790 vaccine related incidents during 2005-13.[3] Despite under-reporting of safety incidents, we found 99 reports of BCG related incidents in children at risk of tuberculosis exposure—by living in or having family members from areas with a high prevalence of tuberculosis. A recurrent theme was administration of BCG vaccines to infants of HIV positive mothers in whom full assessment of their HIV status had not been completed. Children infected with HIV are at risk of disseminated BCG disease.[2] Public Health England advises that BCG vaccinations are given only after two appropriately timed negative HIV tests.[4] Poor communication between health services—maternity care, child health, and general practice—is often implicated. Typically, infants are sent appointments by child health services as a result of deficiencies or discrepancies between maternal and child health records. This creates a situation whereby healthcare professionals are unaware of a child's vulnerability.

Vaccine errors remain a threat to patient care.[5] Contraindications to BCG must be explicitly stated within parent held records. Better linkage of maternal and child health records that are accessible in primary and secondary care is also needed.

Healthcare professionals must not rely solely on medical records but should consider, double check, and fully explore with parents (including use of translation services if needed) the child's suitability for the vaccine before administration.

Competing interests: AC-S and AE are co-chief investigators of a National Institute for Health Research Health Services and Delivery Research grant to characterise patient safety incident reports in primary care. PR is a research assistant employed to work on the study. HE and ML have no conflicts of interest. SP is a former clinical adviser at the National Patient Safety Agency (2008-10) and an academic clinical fellow at Imperial College London working for the National Reporting and Learning System research programme.

Full response at: www.bmj.com/content/349/bmj.g4643/rr/762808.

1 Roy A, Eisenhut M, Harris RJ, Rodrigues LC, Sridhar S, Habermann S, et al. Effect of BCG vaccination against Mycobacterium tuberculosis infection in children: systematic review and meta-analysis. *BMJ* 2014;349:g4643. (5 August.)
2 Hesseling AC, Marais BJ, Gie RP, Schaaf HS, Fine PE, Godfrey-Faussett P, et al. The risk of disseminated Bacille Calmette-Guerin (BCG) disease in HIV-infected children. *Vaccine* 2007;25:14-8.
3 National Institute for Health Research. Characterising the nature of primary care patient safety incident reports in England and Wales: mixed methods study. www.nets.nihr.ac.uk/projects/hsdr/1264118.
4 Public Health England. Contraindications and special considerations. In: Immunisation against infectious disease. 2013:41-8. www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6.
5 Derrough TF, Kitchin NR. Occurrence of adverse events following inadvertent administration of childhood vaccines. *Vaccine* 2002;21:53-9.

Cite this as: *BMJ* 2014;349:g5388

carson-stevensap@cardiff.ac.uk

1.2 Archives of disease in childhood letter (socially deprived children)

Rees P, Edwards A, Powell C, Evans H, Panesar S, Carson-Stevens A. Disparities in the quality of primary healthcare for socially deprived children. Arch Dis Child. 2015 Mar;100(3):299-300. doi: 10.1136/archdischild-2014-307618.

LETTERS

Disparities in the quality of primary healthcare for socially deprived children

Mbeledogu *et al*[1] demonstrate a reduction in unintentional poisonings in children in England, yet highlight the protracted social disparities among these children. This resonates with our exploration of over 20 000 paediatric safety incidents from primary care in England and Wales where the 'Inverse Care Law' features prominently.[2] These reports include: looked-after children, immigrants, travellers, parents with addiction problems and those belonging to other disadvantaged groups. Data mining identified over 500 reports involving these groups and 33 reports involving homeless children or families. Such a reporting system has not previously been used to assess unsafe care in socially deprived groups.

Thematic analysis of free-text in reports involving homeless children was undertaken and five overarching failures were identified (see table 1). Some disclosure failures resulted in *breaches of confidentiality* where the location of an abused child was revealed to their abusers through administrative errors (see table 1, example 1). Conversely, *uncertainty around when to disclose information* to members from other disciplines or services was also reported (see table 1, example 2). This led to service fragmentation (eg, no health visitor or general practitioner input) and poor continuity of care (eg, missed safeguarding visits) for at-risk families. Difficulties accessing primary and social care featured often, where some general practices *refused to register children with temporary addresses*—a typical problem for the homeless (see table 1, example 3). In addition, the child was *unable to access care if their mother was not concurrently registered* at the practice. Example 4 illustrates how this culminated in a child not receiving primary healthcare for 4 months. Frequent relocation of families resulted in *untimely transfer of records*. In example 5, an at-risk child was without health visitor support for several weeks.

Our thematic analysis of 33 reports has identified several important issues for consideration by healthcare professionals and policymakers. We recommend general practices review their policies on child registration and have a process in place to make exceptions to any rules, for example requiring co-registration with a parent, for vulnerable children. In addition, all healthcare professionals must be aware of what constitutes a confidentiality breach. Finally, alerting an abuse perpetrator to the location of a victim of abuse should be considered a 'never event'. Never events are unacceptable and preventable incidents that could result in severe harm or death, with defined criteria, and must be reported to the Department of Health.[3]

It is unclear whether these are isolated incidents disclosed within the free-text, or systemic failures particular to homeless families since important patient characteristics (eg, socioeconomic status) are missing from most reports. The value of data linkage to evaluate the impact of patient characteristics on healthcare outcomes was demonstrated in a recent UK-wide enquiry into child mortality.[4] From our characterisation of reports involving children, insights for prioritising and designing future safety interventions could be gained by linking incident reporting systems with electronic medical records and other public or social care registries. This would enable the identification of incident reports relevant to specific groups.

Philippa Rees,[1] Adrian Edwards,[1] Colin Powell,[2] Huw Evans,[1] Sukhmeet Panesar,[3] Andrew Carson-Stevens[1]

[1]Healthcare Quality and Communication Research Group, Cochrane Institute for Primary Care and Public Health, School of Medicine, Cardiff University, Cardiff, UK
[2]Institute of Molecular & Experimental Medicine, School of Medicine, Cardiff University, Cardiff, UK
[3]Centre for Population Health Sciences, The University of Edinburgh, Edinburgh, UK

Correspondence to Dr Andrew Carson-Stevens, Cochrane Institute of Primary Care and Public Health, 3rd Floor, Neuadd Meirionnydd, School of Medicine, Cardiff University, Cardiff CF14 4YS, UK; Carson-StevensAP@cardiff.ac.uk

Competing interests AC-S and AE are co-chief investigators of a NIHR HS&DR grant to characterise patient safety incident reports in primary care. PR is a research assistant employed to work on the study. HE and CP have no conflicts of interest. SP is a former clinical adviser at the NPSA (2008–2010) and an Academic Clinical Fellow at Imperial College London working for the NRLS research programme.

Funding This project was funded by the National Institute for Health Research HS&DR (project number 12/64/118). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HS&DR, NIHR, NHS or the Department of Health.

Table 1 Opportunities for health and social care improvement and free text examples

Opportunity for improvement	Free-text extracts
Breaches of confidentiality	*Example 1*. 17 year-old victim of domestic abuse had been an inpatient and is pregnant. During admission a referral was sent to ultrasound. This patient was discharged to a refuge for safety, and her address changed. I later noticed that her address was changed back–to that of the perpetrator of the domestic abuse–by staff in radiology. This patient's appointment has been sent to the perpetrator's address.
Health and social care professional uncertainties around when to disclose information	*Example 2*. A health visitor attempted a home visit for a baby on the child protection register for neglect. Information regarding the mother and baby being moved to a refuge were withheld. The social worker was reluctant to give the forwarding address and contact number to the health visitor.
Inability to access or register for primary care using a temporary address	*Example 3*. A Social Services department refused to accept a referral as the refugee is only at a temporary address. The family intend to stay in *** this was communicated to the *** department who still declined to accept the referral.
Inability to access primary care if mother is not concurrently registered	*Example 4*. The patients' mother fled domestic violence, registered as homeless and was stabilised on methadone. Registration was arranged with Surgery A, who have subsequently de-registered the child as mother requires on-going support for her addiction [not available at that practice]. Centre B stated that the child was outside of their catchment area. Centre C cannot register a child without the parent (they cannot offer opiate substitution). Therefore a child in contact with services for 4 months is not registered for primary care. This child known to social services does not have a named social worker.
Untimely transfer of records on relocation	*Example 5*. A family were rehoused in the local area with no indication of vulnerability. On examination of the notes, I found that the family was known to social services with concerns regarding the safety of the child. The support team was contacted but the family were not known to them. The family moved from *** to ***. Notes were sent to a health visitor for the homeless but the family had already moved again. Therefore a vulnerable family with a young baby were without support for weeks, putting a child at risk.

1.3 Lancet letter (UK child mortality)

Rees P, Panesar SS, Edwards A, Carson-Stevens A. Child mortality in the UK. Lancet. 2014 Nov 29;384(9958):1923-4. doi: 10.1016/S0140-6736(14)62272-8.

Child mortality in the UK

The UK did particularly poorly in terms of the mortality estimates for children younger than 5 years, produced by the Global Burden of Diseases team (Sept 13, p 957).[1] At 4·9 deaths per 1000 in 2013, the UK has almost the highest rate in western Europe, double that of Sweden, a country with one of the lowest mortality estimates.[2] Furthermore, high-income countries with a high proportion of children living in relative poverty, have a high rate of under-5 mortality (figure).[1,2]

Child poverty in high-income countries varies greatly, suggesting that the level of poverty might be a policy choice, amenable to change by national governments. Analyses consistently show that much of this variation is directly related to differences in tax and benefit systems.[3] Unfortunately, signs of concern suggest that present policies in the UK might be making the situation worse.[4]

Absolute child poverty increased for the first time in 17 years in the UK, during changes to the tax and benefit system that are reducing the adequacy, eligibility, and access to benefits, especially for some families with lowest incomes with children.[4] Governmental cuts to spending for the public sector are affecting services relied on by families with low incomes who have children, with the largest spending cuts to budgets of local authorities in deprived areas.[5]

If we are to reduce the number of child deaths in the UK we need a welfare system that prioritises children, with a renewed focus on improving the circumstances in which children grow up, alongside systematic improvements in health services.[6]

We declare no competing interests.

*David Taylor-Robinson, Jonathan Bradshaw, Ben Barr, Margaret Whitehead
dctr@liv.ac.uk

Department of Public Health and Policy, University of Liverpool, Liverpool L69 3GB, UK (DT-R, BB, MW); Population, Policy and Practice, Institute for Child Health, University College London, London, UK (DT-R); and Department of Social Policy and Social Work, University of York, Heslington, UK (JB)

1 Wang H, Liddell CA, Coates MM, et al. Global, regional, and national levels of neonatal, infant, and under-5 mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2014; **384:** 957–79.
2 UNICEF. Child well-being in rich countries: a comparative overview. 2011. http://www.unicef.org.uk/Images/Campaigns/FINAL_RC11-ENG-LORES-fnl2.pdf (accessed May 10, 2014).
3 Marx I, Nelson K. Minimum income protection in flux. Houndmills, Basingstoke, Hampshire, UK: Palgrave Macmillan, 2013.
4 Taylor-Robinson D, Harrison D, Whitehead M, Barr B. Doctors need to take the lead on poverty's effects on health. *BMJ* 2013; **347:** f7540.
5 Taylor-Robinson D, Gosling R. English north-south divide. Local authority budget cuts and health inequalities. *BMJ* 2011; **342:** d1487.
6 Wolfe I, Thompson M, Gill P, et al. Health services for children in western Europe. *Lancet* 2013; **381:** 1224–34.

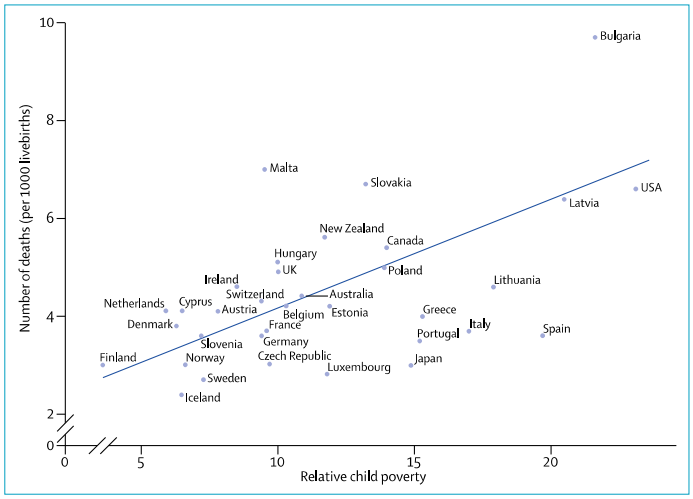


Figure: **Child poverty and mortality in 35 countries in the Organisation for Economic Co-operation and Development**
Child relative poverty rates (having equivalised household income of less than 50% of the national median) are from the 2013 UNICEF report.[2] Mortality estimates are for children younger than 5 years for 2013 from the Global Burden of Diseases analysis by Wang and colleagues.[1] Linear regression trend line; mortality in children younger than 5 years is calculated by 1·94 + 0·22 × relative child poverty; p<0·0001; R2=0·40.

Haidong Wang and colleagues[1] emphasise the importance of global monitoring to identify countries most in need of improvement. Although we support this ambition, we recognise that every country has a responsibility to build infrastructure and assimilate data sources (old and new) to identify opportunities to improve the quality of health and provision of social care for children. A review[2] suggested that more than 20% of child deaths in the UK in 2013 had so-called modifiable factors, whereby health care could have intervened to mitigate the risk of death. Analysis of routine data sources, such as data from incident reports for patient safety, could help to understand what common contributory, modifiable factors might be.[3]

A global registry for paediatric safety using a minimum dataset from every country, irrespective of economic setting, would allow the necessary surveillance to ensure harm was mitigated against and indeed solutions developed to prevent these avoidable deaths in children. This registry will need a combination of analytics with clinical expertise to generate action-orientated outputs with strong face validity in the health-care profession.

AE, AC-S, SSP, and PR work on a project funded by the National Institute of Health Research (NIHR) Health Services and Delivery Research (HS&DR) to characterise patient safety incident reports in primary care. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HS&DR, NIHR, UK National Health Service, or the Department of Health (UK).

1.4 Pediatrics manuscript (safety incidents in general practice)

Rees P, Edwards A, Panesar S, Powell C, Carter B, Williams H, Hibbert P, Luff D, Parry G, Mayor S, Avery A, Sheikh A, Donaldson SL, Carson-Stevens A. Safety incidents in the primary care office setting. Pediatrics. 2015 Jun;135(6):1027-35. doi: 10.1542/peds.2014-3259

Safety Incidents in the Primary Care Office Setting

Philippa Rees, BSc (Hons)[a], Adrian Edwards, PhD[a], Sukhmeet Panesar, MD[b], Colin Powell, MD[c], Ben Carter, PhD[a], Huw Williams, MBBS[a], Peter Hibbert, Grad Dip Econ[d], Donna Luff, PhD[e,f], Gareth Parry, PhD[g,h], Sharon Mayor, PhD[a], Anthony Avery, DM[i], Aziz Sheikh, MD[b,j,k], Sir Liam Donaldson, MD[l], Andrew Carson-Stevens, MPhil[a,m]

abstract

BACKGROUND: In the United Kingdom, 26% of child deaths have identifiable failures in care. Although children account for 40% of family physicians' workload, little is known about the safety of care in the community setting. Using data from a national patient safety incident reporting system, this study aimed to characterize the pediatric safety incidents occurring in family practice.

METHODS: We undertook a retrospective, cross-sectional, mixed methods study of pediatric reports submitted to the UK National Reporting and Learning System from family practice. Analysis involved detailed data coding using multiaxial frameworks, descriptive statistical analysis, and thematic analysis of a special-case sample of reports. Using frequency distributions and cross-tabulations, the relationships between incident types and contributory factors were explored.

RESULTS: Of 1788 reports identified, 763 (42.7%) described harm to children. Three crosscutting priority areas were identified: medication management, assessment and referral, and treatment. The 4 incident types associated with the most harmful outcomes are errors associated with diagnosis and assessment, delivery of treatment and procedures, referrals, and medication provision. Poor referral and treatment decisions in severely unwell or vulnerable children, along with delayed diagnosis and insufficient assessment of such children, featured prominently in incidents resulting in severe harm or death.

CONCLUSION: This is the first analysis of nationally collected, family practice–related pediatric safety incident reports. Recommendations to mitigate harm in these priority areas include mandatory pediatric training for all family physicians; use of electronic tools to support diagnosis, management, and referral decision-making; and use of technological adjuncts such as barcode scanning to reduce medication errors.

[a]*Cochrane Institute of Primary Care and Public Health, Cardiff University, Cardiff, Wales;* [b]*Centre for Medical Informatics, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Edinburgh, Scotland;* [c]*Institute of Molecular and Experimental Medicine, School of Medicine, Cardiff University, Cardiff, Wales;* [d]*Australian Institute of Health Innovation, Macquarie University, Sydney, New South Wales, Australia;* [e]*Department of Anaesthesia,* [g]*Department of Pediatrics, and* [j]*Department of Medicine, Harvard Medical School, Boston, Massachusetts;* [f]*Institute for Professionalism and Ethical Practice and Department of Anesthesia, Boston Children's Hospital, Boston, Massachusetts;* [h]*Institute for Healthcare Improvement, Cambridge, Massachusetts;* [i]*Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, United Kingdom;* [k]*Division of General Internal Medicine and Primary Care, Brigham and Women's Hospital, Boston, Massachusetts;* [l]*Department of Surgery and Cancer, Imperial College London, London, United Kingdom; and* [m]*Department of Family Practice, University of British Columbia, Vancouver, British Columbia, Canada*

Professors Edwards, Avery, Sheikh, and Donaldson, Drs Panesar, Mayor, and Carson-Stevens, and Mr Hibbert conceptualized the study; Professors Edwards, Avery, Sheikh, and Donaldson, Drs Panesar, Mayor, Parry, and Carson-Stevens, and Mr Hibbert designed the study; Dr Luff provided invaluable guidance on the use of qualitative methods and study design; Drs Carter and Parry were responsible for quantitative analysis; Miss Rees and Drs Panesar and Carson-Stevens were responsible for data coding, qualitative analysis, and interpretation of results; Professors Edwards, Avery, Sheikh, and Donaldson, Drs Powell, Williams, Luff, and Mayor, and Mr Hibbert were involved in the interpretation of results; Professor Edwards and Drs Carson-Stevens, Powell, and Williams created recommendations for practice; Miss Rees drafted the initial manuscript; Professors Edwards, Avery, Sheikh, and Donaldson, Drs Panesar, Powell, Carter, Williams, Luff, Mayor, and Parry, and Mr Hibbert reviewed the manuscript; Miss Rees and Dr Carson-Stevens revised the final manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

www.pediatrics.org/cgi/doi/10.1542/peds.2014-3259

DOI: 10.1542/peds.2014-3259

Accepted for publication Mar 19, 2015

WHAT IS KNOWN ON THIS SUBJECT: More than a quarter of child deaths in the United Kingdom are estimated to have identifiable failures in care. Although children account for 40% of the family practice workload, little is known about iatrogenic harm to children in this setting.

WHAT THIS STUDY ADDS: This is the first analysis of nationally collected pediatric safety incident reports from family practice. To mitigate harm to children, priority areas requiring improvement include medication provision, referral of unwell children, provision of evidence-based treatment, and adequate diagnosis and assessment.

The quality and safety of health care is an established public health concern.[1–3] Efforts to improve health care delivery have largely been in high-income countries and in hospital rather than community settings.[4] There has also been relatively little focus on child health and pediatric services.[5] Although children account for 40% of family physicians' workload, little is known about the safety of care delivered to children in the community setting.[6,7] In the United Kingdom, family practice is usually the patient's first point of contact with the health care service; most health care encounters occur in this setting, and it acts as a gateway to acute and specialist hospital-based services.

Several methods have been used to measure health care–associated harm in pediatrics, and challenges remain.[8] A child mortality review in the United Kingdom found that 43% of child deaths had potentially avoidable factors, and 26% had identifiable failures in care.[9,10] However, because of the relatively low number of deaths, mortality data are not powered to provide epidemiologic associations on the impact of patient safety issues.[11] In contrast, incident reporting systems have a well-established infrastructure, can provide large quantities of data on pediatric safety, and have the potential for greater insight and hypothesis generation than mortality data alone.[12]

This study is the first systematic, mixed-methods analysis of nationally collected patient safety incident reports involving children in family practice. Previous studies have demonstrated the value of using incident reporting systems to improve care quality in neonatal settings.[13] National repositories of patient safety incident reports permit the identification of clusters of similar reports that could be potentially overlooked as rare events at a local level. Priority areas for practice can be identified at a national level, and insights can be gained from exploring common contributory factors related to incident type. These can inform the basis of recommendations for improvements in pediatric care.[5,14,15]

This study aimed to explore the nature and severity of pediatric safety incidents occurring in family practice and their potential contributory factors. Our objective was to identify potential priority areas for intervention.

METHODS

National Reporting and Learning System

The England and Wales National Reporting and Learning System (NRLS) was established in 2003 as a national repository of reports about patient safety incidents, defined as "any unexpected or unintended incident[s] which could have, or did, lead to harm to one or more patients."[16] The NRLS receives ~100 000 reports per month written by patients or health care providers from any National Health Service organization in England and Wales, and annually >65 000 reports involve children.[5] Reports can be submitted directly to the NRLS online, or staff can report incidents to their local health boards, which subsequently upload the reports to the NRLS; all reports are anonymized. Each NRLS report contains several categories of data, including patient age, incident location, date of incident, free-text fields containing descriptions of the incident, and severity of harm outcome (no harm, low harm, moderate harm, severe harm, and death).

Sample selection

Incident reports from family practice in England and Wales (April 2003 to June 2012) involving patients aged <18 years were identified by manually applying an age filter to all 46 902 family practice reports available. On reading the reports, some were still evident as adult cases and excluded.

Methodology

We undertook a retrospective, cross-sectional, mixed-methods study combining a detailed data coding process, frequent generation of data summaries using descriptive statistical analysis, and thematic analysis of a theoretical and special-case sample of reports. New ideas and hypotheses emerged throughout each step of analysis for later corroboration.

Data Coding

We used an inductive, grounded approach to apply codes to each incident report from a codebook containing 2 distinct multiaxial coding frameworks (empirically developed in-house) to describe the type of safety incident (administration, medication, etc.) and contributory factors (patient, staff, environmental, etc.), as well as the World Health Organization (WHO)

TABLE 1 Severity of Harm Described Within Reports

Severity of Harm	Reports, *n* (%)
No harm: patient outcome is not symptomatic and no treatment is required	1025 (57.3)
Low harm: patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal and intermediate but short term, and no or minimal intervention is required	675 (37.8)
Moderate harm: patient outcome is symptomatic requiring intervention, an increased length of stay, or causing permanent or long-term harm or loss of function	71(4)
Severe harm: patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function	9 (0.5)
Death: on balance of probabilities, death was caused or brought forward in the short term by the incident	8 (0.4)
Total	1788 (100)

International Classification of Patient Safety to describe harm severity (see Table 1 for definitions).[17,18]

We concluded from early pilot work that existing classification systems for primary care did not permit us to code at the level of detail needed to answer our research questions. Thus, we empirically developed 2 coding frameworks to describe the incidents in detail and capture the complex and often multiple contributory factors. We acknowledge that at initial conceptual level, preexisting taxonomies (largely the WHO International Classification of Patient Safety and the Learning from International Networks about Errors and Understanding Safety in Primary Care [LINNAEUS Euro-PC] taxonomy) informed our high-level considerations for both frameworks, as we recognized this was important to permit comparison between studies of this nature.[17,19]

Initially, an iterative constant comparative method was used: a small number of incident narratives were read, preliminary codes were extracted, and these codes were revised through further reading of additional reports. This cycle was repeated until a stable set of codes was developed between 2 authors (Miss Rees and Dr Carson-Stevens, both trained in root cause analysis and human factors). Subsequent codes were discussed and frameworks were iterated at weekly coding meetings involving family physicians, health services researchers, and anthropologists.[20] This process enabled development of codes particular to reports about children in family practice.

One to 4 codes were used to describe the incidents and 1 to 4 codes to describe the potential contributory factors, in keeping with 9 recursive incident analysis rules developed by the Australian Patient Safety Foundation (see Supplemental Appendix 1).[21] Twenty percent of the reports were independently double-coded (Miss Rees and Dr Carson-Stevens). Interrater reliability (Cohen's κ statistics) were calculated for the primary incident type (chronologically closest to the outcome experienced by the patient) and contributory factors. These were κ = 0.88 (95% confidence interval 0.85–0.9) and κ = 0.86 (95% confidence interval 0.82–0.9), respectively. Disagreements in coding were resolved by a third reviewer (Dr Panesar) and discussion with the coding team. Coding of free-text entries allowed categorization of reports by incident type to provide the basis for subsequent data analysis. Similar methods have been used in previous research involving hospital NRLS reports.[22,23]

Where the severity of harm stated in the NRLS report conflicted with the report's free-text incident description, the level of harm was adjusted using the WHO's International Classification of Patient Safety definitions.[17]

Data Analyses

Qualitative codes were transformed into dichotomous variables for quantitative analyses, frequency distribution, and cross-tabulation, to explore the relationship between each incident type and the respective contributory factors.[24] All severe harm and death reports underwent a thematic analysis by Miss Rees and Dr Carson-Stevens to provide more in-depth insights into this subset of reports.[20] Priority areas for improvement were identified based on frequently harmful incidents that also resulted in severe harm or death. Recommendations for improving these priority areas were informed by the factors contributing to them, systematic literature searches, and consultation with subject matter experts. Recommendations were articulated in an improvement tool called a driver diagram.[25,26]

Ethical Approval

Aneurin Bevan University Health Board research risk review committee waived the need for ethics review given the anonymized nature of the data (ABHB R and D reference number SA/410/13).

RESULTS

Baseline Characteristics

We included 1788 incident reports in the analysis after excluding 350 reports because they were about adult patients (n = 216), contained insufficient free-text information (n = 82), were reports about system issues that did not result in a patient safety incident (n = 32), or described deaths not associated with health care (n = 20).

Of the 1788 reports included, 763 described incidents in which children experienced harm, including 675 reports of low harm, 71 reports of moderate harm, 9 reports of severe harm, and 8 reports of death (see Table 1 for definitions). Incidents that resulted in severe harm and death will be referred henceforth as the "most harmful" incidents. Twelve parent incident types were evident, including those related to administration, medication, referral, and vaccination that were responsible for 71.8% of reports (see Fig 1 and Table 2). The most frequent contributory factors included documentation-related errors such as inaccurate medical records, resource issues such as staffing, staff cognitive issues (ie, mistakes), and clinical skills errors such as inadequate patient assessment (see Table 3).

Vaccine-related incidents were the most frequently described and contained the most descriptions of harm to patients (n = 472, 70.6%), including 459 cases of low harm and 13 cases of moderate harm. Administration of vaccines at the wrong time (n = 104), the wrong number of doses (n = 237), and the wrong vaccine (n = 154) were the most frequently described vaccination incidents. The key factors contributing to these incidents

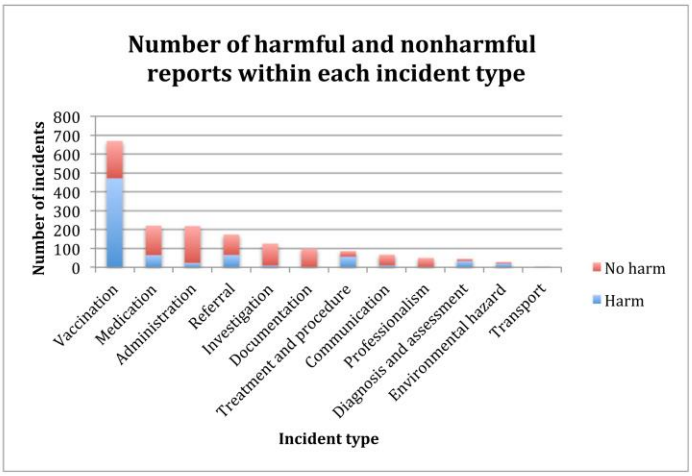


FIGURE 1
Twelve parent incident types and the proportion of harmful incidents described within each incident type.

included documentation errors (n = 129) and staff mistakes (n = 101). However, vaccination incidents did not result in any cases of severe harm or death. We present a summary of findings from the most frequent and most harmful incident types that were described as resulting in severe harm or death. The 4 key incident types presented (diagnosis and assessment, treatment and procedures, referral issues, and medication provision) form the basis of 3 crosscutting priority areas requiring improvement (see Table 2 and Fig 2). Although administration incidents did result in severe harm and death, they were infrequently harmful and were therefore not prioritized for inclusion here.

Diagnosis and Assessment–Related Incidents

Diagnosis and assessment incidents were described in 45 reports, and most (n = 34, 76%) described harm, including 4 deaths, 3 cases of severe harm, 11 cases of moderate harm, and 16 cases of low harm. The most harmful incidents frequently described delayed diagnosis or insufficient assessment of children with signs of child maltreatment, respiratory distress, diabetes, peritonsillar abscess, cervical fracture, and gastroenteritis during an *Escherichia coli* 0157 outbreak (see examples 4.1 and 4.2 in Table 4). Potential contributory factors were described for 40% (n = 18) of incidents (Table 5). Knowledge-related errors (n = 7), such as missing signs of child maltreatment (example 4.1) and errors of patient assessment (example 4.2) (triaging, history taking, examination, and investigation) (n = 7), were most frequently described.

TABLE 2 Twelve Parent Incident Types Presented With Their Frequency and the Proportion of Harmful Reports

Incident Type	Incidents		
	All, n	Harmful, n (%)	Severe Harm and Death, n
Diagnosis and assessment	45	34 (76)	7
Environmental hazard[a]	28	20 (71)	0
Vaccination	669	472 (70.6)	0
Treatment and procedure	86	57 (66)	2
Transport[a]	4	2 (50)	0
Referral	174	66 (38)	3
Medication	221	65 (30)	2
Communication	67	10 (15)	0
Administration	219	24 (11)	3
Investigation	126	10 (8)	0
Documentation	99	2 (2)	0
Professionalism	50	1 (2)	0
Total	1788	763 (42.7)	17

[a] Rare (frequency <30).

Treatment and Procedure–Related Incidents

Most (n = 57, 66%) treatment and procedure incidents described harm to children; these included 1 death, 1 case of severe harm, 6 cases of moderate harm, and 49 cases of low harm. The most harmful incidents were often the result of incorrect treatment decisions, particularly treatment of asthma and diabetes (see examples 4.3 and 4.4 in Table 4). Potential contributory factors were described for 71% (n = 61) of incidents, including mistakes (n = 23) such as inadvertently getting glue in a child's eye when gluing a forehead laceration; poor-quality equipment (n = 13) such as a broken refrigerator; and poor knowledge (n = 10) such as how to correctly manage first presentation of diabetes in children (example 4.3, Table 5).

Referral–Related Incidents

Harm from referral-related incidents was described in 66 reports, including 2 deaths, 1 case of severe harm, 23 cases of moderate harm, and 40 cases of low harm (see examples 4.5 and 4.6 in Table 4). Referral decisions were frequently reported as harmful (n = 20, 59% of reports) and were often (n = 10, 50%) preceded by incidents of diagnosis and assessment (example 4.5). Example 4.5 illustrates a failure to refer a child as a result of insufficient assessment and diagnosis, whereas example 4.6 illustrates a referral issue, which is not described as the result of insufficient

TABLE 3 Frequency of Reported Contributory Factors

Contributory Factors	Reports, *n* (%)
Documentation errors (inadequate handling or updating of patient records)	207 (11.6)[a]
Inaccurate patient records	135 (7.6)
Transfer of records	80 (4.5)
Staff mistakes (cognitive lapses including inattention and distraction)	149 (8.3)
Resource issues (inadequate supply of treatment, equipment, or staff)	145 (8.1)[a]
Human resources (staffing)	74 (4.1)
Equipment availability and safety	40 (2.2)
Treatment availability	31 (1.7)
Other resources	2 (0.1)
Failure to follow protocol (not adhering to organizational guidelines)	109 (6.1)[a]
Treatment protocol	44 (2.5)
Other and nonspecific protocols	37 (2.1)
Child protection protocol	21 (1.2)
Acutely unwell patients	7 (0.4)
Clinical skills errors (inadequate execution of routine tasks)	93 (5.2)[a]
Communication	70 (3.9)
Error in patient assessment	20 (1.1)
Other clinical skills	5 (0.3)
Treatment provision errors (issues with the process of medication delivery)	81 (4.5)
Medication names confused	43 (2.4)
Other	34 (1.9)
Patient names confused	4 (0.2)
Knowledge errors (insufficient knowledge or inadequate application of it)	53 (3.0)
Inadequate guidelines or protocols (existing guidelines not fit for purpose)	31 (1.7)
Poor continuity of care (issues with the coordination of services)	29 (1.6)
Total	897 (50.2)

[a] Some reports contained descriptions of multiple types of a contributory factor.

diagnosis and assessment. Among the most harmful incidents, themes included failure to refer children with child protection concerns; decisions not to refer acutely unwell children with respiratory difficulties; and failure to follow up or refer children with development delays. In addition, a sudden unexplained death was reported in a child with a history of seizures for which there was no evidence of referral.

Potential contributory factors were described for 68% (n = 118) of referral-related incidents including errors of patient assessment (n = 13), failure to follow child protection protocols (n = 16, example 4.5), staffing issues (n = 26), documentation errors (n = 25), and poor knowledge (n = 18) (Table 5).

Medication–Related Incidents

Most (n = 156, 70.6%) medication-related incident reports did not describe harmful outcomes, although 2 reports described severe harm, 12 described moderate harm, and 51 described low harm. Of the incidents resulting in moderate or severe harm, prescribing or dispensing a medication overdose was a recurring theme. Two incidents involved furosemide overdose, and another involved

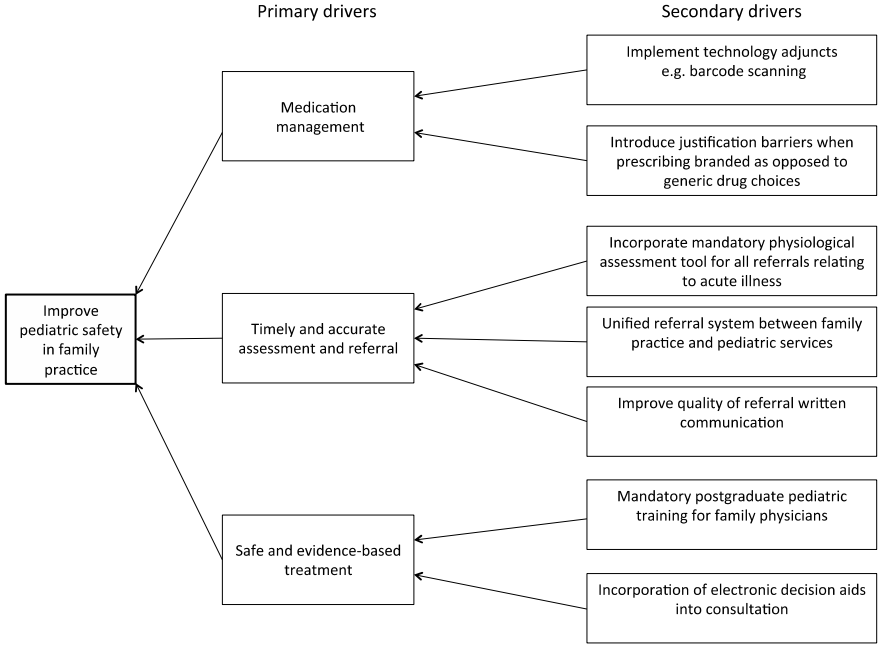


FIGURE 2
Driver diagram demonstrating priority areas for improved pediatric care in family practice

TABLE 4 Edited Extracts From Incident Reports

Diagnosis and Assessment–related Incidents

Example 4.1: Mother of a 3-year-old noticed blood on child's pajamas. Physician diagnosed cystitis and prescribed antibiotics without examining child or taking a urine sample. Bleeding in a 3-y-old is unusual, and physician should have sought a pediatric review. Patient seen by pediatrician 5 d later when it was discovered that child had been sexually abused. (Severe harm)

Example 4.2: Child was wrestling and fell. Child screamed and neck appeared to lock. Out-of-hours physician examined child seated on mother's lap. Child was limited in his movements. Mother felt examination was not thorough. Physician advised the injury was not serious. Child was unable to walk to get to the toilet. Mother was concerned and rang out of hours (unscheduled care) service again. New physician said child was in shock and that he did not have a fracture because she would be able to feel it. On Sunday the child was still immobile and laying flat and complaining of pain. On Tuesday, mother contacted the family physician who believed the child had a serious injury. He has a spinal fracture between C2 and C3. The neck is currently at a 30-degree forward angle. (Severe harm)

Treatment and Procedure–related Incidents

Example 4.3: Patient saw family doctor with 3-week history of symptoms of diabetes. After documenting high blood sugar, she was started on an oral hypoglycemic drug. Brought to emergency department with blurred vision. Patient was inappropriately treated and not referred promptly. (Moderate harm)

Example 4.4: Admitted to ICU with diabetic ketoacidosis. The incident is the result of advice given to mother by the family physician to omit evening insulin. (Severe harm)

Referral–Related Incidents

Example 4.5: Child seen for child protection medical on February 15, with facial bruising, described as being suggestive of possible slap mark and finger print bruising. On February 13, child was seen by 2 practice nurses for another matter who advised mother to take child to the out-of-hours family physician if bruising got worse or if the child became unwell. The serious significance of the bruising nor the need for a referral to be made did not seem to be considered. (Severe harm)

Example 4.6: Boy seen by family physician July 14 with history of increased thirst, polyuria, waking up in the night for micturition, lethargy, tiredness for 2 to 3 wks. Blood tests (July 17) showed high blood sugar (13.9 mmol/L). Notes (July 19) say to review and consider if he needs to be referred. July 20, child was seen with sugar and ketones in urine and referred to hospital in ketosis. Any child with suspected diabetes should be referred within 24 h to hospital pediatrician. (Moderate harm)

Medication–related Incidents

Example 4.7: Risperidone dose (5 mg twice daily) recommended by child and adolescent mental health team for a child that they had assessed. The family doctor requested a consultant's opinion and was informed that this was the dose agreed by the team. Patient later presented with signs of toxicity (dyskinetic tongue). (Severe harm)

Example 4.8: Dispensed [acetaminophen] elixir instead of lactulose—similar products stored together in same-colored containers. (Low harm)

a 10-fold overdose that resulted in prolonged hospitalization of the child. Another report described a risperidone overdose prescribed by a family physician on the instruction of a child psychiatrist (example 4.7).

Table 4 illustrates examples of medication-related reports. Most medication incidents (n = 119, 53.8%) were prescribing errors (see Table 6). Potential contributory factors were described for 33% of those reports (n = 73). Errors in the process of treatment provision (n = 24), such as confusing medication names (n = 12), were frequently described. Communication errors (n = 10, example 4.7) and staff mistakes, such as misreading medication names (n = 17, example 4.8), were also frequently described (Table 5).

TABLE 5 Frequency of Contributory Factors Described for Each Key Incident Type

Contributory Factors	Incident Type, n			
	Diagnosis and Assessment	Treatment and Procedure	Referral	Medication
Documentation errors	1	2	40	4
Staff mistakes	0	23	1	17
Resource issues	3	21	28	7
Failure to follow protocol	4	4	28	6
Clinical skills errors	9	6	26	15
Treatment provision errors	1	0	0	24
Knowledge errors	7	10	16	8
Inadequate guidelines or protocols	0	4	11	1
Poor continuity of care	1	1	6	3
Total	26	71	156	85

Note: some incidents had multiple contributory factors.

Driver Diagram

Three broad crosscutting priority areas (denoted "primary drivers") with more specific articulations of the priority concepts (denoted "secondary drivers") were identified as candidate areas eligible for development and testing of interventions in practice to improve pediatric care (see Fig 2). The driver diagram was authored collaboratively by all study authors after analysis.

DISCUSSION

Of the harmful incidents reported from family practice, key pediatric safety issues include timely diagnosis, assessment, and referral of unwell children to the hospital; reliability of safe, evidence-based treatment; and prescribing and dispensing of medications. These priority areas include the 4 most harmful and frequently reported incident types. We recommend that improvements in these areas focus on the factors frequently reported to contribute to them. Examples are included in Fig 2 as a driver diagram that family practice teams could use as the basis for planning their own improvement efforts, supplemented by insights from their own locally available patient safety data.[15]

This is the first analysis of a large volume of pediatric incidents in family practice from a national database. Rigor was improved by careful consideration of methods

TABLE 6 Subtypes of Medication Incidents Reported

Medication Incident Subtypes	Reports, *n*
Prescribing	119
Dispensing	53
Administering	25
Adverse reaction	9
Other	15
Total	221

before analysis, double-coding, weekly meetings to discuss coding, and keeping an audit trail to aid reflexivity.[20,27]

Reporting systems rely on data input (reporting) to generate learning; unfortunately, only 50% of reports included in this analysis described potential contributory factors, and reporters do not routinely describe the root-cause, system-level factors contributing to incidents. In addition to variable data quality, underreporting is a well-acknowledged issue with the NRLS.[28] This affects the validity and generalizability of our findings, which should be regarded as essentially inductive, and hypothesis generating, requiring confirmation in further studies.[29,30] Despite this, reporting to the NRLS has increased in the last decade, providing large quantities of data from which to generate learning.[31,32] There may be other harmful incident types occurring in family practice that are underreported owing to fear of reprimand.[33] However, despite limitations from underreporting and reporting biases, analyses of NRLS data have played an important role in generating lessons to mitigate harmful incidents in other areas of clinical practice.[34,35] Incident report data offer a single lens on patient safety, and our findings must be interpreted cautiously alongside other data sources.

The relatively low number of reports describing diagnosis and assessment errors was unexpected, as family practice has been widely criticized for failures in recognizing sick children.[11,36] For example, Thompson et al found that 50% of children with meningococcal infection are sent home from their first consultation.[37] Such failures likely contribute to the United Kingdom's relatively high child death rates from meningococcal disease, pneumonia, and asthma, where first-access services such as primary care are integral.[38,39] Diagnosis and assessment incidents tend to be a reflection of providers' skills and competencies and may be less likely to be reported.

Management of long-term pediatric conditions, such as epilepsy, asthma, and diabetes, has been repeatedly cited as requiring improvement.[9,11,36,39] For example, most (75%) pediatric asthma-related hospital admissions are thought to be preventable with better primary care.[40] Our findings reflect the significant potential for harm to children that exists as a result of poor management and treatment of long-term pediatric conditions in primary care.

Referrals made to hospitals, management of long-term conditions, and diagnosis and assessment of acutely ill children were all identified as problem areas, for which training interventions could be a generic improvement strategy. The numerous reports describing referral issues were anticipated, as UK primary care acts as a gateway to specialist hospital services. However, ~36% of referrals to pediatricians are thought to be avoidable with better family physician training.[39,41] Currently, as few as 40% of family physicians have pediatric training at a postgraduate level, causing many to support mandatory family physician pediatric training.[39]

Our findings support such calls for mandatory pediatric training, as reported harm from incidents related to referral, treatment, diagnosis and assessment were frequently associated with errors of knowledge and patient assessment.[39] Training should be accompanied by regular measurement and monitoring of physician performance. Improvement in the timely referral of unwell children should focus on simplifying referral protocols for children at high risk, making them easier to follow and giving them face validity; for example, using an electronically generated and transmitted unified referral form. This could be supplemented with online decision support for physicians' decisions regarding the management, diagnosis, assessment, and referral of unwell children.[42]

High numbers of reports describing harmful medication incidents were expected, as they are often harmful and widely cited as the most common medical errors.[1,43–46] In addition, medication incidents in pediatrics may be ≤3 times more common than in adults.[43,47] Most medications are prescribed off license and can require complex dose calculations.[48,49] Pediatric medication incidents (including their extent and methods to reduce them) have been extensively explored in the hospital setting, but less so in family practice.[43,47,50–54] Our findings emphasize the importance of verification procedures and support barcode scanning of medications during dispensing and using generic medication names (rather than brand names) to reduce mistakes from inattention or distraction and communication errors.[55–57]

CONCLUSIONS

This is the first analysis of nationally collected pediatric safety incidents from family practice. Potential priority areas for improved care for children in this setting have been identified in timely diagnosis, assessment, and referral of unwell children; reliable delivery of safe treatment; and medication provision. Suggested

improvements in these areas include mandatory pediatrics training for all family physicians; use of electronic tools to support diagnosis, management and referral decision-making; and, use of technological adjuncts such as barcode scanning systems for medication provision.

Address correspondence to Dr Andrew Carson-Stevens, 3rd Floor Neuadd Meirionnydd, Cochrane Institute of Primary Care and Public Health, School of Medicine, Cardiff University, Cardiff, CF14 4YS, Wales. E-mail: carson-stevensap@cardiff.ac.uk

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: All authors are contributing to a project funded by the National Institute for Health Services and Delivery Research (HS&DR) program (project number 12/64/118). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of HS&DR, the National Institute for Health Research (NIHR), the National Health Service, or the Department of Health.

POTENTIAL CONFLICT OF INTEREST: Dr Carson-Stevens and Professor Edwards are co-chief investigators, and Drs Panesar, Professor Sheikh, Dr Mayor, Professor Avery, and Professor Donaldson are co-applicants, of a NIHR HS&DR grant to characterize patient safety incident reports in primary care. Professor Donaldson was the Chairman of the National Patient Safety Agency (NPSA) (2010 to 2012) and is currently involved in the program of research associated with the National Reporting and Learning System (NRLS); he is also the World Health Organization's Patient Safety Envoy. Dr Panesar is a former clinical adviser at the NPSA (2008 to 2010), then special adviser to Professor Donaldson (2010 to 2012), and a former academic clinical fellow at Imperial College London working for the NRLS research program.

REFERENCES

1. Department of Health. *An organisation with a memory.* London: Stationary Office; 2000
2. WHO. 10 Facts on Patient Safety. Available at: www.who.int/features/factfiles/patient_safety/en/. Accessed June, 11, 2014
3. Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academies Press; 2001
4. Sheikh A, Panesar SS, Larizgoitia I, Bates DW, Donaldson LJ. Safer primary care for all: a global imperative. *Lancet Glob Health.* 2013;1(4):e182–e183
5. Carson-Stevens A, Edwards A, Panesar S, et al. Reducing the burden of iatrogenic harm in children. *Lancet.* 2015, In press.
6. Cresswell KM, Panesar SS, Salvilla SA, et al; WHO Safer Primary Care Expert Working Group. Global research priorities to better understand the burden of iatrogenic harm in primary care: an international Delphi exercise. *PLoS Med.* 2013;10(11):e1001554
7. Hippisley-Cox J, Fenty J, Heaps M. Trends in consultation rates in general practice 1995 to 2006: analysis of the QRESEARCH database. QRESEARCH research highlights. Leeds: The Information Centre; 2007:29
8. Walsh KE, Bundy DG, Landrigan CP. Preventing health care-associated harm in children. *JAMA.* 2014;311(17):1731–1732
9. Pearson G. *Why Children Die: A Pilot Study 2006 England (South West, North East and West Midlands), Wales and Northern Ireland. Confidential Enquiry into Maternal and Child Health.* London: CEMACH; 2008
10. Department of Education. Child Death Reviews: Year Ending March 31, 2013. Available at: www.gov.uk/government/statistics/child-death-reviews-year-ending-31-march-2013. Accessed March 2015
11. Wolfe I, Macfarlane A, Donkin A, Marmot M, Viner R. *Why Children Die: Death in Infants, Children and Young People in the UK.* London: Royal College of Paediatrics and Child Health; 2014
12. Noble DJ, Panesar SS, Pronovost PJ. A public health approach to patient safety reporting systems is urgently needed. *J Patient Saf.* 2011;7(2):109–112
13. Suresh G, Horbar JD, Plsek P, et al. Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pediatrics.* 2004;113(6). Available at: www.pediatrics.org/cgi/content/full/113/6/e1609
14. Rees P, Evans H, Panesar S, Llewelyn M, Edwards A, Carson-Stevens A. Contraindicated BCG vaccination in "at risk" infants. *BMJ.* 2014;349(7974):g5388
15. Rees P, Carson-Stevens A, Williams H, Panesar S, Edwards A. Quality improvement informed by a reporting and learning system. *Arch Dis Child.* 2014:99:702–703
16. National Reporting and Learning System. Organisation Patient Safety Incident Reports. Available at: www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/. Accessed September 10, 2014
17. WHO. The Conceptual Framework for the International Classification for Patient Safety. Available at: http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf. Accessed March 2015
18. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, eds. *Analyzing Qualitative Data.* London: Routledge; 1994:173–194
19. LINNEAUS Euro-PC. Patient Safety Incident Classification for Primary Care (PSIC-PC). Available at: www.linneaus-pc.eu/cms-assets/documents/117326-607818.psic-pc-version-3-1.pdf. Accessed March 2015
20. Green J, Thorogood N. Qualitative Methods for Health Research, 2nd ed. Thousand Oaks, CA: Sage; 2009
21. Hibbert PD, Runciman WB, Deakin A. A Recursive Model of Incident Analysis. Adelaide, Australia: Australian Patient Safety Foundation. Available at: www.apsf.net.au/dbfiles/A%20Recursive%20Model%20of%20Incident%20Analysis.pdf. Accessed March 2015

22. Latif A, Rawat N, Pustavoitau A, Pronovost PJ, Pham JC. National study on the distribution, causes, and consequences of voluntarily reported medication errors between the ICU and non-ICU settings. *Crit Care Med*. 2013;41(2):389–398

23. Harris DM, Westfall JM, Fernald DH, et al. Mixed methods analysis of medical error event reports: a report from the ASIPS Collaborative. In: Henriksen K, Battles JB, Marks ES, et al. ed. *Advances in Patient Safety: From Research to Implementation, Vol. 2*. Rockville, MD: Agency for Healthcare Research and Quality; 2005:133–147

24. Scobie A, Cook S. Analysis of health care error reports. In: Hurwitz B, Sheikh A, eds. Health Care Errors and Patient Safety. New York: Wiley & Sons; 2011

25. Reed JE, McNicholas C, Woodcock T, Issen L, Bell D. Designing quality improvement initiatives: the action effect method, a structured approach to identifying and articulating programme theory. *BMJ Qual Saf*. 2014;23(12):1040–1048

26. NHS Institution for Innovation and Improvement. Quality and Service Improvement Tools: Driver Diagrams. Available at: www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/driver_diagrams.html. Accessed February 14, 2015

27. Mays N, Pope C. Rigour and qualitative research. *BMJ*. 1995;311(6997):109–112

28. Sari AB, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ*. 2007;334(7584):79

29. Panesar SS, Cleary K, Sheikh A. Reflections on the National Patient Safety Agency's database of medical errors. *J R Soc Med*. 2009;102(7):256–258

30. Vincent C, Aylin P, Franklin BD, et al. Is health care getting safer? *BMJ*. 2008;337(7680):a2426

31. Panesar SS, Carson-Stevens A, Salvilla SA, Patel B, Mirza SB, Mann B. Patient safety in orthopedic surgery: prioritizing key areas of iatrogenic harm through an analysis of 48,095 incidents reported to a national database of errors. *Drug Healthc Patient Saf*. 2013;5:57–65

32. Pham JC, Gianci S, Battles J, et al. Establishing a global learning community for incident-reporting systems. *Qual Saf Health Care*. 2010;19(5):446–451

33. Lawton R, Parker D. Barriers to incident reporting in a healthcare system. *Qual Saf Health Care*. 2002;11(1):15–18

34. Lamont T, Watts F, Panesar S, MacFie J, Matthew D. Early detection of complications after laparoscopic surgery: summary of a safety report from the National Patient Safety Agency. *BMJ*. 2011;342(7790):c7221

35. Lamont T, Beaumont C, Fayaz A, et al. Checking placement of nasogastric feeding tubes in adults (interpretation of x ray images): summary of a safety report from the National Patient Safety Agency. *BMJ*. 2011;342(7806):d2586

36. Harnden A, Mayon-White R, Mant D, Kelly D, Pearson G. Child deaths: confidential enquiry into the role and quality of UK primary care. *Br J Gen Pract*. 2009;59(568):819–824

37. Thompson MJ, Ninis N, Perera R, et al. Clinical recognition of meningococcal disease in children and adolescents. *Lancet*. 2006;367(9508):397–403

38. WHO Regional Office for Europe. European Detailed Mortality Database. Available at: www.euro.who.int/en/what-we-do/data-and-evidence/databases/european-detailed-mortality-database-dmdb2. Accessed January 17, 2015

39. Wolfe I, Cass H, Thompson MJ, et al. Improving child health services in the UK: insights from Europe and their implications for the NHS reforms. *BMJ*. 2011;342(7803):d1277

40. Asthma UK. The asthma divide: inequalities in emergency care for people with asthma in England. London: 2007.

41. Milne C, Forrest L, Charles T. Learning from analysis of general practitioner referrals to a general paediatric department. *Arch Dis Child*. 2010;95(Suppl 1):A71

42. Graber M, Gordon R, Franklin N. Reducing diagnostic errors in medicine: what's the goal? *Acad Med*. 2002;77(10):981–992

43. Wong IC, Wong LY, Cranswick NE. Minimising medication errors in children. *Arch Dis Child*. 2009;94(2):161–164

44. Department of Health. *Building a Safer NHS for Patients. Implementing an Organisation with a Memory*. London: Stationary Office; 2001

45. Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press; 1999

46. Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005-2010). *Br J Clin Pharmacol*. 2012;74(4):597–604

47. Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA*. 2001;285(16):2114–2120

48. Blum KV, Abel SR, Urbanski CJ, Pierce JM. Medication error prevention by pharmacists. *Am J Hosp Pharm*. 1988;45(9):1902–1903

49. Davis T. Paediatric prescribing errors. *Arch Dis Child*. 2011;96(5):489–491

50. Conroy S, Sweis D, Planner C, et al. Interventions to reduce dosing errors in children: a systematic review of the literature. *Drug Saf*. 2007;30(12):1111–1125

51. Walsh KE, Kaushal R, Chessare JB. How to avoid paediatric medication errors: a user's guide to the literature. *Arch Dis Child*. 2005;90(7):698–702

52. Selbst SM, Fein JA, Osterhoudt K, Ho W. Medication errors in a pediatric emergency department. *Pediatr Emerg Care*. 1999;15(1):1–4

53. Wilson DG, McArtney RG, Newcombe RG, et al. Medication errors in paediatric practice: insights from a continuous quality improvement approach. *Eur J Pediatr*. 1998;157(9):769–774

54. Kaushal R, Goldmann DA, Keohane CA, et al. Medication errors in paediatric outpatients. *Qual Saf Health Care*. 2010;19(6):e30

55. Rinke ML, Bundy DG, Velasquez CA, et al. Interventions to reduce pediatric medication errors: a systematic review [published online ahead of print July 14, 2014]. *Pediatrics*. doi:10.1542/peds.2013-3531

56. Poon EG, Keohane CA, Yoon CS, et al. Effect of bar-code technology on the safety of medication administration. *N Engl J Med*. 2010;362(18):1698–1707

57. Levine SR, Cohen MR, Blanchard N, et al. Guidelines for preventing medication errors in pediatrics. *J Pediatr Pharmacol Ther*. 2001;6:426–442

1.5 Lancet commentary (iatrogenic harm in children)

Carson-Stevens A, Edwards A, Panesar S, Parry G, Rees P, Sheikh A, Donaldson L. Reducing the burden of iatrogenic harm in children. Lancet. 2015 Apr 25;385(9978):1593-4. doi: 10.1016/S0140-6736(14)61739-6.

Reducing the burden of iatrogenic harm in children

In 2013, as many as 6·3 million children worldwide died before their fifth birthday.[1] Children have an increased risk of health-care-related harm because of factors including the complexity of prescribing and dispensing of drugs, a reduced physiological reserve compared with adults, and dependency on others (ie, parents and health-care providers) to recognise the emergence of a hazardous situation.[2] Despite these factors, little research has been done of the contributions of substandard care and iatrogenic harm to deaths in childhood. Furthermore, health-care-related harm has featured little in the Millennium Development Goals; the Sustainable Development Goals must include this issue, and establish priority to resolve the existing paucity of research related to children and young people and promote policy making for strengthening of health-care systems to cater for children's needs.[3,4]

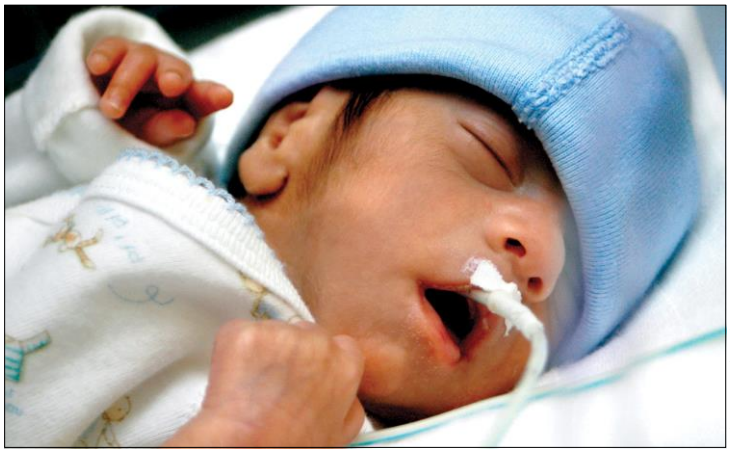
Confidential enquiries into child deaths in the UK showed that 26% of deaths had identifiable failures in care, and a further 43% had potentially avoidable factors.[5,6] In the USA, an estimated 15–35% of children admitted to hospital have health-care-associated harm.[7] Despite patient safety being an established health policy concern for adults, little has been done to estimate the frequency of harm and its associated burden in the care of children.

Research in adults has shown that a range of methods can be successfully used to study substandard care and iatrogenic harm. Trigger tools can identify, within medical records, features suggestive of adverse events. Safety indices can be constructed from administrative data to estimate what incidents happen, whilst methods such as root cause analyses and incident reporting systems can aid understanding of why incidents happen.[7,8] This work now needs to be extended to children and young people. That said, collection, analysis, and use of such data in health care remain problematic, with few health systems showing that they can reduce risk for future patients.

In the England and Wales National Reporting and Learning System, more than 65 000 reports of safety incidents involving children are received every year; about 30% of those reports record incidents that resulted in harm or death to children (Carson-Stevens A, unpublished). Useful lessons can be learned from these reports: 77 safety notices were issued between 2004 and 2012 by the National Patient Safety Agency covering the UK National Health Service in England and Wales, including recommendations for keeping babies with a family history of medium-chain acyl-CoA dehydrogenase deficiency safe in the neonatal period, for prevention of harm to children from parents with mental health problems, and for nasogastric placement in infants.[9] Themes generated from incident reports can help in the design of logic models that can inform quality improvement interventions. Moreover, problems that would be overlooked at a local level because of small numbers can become evident when aggregated across wider areas.

Globally, a systematic approach is needed to generate data of this nature and to construct basic metrics of harm in children and young people, and to ensure that these data are reflected within international development goals. The Global Burden of Disease study[1] could provide annual estimates of the scale of iatrogenic harm and could inform health policy makers about where to direct efforts to mitigate such harm. WHO has proposed a Minimal Information Model to provide a dataset in all countries for sharing of patient safety incident reports.[10] This model could improve understanding of the nature, and particularly the causes, of unsafe care. We believe that present incident reporting systems are undervalued and underused, garnering little respect from the health information and research communities.

An international patient safety learning system is needed, designed to describe care failures or safety incidents, shape priorities for improvement, corroborate



AJ Photo/Science Photo Library

insights from research studies, develop potential solutions for application in practice, and share learning of the context-specific approaches of application of solutions. In view of the different maturity levels of data collection across different economic settings, the system would benefit from a phased effort to develop the necessary infrastructures for data sharing in each country. Member countries of such a system must hold autonomy to undertake their own searches informed by insights gleaned from surveillance of their own national safety data. Moreover, countries need to develop a culture of open reporting from staff, parents, and patients to provide future high-quality incident reports, build improvement capability within their workforce to apply the lessons learned, and educate family and patients for early warning and early action to mitigate care failure. Such development will require a combined enterprise between clinical and patient safety experts and the commitment of health leaders and policy makers.

Andrew Carson-Stevens, Adrian Edwards, Sukhmeet Panesar, Gareth Parry, Philippa Rees, Aziz Sheikh, Liam Donaldson
Cochrane Institute for Primary Care and Public Health, Cardiff University, Cardiff CF14 4YS, UK (AC-S, AE, PR); Department of Family Practice, University of British Columbia, Vancouver, BC, Canada (AC-S); Centre of Medical Informatics, University of Edinburgh, Edinburgh, UK (AC-S, SP, AS); Institute for Healthcare Improvement, Cambridge, MA, USA (GP); Harvard Medical School, Boston, MA, USA (GP, AS); Brigham and Women's Hospital, Boston, MA, USA (AS); and Department of Surgery and Cancer, Imperial College London, London, UK (LD)
carson-stevensap@cardiff.ac.uk

AS was supported by The Commonwealth Fund; the other authors declare no competing interests. AC-S and AE are cochief investigators, and SP, AS, and LD coapplicants, on a National Institute of Health Research (NIHR) Health Services and Delivery Research grant to characterise patient safety incident reports in primary care (12/64/118); PR works on, and GP serves on the Professional Advisory Group of, the study. LD was Chairman of the National Patient Safety Agency (NPSA) in 2010–12, is involved in research on the National Reporting and Learning System (NRLS), and is WHO's Patient Safety Envoy. SP was a former clinical adviser at the NPSA in 2008–10, and works on the NRLS research programme. The views expressed herein are those of the authors and do not necessarily reflect those of the UK Health Services and Delivery Research programme, NIHR, NHS, Department of Health, or The Commonwealth Fund.

1 Wang H, Liddell CA, Coates MM, et al. Global, regional, and national levels of neonatal, infant, and under-5 mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2014; **384:** 957–79.
2 Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001; **285:** 2114–20.
3 Wolfe I, Thompson M, Gill P, et al. Health services for children in western Europe. *Lancet* 2013; **381:** 1224–34.
4 Modi N, Clark H, Wolfe I, et al. A healthy nation: strengthening child health research in the UK. *Lancet* 2013; **381:** 73–87.
5 Pearson GA, ed. Why children die: a pilot study 2006. England (South West, North East & West Midlands), Wales and Northern Ireland. London: CEMACH, 2008. http://www.hqip.org.uk/assets/NCAPOP-Library/CMACE-Reports/1.-May-2008-Why-Children-Die-A-Pilot-Study-2006.pdf (accessed July 18, 2014).
6 Department for Education. Child death reviews: year ending 31 March 2013. London: Department for Education, 2013. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223697/SFR26_2013_Text_v2.pdf (accessed July 18, 2014).
7 Walsh KE, Bundy DG, Landrigan CP. Preventing health care-associated harm in children. *JAMA* 2014; **311:** 1731–32.
8 Parry G, Cline A, Goldmann D. Deciphering harm measurement. *JAMA* 2012; **307:** 2155–56.
9 NHS. National Patient Safety Agency. Alerts. http://www.nrls.npsa.nhs.uk/alerts/ (accessed July 18, 2014).
10 WHO. Reporting patient safety incidents. http://www.who.int/patientsafety/implementation/information_model/en/ (accessed July 18, 2014).

Hip fractures: comprehensive geriatric care and recovery

Published Online February 5, 2015 http://dx.doi.org/10.1016/S0140-6736(14)61592-0
See Articles page 1623

Hip fractures are a worldwide public health issue, with devastating consequences for both patients and their families. In 2000, 1·6 million hip fractures were reported worldwide[1] and epidemiological studies estimate a 12·1% and 4·6% lifetime risk of hip fracture for women and men, respectively.[2] Clinical and social consequences of hip fracture include death, depression, fear of falling, disability, institutionalisation, and social isolation.[3] For old people, the ability to remain mobile is an essential aspect of quality of life, and is crucial for the preservation of independence. Many older patients develop disabilities in mobility after hip fracture surgery, and more than 30% do not regain independent ambulation 1 year later.[4] A better understanding of this suboptimum recovery, and innovative, effective interventions beyond surgery, are clinical and public health priorities.

In *The Lancet,* Anders Prestmo and colleagues[5] present their well designed study providing strong evidence that, for patients aged 70 years or older with hip fractures, perioperative comprehensive geriatric care given in a dedicated ward improves short-term and long-term function in mobility, as compared with treatment in a traditional orthopaedic care unit. 198 patients were randomly assigned to comprehensive geriatric care, and 199 to usual orthopaedic care. Mobility was assessed by the trial's primary endpoint,

1.6 Vaccine manuscript (vaccination errors in primary care)

Rees P, Edwards A, Powell C, Evans HP, Carter B, Hibbert P, Makeham M, Sheikh A, Donaldson L, Carson-Stevens A. Pediatric immunization-related safety incidents in primary care: A mixed methods analysis of a national database. Vaccine. 2015 Jun 26. pii: S0264-410X(15)00869-5. doi: 10.1016/j.vaccine.2015.06.068.

Vaccine xxx (2015) xxx–xxx

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Pediatric immunization-related safety incidents in primary care: A mixed methods analysis of a national database

Philippa Rees[a], Adrian Edwards[a], Colin Powell[a], Huw Prosser Evans[a], Ben Carter[a], Peter Hibbert[b], Meredith Makeham[b], Aziz Sheikh[c,d], Liam Donaldson[e], Andrew Carson-Stevens[a,b,c,f,*]

[a] Primary Care Patient Safety (PISA) Research Group, Division of Population Medicine, Cardiff University, Neuadd Meirionnydd, Heath Park, Cardiff CF14 4YS, UK
[b] Australian Institute for Healthcare Innovation, Macquarie University, Level 6, 75 Talavera Road, Sydney 2109, NSW, Australia
[c] Centre for Medical Informatics, The University of Edinburgh, Medical School, Teviot Place, Edinburgh EH8 9AG, UK
[d] Harvard Medical School, Harvard University, Department of Medicine, 1620 Tremont St, Boston, MA 02120, USA
[e] Imperial College London, 1090a, Queen Elizabeth the Queen Mother Wing (QEQM), St Mary's Campus, Norfolk Place, London W2 1PG, UK
[f] Department of Family Practice, University of British Columbia, 3rd Floor, 5950 University Boulevard, Vancouver, BC, Canada V6 T 1Z3

ARTICLE INFO

Article history:
Received 26 February 2015
Received in revised form 21 May 2015
Accepted 15 June 2015
Available online xxx

Keywords:
Health services
Patient safety
Primary care
Public health
Quality improvement

ABSTRACT

Background: Children are scheduled to receive 18–20 immunizations before their 18th birthday in England and Wales; this approximates to 13 million vaccines administered per annum. Each immunization represents a potential opportunity for immunization-related error and effective immunization is imperative to maintain the public health benefit from immunization. Using data from a national reporting system, this study aimed to characterize pediatric immunization-related safety incident reports from primary care in England and Wales between 2002 and 2013.
Methods: A cross-sectional mixed methods study was undertaken. This comprised reading the free-text of incident reports and applying codes to describe incident type, potential contributory factors, harm severity, and incident outcomes. A subsequent thematic analysis was undertaken to interpret the most commonly occurring codes, such as those describing the incident, events leading up to it and reported contributory factors, within the contexts they were described.
Results: We identified 1745 reports and most ($n = 1077$, 61.7%) described harm outcomes including three deaths, 67 reports of moderate harm and 1007 reports of low harm. Failure of timely vaccination was the potential cause of three child deaths from meningitis and pneumonia, and described in a further 113 reports. Vaccine administration incidents included the wrong number of doses ($n = 476$, 27.3%), wrong timing ($n = 294$, 16.8%), and wrong vaccine ($n = 249$, 14.3%). Documentation failures were frequently implicated. Socially and medically vulnerable children were commonly described.
Conclusion: This is the largest examination of reported contributory factors for immunization-related patient safety incidents in children. Our findings suggest investments in IT infrastructure to support data linkage and identification of risk predictors, development of consultation models that promote the role of parents in mitigating safety incidents, and improvement efforts to adapt and adopt best practices from elsewhere, are needed to mitigate future immunization-related patient safety incidents. These priorities are particularly pressing for vulnerable patient groups.

Abbreviations: NRLS, National Reporting and Learning System; WHO, World Health Organization.

* Corresponding author at: Division of Population Medicine, 3rd floor Neuadd Meirionnydd, School of Medicine, Cardiff University, Cardiff CF14 4YS, Wales, UK. Tel.: +44 0 785 427 1884.
E-mail addresses: ReesPC1@cf.ac.uk (P. Rees), EdwardsAG@cardiff.ac.uk (A. Edwards), PowellC7@cardiff.ac.uk (C. Powell), EvansSH@cardiff.ac.uk (H.P. Evans), CarterBR@cardiff.ac.uk (B. Carter), peter.hibbert@mq.edu.au (P. Hibbert), meredith.makeham@mq.edu.au (M. Makeham), Aziz.Sheikh@ed.ac.uk (A. Sheikh), l.donaldson@imperial.ac.uk (L. Donaldson), carson-stevensap@cardiff.ac.uk (A. Carson-Stevens).

http://dx.doi.org/10.1016/j.vaccine.2015.06.068

Please cite this article in press as: Rees P, et al. Pediatric immunization-related safety incidents in primary care: A mixed methods analysis of a national database. Vaccine (2015), http://dx.doi.org/10.1016/j.vaccine.2015.06.068

1. Introduction

Each immunization represents a potential opportunity for immunization-related safety incidents, and given their prevalence and potential preventability the World Health Organization (WHO) has recognized this as a priority area for healthcare improvement [1]. Without address, population-level protection could be compromised, national campaign efforts to promote uptake hindered, and the trust of patients and families reduced [1,2].

Reviews of patient medical records estimate 27–35% of immunizations involve an error [3–6]. Analysis of patient safety incident reports, such those within the US MedMARx reporting system, have suggested additional doses, the wrong immunization, and the wrong dose given are the main types of errors involved [7]. Further, surveillance systems collecting information about adverse drug reactions, such as the Vaccine Adverse Event Reporting System, have also identified common sources of errors, but they primarily focus and receive reports on the health problems, illnesses or symptoms experienced by patients following immunization [8,9]. Despite those insights, analyses of such reports are often limited by the lack of comprehensiveness of reports.

Whilst previous studies have classified immunization-related safety incidents in terms of their type [7,9,10], few studies have comprehensively explored the underlying factors contributing to them [3–5,7–11]. Incident reporting systems, like the England and Wales National Reporting and Learning System (NRLS)[2], include a range of patient safety incident types, specifically descriptions of, "any untoward incident that may or may not have led to harm" and invite free text descriptions of what happened, perceived potential contributory factors and actions to prevent future occurrence. Examination of report content can support the design of learning interventions to mitigate future events [12,13].

We aimed to characterize the nature and severity of immunization-related patient safety incidents involving children in primary care in England and Wales, in order to: identify priority issues for improvement; and generate hypotheses about change ideas that could form the basis of improvement recommendations and interventions.

2. Method

2.1. National reporting and learning system

The NRLS[2] is a national reporting system that collates locally generated reports that are received from healthcare organizations throughout England and Wales. The NRLS was launched in 2003 and receives approximately 100,000 reports a month, the majority written by healthcare professionals. It receives over 65,000 reports per annum involving children [13]. Reporting patient safety incidents that resulted in severe harm or death of a patient became mandatory in June 2010; however, before this all reporting was voluntary, and reporting remains voluntary for incidents resulting in no, low, or moderate harm [14,15].

Each report contains categorical information about location, patient age, incident type, and reporter perception of harm severity – collected in a structured report form – as well as free-text descriptions of the incident [14,15].

2.2. Sample selection

Over 20,000 pediatric, primary care-related incidents are present in the NRLS. Immunization-related safety incidents were identified by free-text key term searches, which we have found to generate both a sensitive and pragmatic means for identifying reports. Search terms and their permutations were informed by brand and generic vaccine names from the British National Formulary and by an analysis of a pilot sample of over 600 immunization-related reports [10,16]. We included any immunization-related safety incidents occurring in primary care involving a child aged under-18 years between 2002 and 2013.

2.3. Data coding

Incident report free text was read and codes were applied to describe incident type, potential contributory factors, harm severity, and incident outcomes. The 'Recursive Model of Incident Analysis' method was used as a set of rules for applying codes in a chronological order (Supplement 1) [17]. This permitted modeling of the sequence of events leading to the primary incident type that resulted in the outcome experienced by the patient (Supplement 2). A 'severity of harm' had already been assigned to each report by the reporter; based on our interpretation of the report content, the severity of harm was re-classified using definitions from the WHO International Classification of Patient Safety when required (Table 1) [18]. Generic and brand names of vaccines were recorded. Incident types were independently double coded for a random 20% sample of reports (PR and HPE) with 3rd person arbitration (ACS) when necessary.

2.4. Data analysis

Relationships between codes were examined using frequency distributions and cross-tabulations. Two-way cross-tabulations were generated between age, incident type, vaccine type and contributory factors, compared to harm. Associations between these were examined using the Fisher's exact test. To adjust for confounding of vaccine type on the effect of incident type on harm severity, a Mantel Haenszel adjusted approach was taken by stratifying vaccine and incident type.

2.5. Thematic analysis

Reports that contained the most frequently occurring incident type or contributory factor codes were re-read to generate additional insights and interpretations about those incidents and the kind of contexts in which they occurred [12]. Qualitative data software (NVIVO 9, QSR International) was used to independently analyze the reports and create new codes to capture this information. Themes that helped support our understanding of those incidents, and why they might have occurred, were agreed between PR and ACS [12,19].

2.6. Ethical approval

Aneurin Bevan University Health Board research risk review committee waived the need for ethical review given the anonymized nature of these data (ABHB R and D Ref number: SA/410/13).

3. Results

3.1. Characteristics of reports

Free-text searches identified 2298 reports, of which 1745 were included. Reports were excluded if they: were not immunization-error related ($n = 464$), e.g. describing a child who had received appropriate immunizations; contained insufficient free text ($n = 24$); or described issues that did not result in a patient safety incident ($n = 65$). Reports were submitted from 254 NHS providers in England and Wales, including 1052 reports from community nursing and 596 reports from general practice settings. Cohen's

Table 1
The vaccines involved in reported incidents and the number of reports they are involved in (note: *2 vaccines were involved in 1 child's death).

Vaccine	No harm	Low harm	Moderate harm	Death	Frequency (%)
Measles Mumps Rubella (MMR)	86	269	6	–	361 (18.2)
Pneumococcal conjugate (PCV)	140	160	4	3	307 (15.5)
Diphtheria tetanus acellular pertussis/inactivated polio/haemophilus influenza type B (DTaP/IPV/Hib)	97	142	1	1	241 (12.1)
Meningitis C (Men C)	103	122	1	–	226 (11.4)
Haemophilus influenza b/meningitis C (Hib/Men C)	70	123	2	–	195 (10)
Diphtheria tetanus acellular pertussis/inactivated polio (DTaP/IPV)	29	145	1	–	175 (9)
Human papilloma virus (HPV)	52	59	14	–	125 (6)
Bacillus Calmette-Guérin (BCG)	42	52	7	–	101 (5)
Tetanus, diphtheria and inactivated polio (Td/IPV)	15	65	13	–	93 (5)
Haemophilus influenza b (Hib)	13	37	–	–	50 (3)
Hepatitis B	24	10	7	–	41 (2)
Hepatitis A	10	11	0	–	21 (1)
Influenza	11	8	1	–	20 (1)
Other	6	9	1	–	16 (1)
Rotavirus	5	2	–	–	7 (0)
Typhoid	2	4	–	–	6 (0)
Total	705	1218	58	4*	1985 (100)

Definitions of Harm: No harm—patient outcome is not symptomatic and no treatment is require; Low harm—patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal and intermediate but short term, and no or minimal intervention is required; Moderate harm—patient outcome is symptomatic requiring intervention, an increased length of stay, or causing permanent or long-term harm or loss of function; Severe harm—patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function; and, Death—on balance of probabilities, death was caused or brought forward in the short term by the incident.

kappa statistic of inter-rater (coding) reliability was high, $k = 0.77$, $p < 0.001$.

Most reports involved children aged less than three years old ($n = 952$, 55%) and peaks in frequency occurred, as expected, within the age groups children receive most vaccinations. Tables 1 and 2 highlight the most commonly cited vaccines and their associated harm severity outcomes. Most reports ($n = 1135$, 65%) described outcomes, which included: patient inconvenience ($n = 801$, 45.9%) such as receiving unnecessary treatment ($n = 481$, 27.6%) and requiring additional treatment ($n = 379$, 21.7%); clinical patient harm ($n = 205$, 11.7%) such as injuries ($n = 72$, 4%); and exposing the patient to risk ($n = 139$, 8%), for example by leaving them vulnerable to immunization preventable diseases ($n = 108$, 6%).

Administration was the most frequent incident type ($n = 1282$, 73.5%), with 'wrong number of doses', 'wrong timing', and 'wrong vaccine' described in ($n = 1019$, 79.5%) of those reports (Table 2). These are analyzed in further detail below.

There was a strong association between the type of administration-related incident and harm ($p < 0.001$) and the type of vaccine and harm ($p < 0.001$). After stratification into both 'incident' and 'vaccine' strata there was an association between type of administration incident and harm (in all vaccine strata $p < 0.001$), thus vaccine type did not explain the varied risk of reported harm.

3.2. Administration of the wrong number of doses

Children who received the wrong number of doses were typically under six years old, most frequently (less than two years old $n = 141$, 30%), and typical vaccines implicated included Measles Mumps Rubella (MMR) ($n = 156$, 33%), Diphtheria Tetanus acellular Pertussis/Inactivated Polio (DTaP/IPV) ($n = 87$, 18%), and Haemophilus influenza b/Meningitis C (Hib/Men C) ($n = 77$, 16%) (Table 4). Reports frequently described harm ($n = 448$, 94.1%), typically because the child received unnecessary additional vaccinations—a low harm event (Example 3.1, Table 3). One incident resulted in an adverse reaction necessitating a hospital admission—a moderate harm. There was no evidence to suggest association between vaccine type and harm ($p = 0.49$) within this stratum (wrong number of doses).

Such incidents were frequently the result of prior incidents involving documentation failures ($n = 188$, 40%), including documentation not being up to date ($n = 128$, 27%), available ($n = 45$, 9%), or accurate ($n = 15$, 3%) (Examples 3.1–3.3, Table 3; Supplement 2). Additional associated incidents included administration of the wrong vaccine ($n = 49$, 10%), communication failures ($n = 26$, 5%), and difficulties making appointments ($n = 19$, 4%).

Table 5 presents the contributory factors described. Patient and parent contributory factors included: inadequate knowledge ($n = 40$, 8%), for example not being aware of which vaccines were needed or had previously been received; being new to the area or family practice ($n = 36$, 8%); and eight incidents (2%) were partly the result of a child being in 'out-of-home' care (e.g. foster care) (Examples 3.2 and 3.3, Table 3). Staff factors included: not following a protocol ($n = 60$, 13%), for example not checking the medical records before administration; and mistakes ($n = 67$, 14%) such as misreading vaccine names ($n = 10$, 2%).

3.3. Administration at the wrong time

Vaccines administered at the wrong time ($n = 294$, 16.8%) were typically described as deviating from the recommended national immunization schedule. Most children were aged under 1 year old ($n = 175$, 60%). Vaccines typically involved were Pneumococcal conjugate (PCV) ($n = 91$, 31%), Diphtheria Tetanus acellular Pertussis/Inactivated Polio/Haemophilus influenza type B (DTaP/IPV/Hib) ($n = 83$, 28%), and the MMR ($n = 48$, 16%) (Table 4). There was no evidence to suggest an association between vaccine type and harm ($p = 0.51$) within this stratum (wrong time).

Of 55 (19%) harmful incidents, eight incidents resulted in moderate harm—typically these reports described delayed prophylactic

Table 2
The frequency and severity of harm described for each age group and for each primary incident type (N.B. this table does not include the frequencies of contributory incidents).

	Severity of harm				
	No harm	Low harm	Moderate harm	Death	Frequency (%)
Age					
Under 28 days	15	7	3	–	25 (1)
1 month to 1 year	307	246	13	3	569 (32.6)
2 to 4 years	206	433	9	–	648 (37.1)
5 to 11 years	41	133	5	–	179 (10)
12 to 17 years	99	188	37	–	324 (18.6)
Incident type					
Vaccination					
Administering	438	824	17	3	1282 (73.5)
Wrong number of doses	28	447	1	–	476
Wrong timing	239	44	8	3	294
Wrong vaccine	97	150	2	–	249
Not administered	14	65	1	–	80
Wrong dose	26	31	–	–	57
Expired vaccine	3	46	–	–	49
Non-specific	10	13	–	–	23
Contraindicated vaccine	14	5	1	–	20
Wrong patient	2	14	–	–	16
Wrong site	1	2	3	–	6
Used needle	3	2	–	–	5
Wrong storage	–	4	–	–	4
Wrong route	1	1	1	–	3
Adverse reaction	–	103	43	–	146 (8)
Prescribing and dispensing	26	–	–	–	26 (1)
Reconstitution error	–	4	–	–	4 (0)
Batch recall	4	–	–	–	4 (0)
Insufficient supply	1	–	–	–	1 (0)
Non-specific	1	–	–	–	1 (0)
Documentation	97	5	1	–	103 (6)
Records not up to date	62	3	1	–	66
Records inaccurate/unclear	29	2	–	–	31
Record availability	6	–	–	–	6
Administration	50	4	2	–	56 (3)
Appointment management	36	3	–	–	39
Transfer of information	12	1	2	–	15
Other	2	–	–	–	2
Procedural skills	4	53	–	–	57 (3)
Communication	44	9	–	–	53 (3)
With patients or parents	42	9	–	–	51
Between HCPs	2	–	–	–	2
Other	3	5	4	–	12 (1)
Total	668	1007	67	3	1745 (100)

administration of Hepatitis B and Bacillus Calmette-Guérin (BCG) vaccines to high-risk newborns. Three other incidents of delayed vaccination-contrary to the national recommended schedule-were potentially implicated in child deaths from meningitis and pneumonia, (Example 3.4, Table 3). Reports describing low harm outcomes typically described children who required additional vaccinations for adequate immunity. Timing-related vaccine incidents were preceded by incidents involving: appointment management ($n = 60$, 20%), documentation failures ($n = 31$, 11%), communication failures ($n = 21$, 7%), transfer of documentation ($n = 16$, 5%), and other vaccine-related incidents such as administration of the wrong vaccine ($n = 12$, 4%) (Supplement 2).

Table 5 highlights contributory factors implicated in these incidents such as: failure to follow protocol ($n = 32$, 11%); poor continuity of care ($n = 22$, 7%), for example community nurses not receiving birth notifications from secondary care; and staff mistakes ($n = 22$, 7%) (Examples 3.4–3.7, Table 3).

3.4. Administration of the wrong vaccine

Administration of the wrong vaccine was described in 249 reports (14.3%) and they were largely given to children under one year old ($n = 121$, 49%). Of these, 152 (61%) incidents resulted in harm, typically because children received unnecessary vaccinations and required additional treatment i.e. the vaccine that was originally required. For example reports described administration of a Hib/Men C combination vaccine ($n = 31$, 12%) when a single (non-combination) Meningococcal C (Men C) vaccine was scheduled. Men C ($n = 87$, 35%), PCV ($n = 85$, 34%), and Hib/Men C ($n = 61$, 25%) vaccines were frequently implicated (Table 4). These incidents were rarely preceded by other incidents; however 18 (7%) resulted from documentation failures, and six (2%) resulted from immunizing the wrong child (Example 3.8, Table 3; Supplement 2). Within this stratum (wrong vaccine) there was strong evidence for an association between vaccine type and harm ($p < 0.001$).

Contributory factors described were: staff issues which included mistakes ($n = 87$, 35%) such as confusing vaccines with similar names or appearances ($n = 37$, 15%) and failure to follow protocols ($n = 35$, 14%), such as concurrently preparing vaccines for multiple children (Example 3.9, Tables 3 and 5).

3.5. Overarching themes—Responsibility and vulnerability

Many reports implied parents were partly responsible for the occurrence of incidents, for example if the parent did not bring parent-held records to appointments or did not provide accurate medical histories (Example 3.3, Table 3). An underlying expectation that parents should be aware of their child's immunization needs and history was apparent. However parents appeared to have similar expectations of, and confidence that, healthcare professionals

Table 3
Edited extracts from incident reports.

Wrong number of doses

*Example 3.1: Patient presented with **stepmother** for pre-school booster. Written **consent** from **father** was brought but **parental held record** was **not available**. Nurse explained she was giving repevax and **MMR**. The following day stepmother called expressing concern that **MMR** had **already** been **given** in 2004. **Incomplete documentation** of initial dose of MMR booster. (Low harm)*

*Example 3.2: Child placed with **adoptive parents** who were **advised** by **Social Worker** to attend physician to complete primary vaccinations. Attended surgery with parental held records but **no family practice records** were **available.** Only **two immunizations** were **recorded** in the parental held record. Immunization given with consent. Later informed by social services that child had **already completed** her **primary immunizations**. Family practice records checked and confirmed above. (Low harm)*

*Example 3.3: Patient received the third primary immunizations **twice** in error once in **Ghana** and once at the health center. Mother **failed to notify** the health visitor of the first immunization. (Low harm)*

Wrong timing

*Example 3.4: An infant died from a streptococcal pneumonia—which **could have been prevented** if the child had received childhood immunizations. The mother stated she was **not aware** that her child should be immunized and the child was **not registered** at a family practice until *** Identified areas of concern include: the management of the child immunization processes, family practice **registration processes** and **notifying** child health of **non-registered** patients. (Death)*

*Example 3.5: Patients mother rang after receiving birthday card for child and realizing that her daughter had **not received** an **immunization appointment** since **transferring into the area**. Child health still had old address and old family practice details. Mother told to book immunization appointments with new family practice. (No harm)*

*Example 3.6: Patient's relative contacted health visitors regarding her child's immunizations, she reported she had **not received** any **appointments** for her child's third primary immunizations. **Child health** computer had **recorded wrongly** that the child had his third immunizations on the same day as he had his second immunizations. The patient **received** his third primary **immunizations late** because of this. Child health would not have been aware of this if the **parent** had not **contacted** the **service**. (No harm)*

*Example 3.7: Patient was scheduled for Hib/Men C vaccine, staff checked his immunization record and became aware that he already had this immunization. At this point **I made an error**. I told the mother that we could give the MMR/Prevenar. **Mother's English is not perfect** and she agreed. As I came to record the immunization, I realized my error there was a two-week gap between immunizations not 4. (No harm)*

Wrong vaccine

*Example 3.8: I was covering an immunizations session where normally there are 2 immunizers, the 2nd immunizer was sent home sick ten minutes prior to the start of the session. The healthcare assistant went to get the child and the mother for the immunization. The **wrong immunization** was **administered** to the child as we had the **paperwork for a different child**. The error was realized immediately, the child received Hib/Men C and MMR instead of 5 in 1 and Men C. (Low harm)*

*Example 3.9: Mother took her five-month-old baby to her family physician for his second DTaP/IPV/Hib vaccination. The staff nurse administered the **wrong injection** because she **did not consult** his **medical records**. The baby was given an MMR vaccination that should not be given until he is 13 months old. Staff Nurse says she was **distracted** during the appointment. The Nurse will **re-train** and demonstrate her competency through supervision. (Low harm)*

Vulnerable child

*Example 3.10: Baby received routine immunizations in baby clinic. The baby's consultant had written to the family physician requesting that the baby **not receive immunizations** until he is **one-year post chemotherapy**. **Mother believed** baby **should have immunizations** as he had received two flu vaccines between two sessions of chemotherapy previously. Family physician had seen this letter and had put a note on baby record but the **note was not dated** and believed to be an automatic warning. (No harm)*

should be aware which immunizations their child required (Example 3.7, Table 3).

Collaboration between healthcare professionals and parents was reported as preventing some near-miss immunization-related safety incidents. There were reports detailing how parents had mitigated harm and prevented incidents by advocating for their children, chasing appointments, informing staff when the wrong vaccine was prepared, or reminding staff when a vaccine was contraindicated (Examples 3.5 and 3.6, Table 3). Lack of this parental safety net could be a factor in the immunization-related incidents described in children in 'out-of-home' care.

Socially vulnerable children such as those in 'out-of-home' care, and children of immigrant or traveller families, were described as experiencing incidents as a result of difficulty accessing care, poor continuity of care, and documentation failures. Accessing appropriate care was difficult for those vulnerable children for a range of reasons, including language barriers and inadequate parental knowledge of the need for vaccination or how to access primary care services, and in one case a child died (Example 3.4, Table 3).

Medically vulnerable children such as pregnant adolescents, those at risk of TB, Hepatitis B or HIV, or immunocompromised children, who required additional vaccinations or had contraindications to certain vaccines, were commonly represented in these reports. Numerous factors featured across those incident reports including: communication failures with children and parents; non-disclosure of medical conditions; non-adherence to the advice that parents were given by pediatricians; and poor staff and parent knowledge of vaccine contraindications in certain medical conditions (Example 3.10, Table 3).

4. Discussion

This study has shown that the types of immunization-related safety incidents experienced by children are consistent with studies undertaken in other countries. Safer immunization is a priority area for quality improvement, which should focus on administering the correct vaccine, the correct number of times, and at the correct time for all children, and the timely and correct immunization of

Table 4
the vaccines involved in the most frequently reported incident types and their frequencies.

Type of administration incident	Vaccines														
	MMR	PCV	DTaP/IPV/Hib	Men C	Hib/Men C	DTaP/IPV	HPV	BCG	Td/IPV	Hib	Hepatitis B	Other	Hepatitis A	Influenza	Total
Wrong number of doses	156	75	63	49	77	87	8	20	36	16	–	5	3	1	596
Wrong timing	48	91	83	37	29	7	16	14	2	2	21	6	1	–	357
Wrong vaccine	41	85	56	87	61	49	8	3	23	1	1	5	6	4	430
Not administered	12	2	5	13	4	3	1	6	1	28	1	–	1	–	77
Wrong dose	12	1	1	7	3	1	2	9	–	–	5	1	5	3	50
Expired vaccine	12	–	1	2	4	7	1	5	1	3	1	1	2	2	42
Contraindicated vaccine	2	1	–	1	–	2	–	5	1	–	–	2	–	2	16
Wrong patient	7	1	4	2	1	1	2	–	1	–	–	–	–	–	19
Other	2	5	2	3	4	1	2	5	–	–	2	3	–	2	31

Table 5
Frequency of described contributory factors (note: *some reports described more than one type of mistake).

	Frequency (%)
Patient/parent factors	
Patient/parent behavior—the way in which patients or parents act or conduct themselves	74 (8)
Non-compliance	60
Non-disclosure	12
Other	1
Violence	1
Patient/parent geography—the area where patients live	64 (7)
New to area	62
Access difficulties	2
Patient health—factors relating to the patient's physical and mental wellbeing	37 (4)
Allergy	22
Non-specific	4
Disability	4
Immunocompromised	3
Abnormal coagulation	2
Pregnancy	2
Patient/parent knowledge—insufficient knowledge or inadequate application of knowledge	48 (5)
Out-of-home care—children not in the care of their parents e.g. in foster care	18 (2)
Patient/parent language—patient or parent unable to communicate in English	5 (1)
Staff factors	
Mistake—cognitive lapses	*240 (25.2)
Non-specific mistake	139
Similar vaccine appearances	45
Distraction	22
Misreading	18
Inattention	10
Similar patient names	9
Failure to follow protocol—not adhering to organizational guidelines	186 (20)
Knowledge—insufficient knowledge or inadequate application of knowledge	19 (2)
Fatigue/stress—extreme tiredness, mental or emotional strain	5 (1)
Other factors	3 (0)
Equipment/vaccine factors	
Failure of equipment/vaccine—the equipment or vaccine is faulty	36 (4)
Equipment/vaccine packaging—he packaging is impractical inadequate or faulty	25 (3)
Equipment/vaccine storage—inadequate impractical storage	25 (3)
Poor equipment/vaccine design—the design is impractical, inadequate or faulty	3 (0)
Organizational factors	
Working Conditions—factors relating to the work environment	52 (5)
Continuity of care—issues with the co-ordination of services	48 (5)
Education and training—insufficient education and training of staff	36 (4)
Inadequate guidelines or protocols—existing guidelines not fit for purpose	27 (3)
Total	951 (100)

medically and socially vulnerable children. Crosscutting reported contributory factors for quality improvement interventions include staff mistakes, coordination and verification procedures, and parents' and staff knowledge and consequent behaviors.

4.1. Strengths and limitations

This is the largest examination of reported contributory factors for immunization-related patient safety incidents in children. Incident report data are prone to numerous and well-acknowledged biases including under-reporting and selective deposit bias [20]. For example, although the NRLS accepts reports from patients and parents, such reports were not apparent in our dataset. Further, there was likely differential reporting between organizations, those with good reporting cultures likely contribute more than those without such cultures [21].

Methodological rigor was ensured by keeping an audit trail of all coding-related decisions, holding weekly meetings to discuss analysis, and independent double-coding of 20% of reports indicating a high degree of concordance [22]. Our findings are hypothesis generating, inductive in nature, and require testing and development in further research and future clinical practice.

4.2. Reviewing these findings in the context of other literature

High numbers of reports describing administration of the wrong number of doses was expected because they are usually apparent to those involved (the healthcare professional, patient or parent) and thus more likely to be reported. Previous studies investigating immunization-related safety incidents mirror our findings and demonstrate receipt of additional vaccines is a widespread problem often resulting from poor documentation e.g. where a child is immunized but this goes undocumented resulting in that child receiving that same vaccine later [4,7,23]. In one U.S. study, over 20% of children received unnecessary duplicate vaccinations [4].

Our data contained reports of delayed vaccination or receipt of vaccines out-of-schedule with the national immunization schedule. Experts determine the vaccination schedule to afford children maximum protection from diseases and to minimize the risk of vaccine interaction. The consequences of deviating from this schedule are unclear [7,24,25].

Wrong vaccine administration is a recognized issue [7,23,26,27]. Children who receive the wrong vaccine, but in whom the error goes undetected could be both under-protected and at risk since their inadequate immunity would be unrecognized [7,23]. The potentially severe consequences of immunization-related safety incidents in medically vulnerable children have also been highlighted by other studies [28,29].

Socially vulnerable children were commonly represented in this sample and the inverse care law, where those most in need of high quality care are the least likely to receive it, is evident in this context [30]. Poorer vaccination uptake in vulnerable children is described in the literature [31–33], yet the challenges of conducting research with marginalized populations could perhaps explain the limited interventional efforts to date [34].

4.3. Recommendations for improvement

Continued efforts by manufacturers to create vaccines with different packaging and distinguishable names are needed [35,36].

Our findings support targeted community nurse visits to socially vulnerable children [37], to educate parents about the need for timely vaccination, and to encourage vaccine uptake. In addition, providing parents with access to all of their children's records could reduce documentation discrepancies and appointment-related incidents, as well as provide healthcare professionals with a safety net [38]. This could also be enhanced with better accessibility of unified immunization records for staff [39]. Building IT infrastructure and functionality capable of sharing data between health and social care providers could support identification of predictors of risk and inform interventions to mitigate future incidents [40].

Encouraging parental involvement, and creating a culture where parents feel comfortable challenging healthcare professionals, could also prevent safety incidents [38]. Co-production methods, where patients and providers co-design new models and methods of care delivery could be used to inform local improvement

initiatives that advance this parent–provider relationship for child safety [41–43]. Public health organizations and researchers must seek to establish what methods of communication work best for different patient and parent groups, and embrace the challenge of undertaking research with and for marginalized patient populations.

To reduce staff mistakes, locally-owned efforts to adopt and adapt best practices proven to be effective elsewhere should be explored for verification and standardized preparation of vaccines [36,44].

5. Conclusions

The types of immunization-related safety incidents experienced by children in England and Wales are consistent with those described in studies undertaken in other countries. This is the largest examination of reported contributory factors for immunization-related patient safety incidents in children, and based on this analysis we have made a number of priority recommendations for policy, practice, and research. These include: investments in IT infrastructure to support data linkage and the identification of risk predictors; development of consultation models to enhance parental roles in mitigating safety incidents; and improvement efforts to adapt and adopt best practices from elsewhere. These priorities are particularly pressing for medically and socially vulnerable patients.

Funding source

All co-authors are contributing to a project funded by the National Institute for Health Services and Delivery Research program (project number 12/64/118). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HS&DR program, NIHR, NHS or the Department of Health.

Financial disclosure

The authors have no financial relationships relevant to this article to disclose.

Contributor statements

Ms Rees was responsible for primary data coding, qualitative analysis, interpretation of results, and drafting the manuscript. Professor Edwards conceptualized and designed the study. He carried out interpretation of the results, created the recommendations for practice and reviewed the manuscript. Dr Powell provided the clinical interpretation of results, creation of recommendations for pediatric practice, and reviewed the manuscript. Dr Carter was the study statistician and responsible for data analysis, and interpretation of the results and reviewed the manuscript. Dr Evans was the project clinical informatics lead and responsible for development of the data storage infrastructure, clinical interpretation of results and creating recommendations for improvement. Mr Hibbert conceptualized and designed the study and development of the in-house classification systems. He interpreted the results and reviewed the manuscript. Dr Makeham contributed to the clinical interpretation of results, creation of recommendations for family practice, and reviewed the manuscript. Professor Sheikh conceptualized and designed the study interpretation of results, and reviewed the manuscript. Professor Donaldson conceptualized and designed the study interpretation of results, and reviewed the manuscript. Dr Andrew Carson-Stevens conceptualized and designed the study. He was responsible for data coding, qualitative analysis, interpreting results, developing recommendations for clinical practice, and revising the manuscript. He is also the study guarantor. All co-authors approved the final manuscript as submitted.

Conflict of interest statement

ACS and AE are co-chief investigators, and AS and LD are co-applicants on a NIHR HS&DR funded study to characterize primary care patient safety incident reports.

Acknowledgements

PCR and ACS had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. We acknowledge the contributions of: Anthony Avery, Donna Luff, Sukhmeet Panesar, Gareth Parry, and Huw Williams (the PISA study group) for reviewing the final manuscript.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.vaccine.2015.06.068

References

[1] World Health Organization. Global manual on surveillance of adverse events following immunization. Geneva: World Health Organization; 2014.
[2] Health Protection Agency. Vaccine incidents guidance: actions to take in response to vaccine errors. Health Protection Agency; 2012.
[3] Lang S, Ford KJ, John T, Pollard AJ, McCarthy ND. Immunisation errors reported to a vaccine advice service: intelligence to improve practice. Qual Prim Care 2014;22:139–46.
[4] Feikema SM, Klevens RM, Washington ML, Barker L. Extraimmunization among US children. JAMA 2000;283:1311–7.
[5] Hamlin JS, Wood D, Pereyra M, Grabowsky M. Inappropriately timed immunizations: types, causes, and their relationship to record keeping. Am J Public Health 1996;86:1812–4.
[6] Butte AJ, Shaw JS, Bernstein H. Strict interpretation of vaccination guidelines with computerized algorithms and improper timing of administered doses. Pediatr Infect Dis J 2001;20:561–5.
[7] Bundy DG, Shore AD, Morlock LL, Miller MR. Pediatric vaccination errors: application of the "5 rights" framework to a national error reporting database. Vaccine 2009;27:3890–6.
[8] Varricchio F. Medication errors reported to the vaccine adverse event reporting system (VAERS). Vaccine 2002;20:3049–51.
[9] Hibbs BF, Moro PL, Lewis P, Miller ER, Shimabukuro T. Vaccination errors reported to the vaccine adverse event reporting system, United States, 2000–2013. Vaccine 2015;33(28):3171–8.
[10] Rees P, Carson-Stevens A, Williams H, Panesar S, Edwards A. Quality improvement informed by a reporting and learning system. Arch Dis Child 2014;99:702–3.
[11] Petridou E, Kouri N, Vadala H, Dalamaga M, Sege R. Frequency and nature of recorded childhood immunization-related errors in Greece. J Toxicol Clin Toxicol 2004;42:273–6.
[12] Rees P, Edwards A, Panesar S, Powell C, Carter B, Williams H, et al. Safety incidents in the primary care office setting. Pediatrics 2015;135(6):1027–35, http://pediatrics.aappublications.org/content/early/2015/04/28/peds.2014-3259.abstract (Accessed May 20th, 2015).
[13] Carson-Stevens A, Edwards A, Panesar S, Parry G, Rees P, Sheikh A, et al. Reducing the burden of iatrogenic harm in children. Lancet 2015;385:1593–4, http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61739-6/abstract (Accessed May 20th, 2015).
[14] Donaldson LJ, Panesar SS, Darzi A. Patient-safety-related hospital deaths in England: thematic analysis of incidents reported to a national database, 2010–2012. PLoS Med 2014;11:e1001667.
[15] National Reporting and Learning System. Organisation patient safety incident reports. London: NHS; 2015, http://www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incidentreports/ (Accessed February 23rd, 2015).
[16] Paediatric Formulary Committee. BNF for children (online). London: BMJ Group, Pharmaceutical Press, and RCPCH Publications; 2013.
[17] Hibbert PD, Runciman WB, Deakin A. A recursive model of incident analysis. Australian Patient Safety Foundation; 2015, http://www.apsf.net.au/dbfiles/A%20Recursive%20Model%20of%20Incident%20Analysis.pdf (Accessed February 23rd, 2015).
[18] World Health Organisation. The conceptual framework for the international classification for patient safety. World Health Organisation; 2009.

Appendix 2

2.1 Search terms used to retrieve vaccination-related reports

1. BCG
2. Booster
3. Cervarix
4. Conjugate
5. Diphtheria
6. DTP
7. DTaP
8. Gardasil
9. Havrix
10. Haemophilus
11. Hep A
12. Hep B
13. Hepatitis A
14. Hib
15. HPV
16. Human papilloma
17. Imms
18. Immuni
19. Infanrix
20. Influenza
21. Inject
22. IPV
23. Jab
24. Measles
25. Men c
26. MenC
27. Meningitis C
28. Meningococcal
29. Menitorix
30. MMR
31. Mumps
32. Pandemrix
33. PCV
34. Pediacel
35. Pertussis
36. Pneumococcal
37. Polio
38. Prevenar
39. Priorix
40. PSB
41. Red book
42. Repevax
43. Revaxis
44. Rotavirus
45. Rubella
46. Tetanus
47. Td/IPV
48. Typhoid
49. Vaccin
50. Vacs
51. Varicella

2.2 Search terms used to retrieve reports involving 'unwell' children

1. Abdo pain
2. Abdominal pain
3. Acetazolamide
4. Acute abdo
5. Anorexi
6. Antibiot
7. Apnoe
8. Appendicitis
9. Arrest
10. Arthritis
11. ASD
12. Asperg
13. Asthma
14. Ataxia
15. Atomoxetine
16. Atresia
17. Autis
18. Bacteria
19. Behavioural
20. Blanch
21. Blastoma
22. Blind
23. Blood sugar
24. Breathless
25. Bronchiolitis
26. Bronchitis
27. Burn
28. CAMHS
29. Cancer
30. Carbamazepine
31. Cardiac failure
32. Cellulitis
33. Cerebral palsy
34. Chemo
35. Citalopram
36. Clobazam
37. Clomipramine
38. Clonazepam
39. Clonidine
40. CMHT
41. Coarctation of the Aorta
42. Coelia disease
43. Coeliac disease
44. Coma
45. Congenital
46. Convulsion
47. Cough
48. Cramp
49. Crohn
50. Cyanos
51. Cystic
52. Deaf
53. Dehydrate
54. Depress

55. Deteriorate
56. Development delay
57. Diabet
58. Dialys
59. Diarrhea
60. Diarrhoea
61. Diazepam
62. Dipstick
63. Disab
64. Disorder
65. Dissociative
66. DKA
67. Down syndrome
68. Downs syndrome
69. Drowsy
70. Duloxetine
71. Dystrophy
72. E.coli
73. Ectomy
74. Eczema
75. Ehlers Danlos
76. Epilep
77. Erythema multiforme
78. Ethosuximide
79. Exacerbate
80. Eye syndrome
81. Foetal alcohol
82. Febrile
83. Fever
84. Floppy
85. Fluoxetine,
86. Fracture
87. Gabapentin
88. Gastritis
89. Gastritis
90. Gastroenteritis
91. GCS
92. George syndrome
93. Glucose
94. Glycosuria
95. Growth hormone
96. Haematuria
97. Haemol
98. Haemophilia
99. Haloperidol
100. Head injury
101. Headache
102. Heart
103. Hirschprung syndrome
104. HIV
105. Hydrocephalus
106. Hyper
107. Hypo
108. Imipramine
109. Immuno
110. Impetigo
111. Infect
112. Inhaler
113. Insulin
114. Intra osseous

115. Intra venous
116. Intracranial
117. Intubate
118. Intussusception
119. Irritable
120. IUGR
121. IV access
122. IV antihistamine
123. IV diazepam
124. IV fluid
125. IV sedation
126. Jaundice
127. Kawazaki disese
128. Ketoacidosis
129. Keton
130. Ketosis
131. Kidney
132. Lamotrigine
133. Learning disa
134. Leukae
135. Levetiracetam
136. Life saving
137. Life threatening
138. Life-saving
139. Lithium
140. Liver disease
141. Liver failure
142. Metab
143. Acido
144. Renal failure
145. Phenobarbitone
146. Sepsis
147. Lorazepam
148. lung disease
149. Lung disease
150. Lymph
151. Maln
152. Meningitis
153. Meningitus
154. Meningoco
155. Meningococcal disease
156. Methylphenidate
157. Midazolam
158. Migraine
159. Mirtazapine
160. Myopathy
161. Nebs
162. Nebu
163. Nephrotic syndrome
164. Neuroblastoma
165. Nitrazepam
166. Obstruct
167. Oedema
168. Olanzapine
169. Osteomyelitis
170. Otitis
171. Otitis Media
172. Overdose
173. Oxcarbazepine
174. Palsy

175. Paroxetine
176. Pendred syndrome
177. Perthes disease
178. Petech
179. Phenobarbital
180. Phenytoin
181. Plegia
182. Pneumococcal disease
183. Pneumonia
184. Pneumonitis
185. Polyuria
186. Promazine
187. Psychiat
188. Psychol
189. Psychosis
190. Pulse
191. Pyrexia
192. Quetiapine
193. Qunisy
194. Rash
195. Refeeding syndrome
196. Reflux
197. Renal disease
198. Renal failure
199. Renal func
200. Resp rate
201. Respiratory rate
202. Responsive
203. Retts syndrome
204. Rey's syndrome
205. Risperidone
206. Ritalin
207. Salbutamol
208. Sats
209. Saturation
210. Scabies
211. Scalds
212. Scoliosis
213. Seizure
214. Self harm
215. Self-harm
216. Septic
217. Septic
218. Croup
219. Obstruct
220. Oedema
221. Sertraline
222. Shortness of breath
223. Sick
224. Sickle cell disease
225. Sickle disease
226. Sodium valproate
227. Spina bifida
228. Spinal muscular atrophy
229. Splenectomy
230. Squint
231. Staph
232. Steroid
233. Strattera
234. Streptococcal

235. Suicide
236. SVT
237. Swollen
238. Tachy
239. Talipes
240. Tender
241. Thalassaemia
242. Thrive
243. Thrombo
244. Thyroid
245. Tonsillitis
246. Topiramate
247. Torticollis
248. Transposition of the great arteries
249. Tuberous sclerosis
250. Tumour
251. Undescended
252. Urinary tract
253. Urticaria
254. Valproate
255. Vasculitis
256. Ventilation
257. Ventolin
258. Viral
259. Visual impairment
260. Von willebrand
261. VSD
262. Westerdrout syndrome
263. Wheeze
264. Zolpidem

2.3 Incident descriptors framework

1 ** ADMINISTRATION **

1.1 Filing system - information filed incorrectly

1.2 Message handling - errors in the taking and distributing of messages

1.3 Appointments - errors in managing appointments for healthcare
- 1.3.1 Primary care appointments
- 1.3.2 Secondary care appointments

1.4 Payment - errors in the process of healthcare payment systems

1.5 Ability to access healthcare professional
- 1.5.1 Home visits - professional delayed/ unable to visit patient at home
- 1.5.2 Returning phone calls
- 1.5.3 Out-of-hours
- 1.5.4 Health visiting
- 1.5.5 Child and Adolescent Mental Health Services
- 1.5.6 Occupational therapy

1.6 Transfer of patient information - incorrect or inefficient transfer of patient information across healthcare systems

- 1.6.1 Between care settings
  - 1.6.1.1 From primary to secondary care
    - 1.6.1.1.1 Lost
    - 1.6.1.1.2 Not sent
    - 1.6.1.1.3 Incorrect/incomplete
    - 1.6.1.1.4 Delayed
    - 1.6.1.1.5 Illegible
  - 1.6.1.2 From secondary to primary care
    - 1.6.1.2.1 Lost
    - 1.6.1.2.2 Not sent
    - 1.6.1.2.3 Incorrect/incomplete
    - 1.6.1.2.4 Delayed
    - 1.6.1.2.5 Illegible
  - 1.6.1.3 Between primary care settings
    - 1.6.1.3.1 Lost
    - 1.6.1.3.2 Not sent
    - 1.6.1.3.3 Incorrect/incomplete
    - 1.6.1.3.4 Delayed
    - 1.6.1.3.5 Illegible
- 1.6.2 New diagnoses - incorrect or inefficient transfer of patient information from secondary care regarding new diagnoses

1.6.3 Appropriate follow up - incorrect or inefficient transfer of patient regarding necessary follow-up of patient. e.g. requirements for follow up screening or regular review

1.6.4 Involving out-of-hours - incorrect or inefficient transfer of patient information between in- and out- of hours services

1.6.5 NHS direct

1.7 Breaches of confidentiality

2 ** DOCUMENTATION**

2.1 Medical records

2.1.1 Record(s) unavailable - records could not be accessed when needed

2.1.1.1 Red book
2.1.1.2 General practice records
2.1.1.3 Child health records
2.1.1.4 Lost medical records

2.1.2 Care given but not documented

2.1.3 Record not up to date or complete - information missing from records

2.1.3.1 Discrepancies between vaccine records
2.1.3.1.1 Red book
2.1.3.1.2 General practice records
2.1.3.1.3 Child health records

2.1.4 Inaccurate or unclear medical records / medical record error

2.1.4.1 Red book
2.1.4.2 General practice records
2.1.4.3 Child health records

2.2 Death certificates

3 ** REFERRAL **

3.1 Human

3.1.1 Not performed when indicated

3.1.1.1 Delayed referral - errors in the timely referral of patients

3.1.1.1.1 Secondary care
3.1.1.1.2 Specialist care
3.1.1.1.3 Emergency care
3.1.1.1.4 Nursing
3.1.1.1.5 Social care

3.1.1.1.6 Health visitor
3.1.1.1.7 General practice
3.1.1.1.8 Child and Adolescent Mental Health Services

3.1.1.2 Referral not made when appropriate – referral decision-making error

3.1.1.2.1 Secondary care
3.1.1.2.2 Specialist Care
3.1.1.2.3 Emergency Care
3.1.1.2.4 Nursing
3.1.1.2.5 Health visitor
3.1.1.2.6 Social care
3.1.1.2.7 General practice
3.1.1.2.8 Child and Adolescent Mental Health Service

3.1.1.3 No follow up arranged - did not follow-up or were not asked to follow-up

3.1.2 Incomplete /incorrect referral
3.1.3 Illegible referral
3.1.4 Work inappropriately passed to primary care
3.1.5 Inappropriate referral
3.1.6 Referral refused

3.2 Administration

3.2.1 Not sent- letter of referral erroneously not sent by office
3.2.2 Delayed - letter of referral delayed at office level
3.2.3 Lost - letter of referral lost in the system
3.2.4 Not acted upon - referral successful but patient not seen by physic
3.2.4.1 Refused patient referral refused by receiving office
3.2.5 Inappropriate referral- referral made erroneously at office level
3.2.6 Social work referral issues

4 ** DIAGNOSIS AND ASSESSMENT **

4.1 Diagnosis

4.1.1 Missed diagnosis

4.1.2 Wrong diagnosis

4.1.3 Delayed diagnosis

4.1.3.1 Cancer

4.1.3.2 Emergency condition

4.1.3.3 Contagious condition

4.2 Insufficient assessment

4.2.1 Triage - errors in the process of triaging patients

4.2.1.1 By healthcare professional

4.2.1.2 By non-healthcare professional

4.2.2 History - errors in the process of taking a patient's medical history

4.2.3 Examination - errors in the process of examining patients

4.2.4 Identifying vulnerable or high-risk patient

4.2.5 Emergency vehicle use Inappropriate transfer vehicle used (e.g. private vehicle instead of ambulance)

4.2.6 Discharge planning - premature discharge and poor discharge planning

4.3 Delayed assessment - a delay in assessment for care or care adjunct

5 ** TREATMENT & PROCEDURES (excludes drugs/vaccines)

5.1 Clinical treatment decision

5.1.1 No treatment given

5.1.2 Insufficient treatment given

5.1.3 Wrong treatment given

5.2 Treatment other than medication

5.2.1 Ordering treatments - wrong treatment ordered or treatment not ordered when appropriate
5.2.2 Implementation - error in conducting the correctly chosen process or procedure
5.2.3 Complication

5.2.3.1 Complication from execution of procedure

5.2.3.2 Adverse event suffered by patient as a result of treatment other than medication

5.2.4 Timeliness - treatment other than medication not administered in a timely fashion
5.2.5 Execution of care - error in choosing the correct process or procedure
5.2.6 Wrong anatomical side/site
5.2.7 Insufficient supply of treatment

6 ** MEDICATION & VACCINES **

6.1 Clinical treatment decision

6.1.1 No treatment given

6.1.2 Insufficient treatment
6.1.3 Wrong treatment given
6.1.4 Treatment not ordered

6.2 Medication prescribing

6.2.1 Wrong medication
6.2.2 Wrong patient
6.2.3 Wrong dose
6.2.4 Wrong route
6.2.5 Wrong time
6.2.6 Unsafe medication
6.2.6.1 Teratogenic
6.2.6.2 Contraindicated
6.2.6.3 Allergy - prescribed for patient with known allergy

6.2.7 Wrong formulation
6.2.8 Wrong number of doses
6.2.9 Illegible/ unclear prescription
6.2.10 Incomplete prescription e.g. brand not specified

6.3 Medication dispensing
6.3.1 Wrong medication
6.3.2 Wrong patient
6.3.3 Wrong dose
6.3.4 Wrong route
6.3.5 Wrong time
6.3.6 Wrong formulation
6.3.7 Not dispensed
6.3.8 Allergy - dispensed to a patient with known allergy
6.3.9 Out of date
6.3.10 Wrong label
6.3.11 Wrong number of doses
6.3.12 Inappropriate medication
6.3.13 Medication dispensed in inappropriate container

6.4 Medication administration
6.4.1 Wrong medication
6.4.2 Wrong patient
6.4.3 Wrong dose
6.4.4 Wrong route
6.4.5 Wrong time
6.4.6 Wrong formulation
6.4.7 Out of date
6.4.8 Allergy - medication administered to patient with known allergy
6.4.9 Medication not administered
6.4.10 Reconstitution error

6.5 Monitoring medication - error in the process of monitoring dose-dependent medications, or those with side effects
6.5.1 Lack of monitoring
6.5.2 Medication dose not appropriately adjusted

6.6 Adverse event - patient suffered a complication as a result of medication

6.6.1 Allergy - unknown that patient had any allergies

6.7 Drug omission - medication erroneously not given to or not taken by patient
6.8 Patient self-administered overdose
6.9 Incorrect storage
6.10 Medication timeliness - not commenced in a timely fashion

6.11 Vaccines

6.11.1 Vaccine prescribing
- 6.11.1.1 Wrong vaccine
- 6.11.1.2 Wrong patient
- 6.11.1.3 Wrong dose
- 6.11.1.4 Wrong route
- 6.11.1.5 Wrong time
- 6.11.1.6 Contraindicated
- 6.11.1.7 Wrong formulation
- 6.11.1.8 Wrong number of doses

6.11.2 Vaccine dispensing
- 6.11.2.1 Wrong vaccine
- 6.11.2.2 Wrong patient
- 6.11.2.3 Wrong dose
- 6.11.2.4 Wrong route
- 6.11.2.5 Wrong time
- 6.11.2.6 Wrong number of doses
- 6.11.2.7 Stored incorrectly
- 6.11.2.8 Out of date
- 6.11.2.9 Not dispensed
- 6.11.2.10 Wrong formulation
- 6.11.2.11 Wrong label
- 6.11.2.12 Contraindicated

6.11.3 Vaccine administration

- 6.11.3.1 Wrong vaccine
- 6.11.3.2 Wrong patient
- 6.11.3.3 Wrong dose
- 6.11.3.4 Wrong route
- 6.11.3.5 Wrong time
- 6.11.3.6 Wrong amount
- 6.11.3.7 Stored incorrectly
- 6.11.3.8 Out of date
- 6.11.3.9 Contraindicated vaccine
- 6.11.3.10 Not administered
- 6.11.3.11 Used/dirty needle
- 6.11.3.12 Wrong site

6.11.4 Reconstitution error
6.11.5 Adverse event (reaction to vaccine)
6.11.6 Batch recall

6.12 Vaccine unavailable

7 ** INVESTIGATIONS **

7.1 Laboratory - errors in the process of laboratory investigations

- 7.1.1 Ordering - wrong test ordered or test not ordered when appropriate
- 7.1.2 Implementing - errors in the process of obtaining or processing a laboratory specimen
  - 7.1.2.1 Mislabelled sample
- 7.1.3 Reporting - error in the process of physician receiving accurate test results including errors of delay
- 7.1.4 Responding to results - inappropriate response to a laboratory result

7.2 Diagnostic imaging - errors in the process of diagnostic imaging investigations

- 7.2.1 Ordering - wrong test ordered or test not ordered when appropriate
- 7.2.2 Implementing - errors in the process of obtaining or processing of a diagnostic image
  - 7.2.2.1 Mislabelled request form
- 7.2.3 Reporting - error in the process of physician receiving accurate test results including errors of delay
- 7.2.4 Responding to results - inappropriate response to a laboratory result

7.3 Other investigations

- 7.3.1 Ordering - wrong test ordered or test not ordered when appropriate
- 7.3.2 Implementing – errors in the process of obtaining or processing of other diagnostic investigation
- 7.3.3 Reporting - error in the process of physician receiving accurate test results including errors of delay
- 7.3.4 Responding to results - inappropriate response to a result of other investigations

8 ** COMMUNICATION **

These are human failures, and do not include breakdowns in the systems that are used to communicate information.

8.1 With patients or caregivers - errors in communication between physicians or healthcare professionals and patients or caregivers

- 8.1.1 Wrong advice given to patient or caregiver - includes information about accessing emergency services, self-management or safety netting
  - 8.1.1.1 By healthcare professional
  - 8.1.1.2 By non-healthcare professional
- 8.1.2 Failure to convey seriousness/urgency of patient condition
- 8.1.3 Consent errors - errors in the process of obtaining informed consent

8.2 Between healthcare professionals - errors in communication between healthcare professionals

8.2.1 Failure to convey seriousness/urgency of patient condition
8.2.2 Handover-related inadequacies

8.3 Between healthcare and non-healthcare professionals

9 ** EQUIPMENT **

9.1 Therapeutic adjunct provision
9.2 Insufficient supply
9.3 Failure of equipment
9.3.1 Damaged
9.3.2 Faulty
9.3.3 Misused
9.3.4 Computerised Physician Order Entry

9.4 Stolen equipment

10 ** OTHER **

10.1 Professionalism
10.2 Environmental hazard
10.3 Transport issues
10.4 Failure to prevent fall/injury
10.5 Failure to follow up ‘unwell’ or vulnerable child
10.6 Failure to prevent pressure ulcer

2.4 Contributory factors framework

1 ** PATIENT OR CAREGIVER FACTORS **

1.1 Geography - the area where patients live including its characteristics

- 1.1.1 Out of area - patient new to area
- 1.1.2 Access difficulties because of geography

1.2 Language - patient unable to communicate in English

1.3 Behaviour

- 1.3.1 Non-compliance - patient does not follow advice or instructions
  - 1.3.1.1 Takes own discharge
  - 1.3.1.2 Patient does not take medication as instructed or advise
  - 1.3.1.3 Non-disclosure
  - 1.3.1.4 Violent

1.4 Health - factors related to the patient's physical and mental health

- 1.4.1. Frailty - reduced physiological reserve, fragile
- 1.4.2. Disability
- 1.4.3. Allergy
- 1.4.4 Immunocompromised
- 1.4.5 Coagulation problems
- 1.4.6 Pregnancy
- 1.4.7 Epilepsy
- 1.4.8 Poor renal function

1.5. Knowledge - patient or caregiver of child has poor understanding

1.6. Looked-after child

1.7 Age

- 1.7.1 Weight-based dosing

1.8 Ethnicity

2 ** STAFF FACTORS **

2.1 Physical and mental wellbeing

- 2.1.1 Fatigue

2.2 Task - a piece of work to be done or undertaken.

- 2.2.1 Failure to follow protocol
  - 2.2.1.1 New protocol
- 2.2.2 Inadequate skill set/knowledge

2.3 Cognitive - includes abilities such as perception, learning, memory, language, concept formation, problem solving, and thinking.

2.3.1 Mistake
- 2.3.1.1 Distraction/ inattention/ oversight/forgot
- 2.3.1.2 Similar medication names / appearances confused
- 2.3.1.3 Similar patient names
- 2.3.1.4 Haste/ poor time management
- 2.3.1.5 Misread/ did not read
- 2.3.1.6 Wrong patient's sticky label

2.3.2 Violation - deliberate breaking of a rule

2.3.3 Stress - mental or emotional strain

2.3.4 No or poor supervision or assistance of staff

3 ** EQUIPMENT / MEDICATION/ VACCINE FACTORS **

3.1 Poor design - impractical, faulty or in some way inadequate

3.2 Poor storage

3.3 Poor packaging

3.4 Failure of equipment/ medication/ vaccine

4 ** ORGANISATION FACTORS **

4.1 Protocols or guidelines - inadequate, inefficient absent or not available

- 4.1.1 Mental health
- 4.1.2 Vulnerable patients
- 4.1.3 Investigations
- 4.1.4 Referrals
- 4.1.5 Epilepsy management plan
- 4.1.6 Asthma management plan
- 4.1.7 School care plan
- 4.1.8 Diabetic management plan
- 4.1.9 Palliative care plan

4.2 Interpreter services - communication aids to reduce language barriers

4.3 Continuity of care - the delivery of a 'seamless service' through integration, coordination and the sharing of information between different providers

- 4.3.1 Unknown to staff
- 4.3.2 Within primary care
  - 4.3.2.1 Out-of-hours service

4.3.2.2 Registering with a general practice
4.3.3 Between secondary and primary care
4.3.4 Access block - cannot move a patient on because there is no space to put them
4.3.5 Locum/ agency staff

4.4 Working conditions

4.4.1 Staffing levels
4.4.1.1 Shift pattern
4.4.1.2 Insufficient numbers of staff
4.4.1.2.1 Doctors
4.4.1.2.2 Nurses
4.4.1.2.3 Allied health professionals
4.4.1.3. Sickness
4.4.2 Team factors
4.4.2.1 Culture
4.4.2.2 Inadequate leadership
4.4.2.3 Disagreement amongst teams
4.4.3 Busy/overloaded by work
4.4.4 interruptions

4.5. Education and training
4.5.1 Supervision
4.5.2 Knowledge of others roles
4.5.3 Caregiver training

4.6 Service unavailable
4.7 Long wait for service

5 ** ENVIRONMENTAL FACTORS **

5.1 Care facility has poor access for emergency vehicles

2.5 Incident outcomes framework

1 ** PATIENT HARM **

1.1 Clinical harm
1.1.1 Pain / discomfort
1.1.2 Swelling
1.1.3 Rash
1.1.4 Nausea
1.1.5 Redness
1.1.6 Bruising
1.1.7 Dizziness/ faint/ loss or altered consciousness
1.1.8 Bleeding
1.1.9 Changes in physiological parameters
    1.1.9.1 Fever
    1.1.9.2 Breathless
1.1.10 General deterioration/progression of condition
1.1.11 Pressure ulcer
    1.1.11.1 Pressure ulcer developed
    1.1.11.2 Pressure ulcer deteriorated
1.1.12 Other wound/ulcer
1.1.13 Admitted to the high dependency or intensive care unit
1.1.14 Seizures
1.1.15 Admitted to hospital/ visited emergency department
1.1.16 Infection
1.1.17 Migraine
1.1.18 Poor diabetic control
    1.1.18.1 Diabetic ketosis/ ketoacidosis
1.1.19 Developmental delay
1.1.20 Diarrhoea
1.1.21 Emergency surgery
1.1.22 Liver failure
1.1.23 Constipation

1.2 Injury
1.2.1 Laceration
1.2.2 Perforation
1.2.3 Fracture
1.2.4 Skin tear
1.2.5 Pain / discomfort
1.2.6 Swelling
1.2.7 Redness
1.2.8 Bruising
1.2.9 Bleeding
1.2.10 Needle stick
1.2.11 Burn
1.2.12 Fall

1.3 Psychological / emotional distress
1.4 Death
1.5 Cardio-respiratory arrest

2 ** PATIENT INCONVENIENCE **

2.1 Repeated tests / procedure / additional treatment
2.2 Delays in management (assessment or treatment)
2.3 Increased documentation
2.4 Financial implication
2.5 Repeated visits to/from health care providers
2.6 Unnecessary treatment
2.7 Extended hospital stay
2.8 Hospital admission

3 ** ORGANISATIONAL INCONVENIENCE **

3.1 Increased documentation
3.2 Phone calls/follow-up
3.3 More equipment / supplies used
3.4 Delays in using facilities
3.5 Legal implication
3.6 Complaint made
3.7 Financial implication

Appendix 3

3.1 The frequencies of combinations of incident types described by included vaccination-related reports

Combinations of incident types				Frequency of combination
Wrong vaccine				218
Wrong number of doses				173
Wrong timing				145
Adverse reaction				140
Wrong number of doses	Out of date records			76
Procedural error				57
Out of date records				54
Not administered	Reconstitution error			50
Expired vaccine administered				46
Wrong number of doses	Wrong vaccine			46
Wrong timing	Appointment management			45
Communication - patients/ caregivers				43
Wrong number of doses	Record availability			31
Appointment management				29
Records inaccurate/ unclear				29
Vaccine prescribing and dispensing				24

incident				
Wrong dose				24
Wrong number of doses	Out of date records	Record availability		23
Wrong dose	Procedural error			23
Wrong number of doses	Communication - patients/ caregivers			19
Wrong patient				16
Wrong timing	Communication - patients/ caregivers			16
Transfer of information				15
Vaccine not administered				15
Non-specific vaccine administration incident				14
Wrong timing	Transfer of information			13
Wrong number of doses	Appointment management			12
Wrong number of doses	Records inaccurate/ unclear			12
Contraindicated vaccine				10
Wrong vaccine	Record availability			9
Wrong timing	Record availability			9
Wrong timing	Wrong vaccine			9
Wrong number of doses	Out of date records			8
Wrong number of doses	Out of date records	Communication - patients/ caregivers		7

Wrong number of doses	Transfer of information			7
Wrong timing	Records inaccurate/ unclear			7
Vaccine administered at wrong site				6
Wrong number of doses	Wrong patient			6
Wrong vaccine	Wrong patient			6
Wrong timing	Appointment management	Transfer of information		6
Appointment management	Out of date records			5
Environmental hazard				5
Record availability				5
Wrong vaccine	Records inaccurate/ unclear			5
Wrong dose	Vaccine prescribing and dispensing incident			5
Wrong timing	Out of date records			5
Appointment management	Transfer of information			4
Batch recall				4
Reconstitution error				4
Out of date records	Transfer of information			4
Wrong number of doses	Appointment management	Out of date records		4
Wrong number of doses	Record availability	Communication - patients/		4

		caregivers		
Wrong number of doses	Record availability	Out of date records		4
Wrong number of doses	Out of date records	Transfer of information		4
Adverse reaction	Communication - patients/ caregivers			3
Communication - patients/ caregivers	Out of date records			3
Out of date records	Record availability			3
Out of date records	Out of date records			3
Referral for vaccination				3
Used needle				3
Vaccine administered via wrong route				3
Vaccine not administered	Appointment management			3
Vaccine not administered	Procedural error			3
Vaccine not administered	Reconstitution error	Insufficient vaccine supply		3
Vaccine stored incorrectly				3
Wrong number of doses	Record availability			3
Wrong timing	Appointment management	Non-specific administrative incident		3
Wrong timing	Out of date records	Record availability		3
Communication - professionals				2
Communication -	Record			2

patients/ caregivers	availability			
Communication - patients/ caregivers	Wrong vaccine			2
Contraindicated vaccine	Communication - professionals			2
Contraindicated vaccine	Communication - patients/ caregivers			2
Contraindicated vaccine	Records inaccurate/ unclear			2
Non-specific vaccine administration incident	Procedural error			2
Non-specific vaccine administration incident	Out of date records			2
Other administrative incident				2
Used needle	Procedural error			2
Vaccine not administered	Procedural error			2
Vaccine prescribing and dispensing incident	Appointment management	Insufficient vaccine supply		2
Wrong number of doses	Appointment management	Transfer of information		2
Wrong number of doses	Communication - professionals			2
Wrong number of doses	Insufficient vaccine supply			2
Wrong number of doses	Out of date records	Communication - patients/		2

		caregivers		
Wrong number of doses	Out of date records	Record availability		2
Wrong number of doses	Transfer of information	Record availability		2
Wrong vaccine	Communication - patients/ caregivers			2
Wrong vaccine	Out of date records	Record availability		2
Wrong dose	Wrong vaccine			2
Wrong timing	Appointment management	Communication - patients/ caregivers		2
Wrong timing	Appointment management	Records inaccurate/ unclear		2
Wrong timing	Appointment management	Out of date records		2
Wrong timing	Communication - professionals			2
Wrong timing	Non-specific documentation incident			2
Wrong timing	Other administrative incidents			2
Wrong timing	Records inaccurate/ unclear	Appointment management		2
Adverse reaction	Appointment management			1
Adverse reaction	Contraindicated vaccine	Communication - patients/ caregivers		1
Adverse reaction	Out of date records			1
Appointment management	Communication - professionals			1

Communication - patients/ caregivers	Appointment management	Record availability		1
Contraindicated vaccine	Communication error with patients/ caregiver	Records inaccurate/ unclear		1
Contraindicated vaccine	Diagnosis and assessment incident	Communication - patients/ caregivers		1
Contraindicated vaccine	Investigation incident			1
Contraindicated vaccine	Out of date records			1
Insufficient vaccine supply				1
Medication error	Medication error	Adverse reaction		1
Non-specific vaccine administration incident	Communication - patients/ caregivers			1
Non-specific vaccine administration incident	Record availability			1
Non-specific vaccine administration incident	Record availability	Communication - patients/ caregivers		1
Non-specific vaccine administration incident	Out of date records			1
Non-specific vaccine administration incident	Referral for vaccination	Records inaccurate/ unclear		1
Non-specific vaccination-				1

related incident				
Out of date vaccine administered	Insufficient vaccine supply			1
Out of date vaccine administered	Vaccine prescribing and dispensing incident			1
Out of date vaccine administered	Wrong vaccine			1
Professionalism				1
Professionalism	Communication - patients/ caregivers			1
Record availability	Out of date records			1
Records inaccurate/ unclear	Out of date records			1
Records inaccurate/ unclear	Referral for vaccination	Out of date records		1
Out of date records	Communication - professionals			1
Out of date records	Communication - patients/ caregivers			1
Transport	Adverse reaction			1
Vaccine not administered	Communication - patients/ caregivers	Procedural error		1
Vaccine not administered	Insufficient vaccine supply			1
Vaccine not administered	Record availability			1
Vaccine not administered	Wrong vaccine			1
Vaccine stored	Communication -			1

incorrectly	professionals			
Wrong number of doses	Appointment management	Records inaccurate/ unclear		1
Wrong number of doses	Communication - professionals	Record availability		1
Wrong number of doses	Communication - professionals	Out of date records		1
Wrong number of doses	Communication - patients/ caregivers	Appointment management	Out of date records	1
Wrong number of doses	Communication - patients/ caregivers	Out of date records		1
Wrong number of doses	Communication - patients/ caregivers	Transfer of information		1
Wrong number of doses	Other administrative incidents			1
Wrong number of doses	Record availability	Communication - professionals		1
Wrong number of doses	Record availability	Non-specific administrative incident		1
Wrong number of doses	Record availability	Transfer of information		1
Wrong number of doses	Records inaccurate/ unclear	Appointment management	Out of date records	1
Wrong number of doses	Records inaccurate/ unclear	Record availability		2
Wrong number of doses	Out of date records	Communication - professionals		1
Wrong number of doses	Out of date records	Non-specific administrative incident	Record availability	1
Wrong number of	Out of date	Record	Communication -	1

doses	records	availability	patients/ caregivers	
Wrong number of doses	Out of date records	Records inaccurate/ unclear		1
Wrong number of doses	Out of date records	Records inaccurate/ unclear	Communication - patients/ caregivers	1
Wrong number of doses	Out of date records			1
Wrong number of doses	Transfer of information	Communication - patients/ caregivers		1
Wrong number of doses	Transfer of information	Out of date records		1
Wrong number of doses	Wrong vaccine	Record availability		1
Wrong number of doses	Wrong vaccine	Record availability	Appointment management	1
Wrong number of doses	Wrong vaccine	Records inaccurate/ unclear		1
Wrong number of doses	Wrong vaccine	Wrong patient		1
Wrong vaccine	Appointment management			1
Wrong vaccine	Insufficient vaccine supply			1
Wrong vaccine	Records inaccurate/ unclear	Out of date records		1
Wrong vaccine	Out of date records			1
Wrong vaccine	Vaccine prescribing and dispensing incident			1
Wrong vaccine	Wrong vaccine	Records inaccurate/		1

		unclear		
Wrong vaccine	Wrong timing			1
Wrong dose	Non-specific vaccination-related incident	Appointment management		1
Wrong dose	Reconstitution error			1
Wrong dose	Wrong patient			1
Wrong timing	Communication - professionals	Appointment management		1
Wrong timing	Communication - patients/ caregivers	Appointment management		1
Wrong timing	Communication - patients/ caregivers	Out of date records		1
Wrong timing	Insufficient vaccine supply			1
Wrong timing	Other administrative incidents	Appointment management		1
Wrong timing	Reconstitution error			1
Wrong timing	Record availability	Appointment management		1
Wrong timing	Records inaccurate/ unclear	Out of date records	Communication - patients/ caregivers	1
Wrong timing	Out of date records	Communication - professionals		1
Wrong timing	Out of date records	Transfer of information		1
Wrong timing	Transfer of information	Communication - patients/ caregivers		1
Wrong timing	Transfer of information	Out of date records		1
Wrong timing	Transfer of information			1

Wrong timing	Vaccine not administered			1
Wrong timing	Vaccine not administered	Appointment management		1
Wrong timing	Vaccine not administered	Record availability	Insufficient vaccine supply	1
Wrong timing	Wrong vaccine	Communication - patients/ caregivers		1
Wrong timing	Wrong vaccine	Records inaccurate/ unclear		1
Wrong timing	Wrong vaccine	Out of date records		1
				1745

3.2 The frequencies of combinations of contributory factors for the primary incident types related to vaccination

Primary incident type	Contributory factors			Frequency of combination
Wrong number of doses				269
Wrong timing				186
Wrong vaccine				123
Adverse reaction				122
Records not up to date				51
Procedural error	Non-compliance			39
Wrong number of doses	Non-specific mistake			36
Wrong number of doses	Failure to follow protocol			35
Not administered				33
Communication with patient/ caregiver				31
Appointment management				26
Inaccurate records				26
Out of date vaccine				26
Wrong number of doses	Patient/ caregiver knowledge			26
Wrong vaccine	Similar vaccine names			25
Wrong number of doses	Similar vaccine names			23
Wrong vaccine	Non-specific mistake			21
Prescribing/dispensing error				19
Adverse reaction	Patient allergy			18
Wrong vaccine	Failure to follow protocol			18
Wrong dose				16
Wrong timing	Failure to follow protocol			16

Wrong dose	Vaccine/ equipment failure			14
Wrong timing	Non-specific mistake			13
Wrong dose	Non-compliance			11
Non-specific administration error				10
Not administered	Vaccine/ equipment design			10
Procedural error	Vaccine/ equipment failure			10
Wrong number of doses	Continuity of care			8
Out of date vaccine	Failure to follow protocol			7
Procedural error				7
Transfer of records	Continuity of care			7
Transfer of records				7
Wrong number of doses	Misreading			7
Wrong timing	Continuity of care			7
Wrong timing	Working conditions			7
Records not available				6
Records not up to date	New to area			6
Wrong timing	Continuity of care			6
Communication with patient/ caregiver				5
Environmental hazard				5
Non-specific administration error	Failure to follow protocol			5
Wrong number of doses	Non-disclosure			5
Wrong timing	Continuity of care	New to area		5
Communication with patient/ caregiver				4
Communication with patient/ caregiver	Non-specific mistake			4
Contraindicated vaccine				4
Not administered	Non-specific mistake	Vaccine/ equipment packaging		4
Not administered	Vaccine/			4

	equipment failure			
Not administered	Staff distraction			4
Out of date vaccine	Vaccine/ equipment storage			4
Vaccine recall				4
Wrong dose	Failure to follow protocol			4
Wrong patient	Similar patient names			4
Wrong timing	Failure to follow protocol	Education and training		4
Wrong timing	New to area			4
Wrong vaccine	Staff distraction			4
Appointment management	Non-specific mistake			3
Communication with patient/ caregiver	Failure to follow protocol			3
Not administered	Non-specific mistake			3
Not administered	Vaccine/ equipment design			3
Reconstitution error				3
Referral				3
Wrong dose	Non-specific mistake			3
Wrong number of doses	Patient/ caregiver knowledge	Failure to follow protocol		3
Wrong number of doses	Non-specific mistake	Failure to follow protocol		3
Wrong number of doses	Looked-after child			3
Wrong number of doses	New to area	Looked-after child		3
Wrong number of doses	New to area	Continuity of care		3
Wrong patient				3
Wrong site	Failure to follow protocol			3
Wrong timing	Failure to follow protocol			3

Wrong vaccine	Working conditions			3
Wrong vaccine	Similar vaccine names	Vaccine/ equipment storage		3
Wrong vaccine	Non-specific mistake	Failure to follow protocol		3
Wrong vaccine	Non-specific mistake	Inadequate guidelines or protocols		3
Wrong vaccine	Non-specific mistake	Working conditions		3
Wrong vaccine	Non-specific mistake	Vaccine/ equipment storage		3
Adverse reaction	Non-specific patient health	Non-disclosure		2
Adverse reaction	Non-compliance			2
Appointment management	New to area			2
Appointment management	Working conditions			2
Appointment management	Working conditions			2
Appointment management	Failure to follow protocol			2
Communication between professionals				2
Contraindicated vaccine	Non-specific mistake			2
Contraindicated vaccine	Non-disclosure			2
Contraindicated vaccine	Patient allergy			2
Inaccurate records	Failure to follow protocol			2
Non-specific administration error	Non-specific mistake			2
Not administered	Non-compliance			2
Not administered	Staff knowledge			2
Not administered	Failure to follow protocol	Other staff factors		2

Not administered	Staff distraction	Working conditions		2
Not administered	Similar vaccine names	Vaccine/ equipment packaging	Vaccine/ equipment storage	2
Out of date vaccine	Failure to follow protocol	Inadequate guidelines or protocols		2
Out of date vaccine	Misreading			2
Out of date vaccine	Non-specific mistake	Working conditions		2
Prescribing/dispensing error	Similar vaccine names	Vaccine/ equipment storage	Vaccine/ equipment packaging	2
Records not up to date	Working conditions			2
Used needle				2
Wrong dose	Staff distraction			2
Wrong number of doses	Patient/ caregiver knowledge	New to area		2
Wrong number of doses	Failure to follow protocol	Non-specific mistake		2
Wrong number of doses	Inattention			2
Wrong number of doses	Staff distraction			2
Wrong number of doses	Similar patient names			2
Wrong number of doses	Non-specific mistake	Working conditions		2
Wrong number of doses	Other staff factors			2
Wrong number of doses	Inadequate guidelines or protocols			2
Wrong number of doses	Continuity of care			2
Wrong number of doses	Working conditions			2
Wrong number of doses	New to area	Patient/ caregiver knowledge		2
Wrong number of doses	Failure to follow protocol	Education and training		2
Wrong number of doses	Failure to follow	Working		2

	protocol	conditions		
Wrong patient	Non-specific mistake			2
Wrong site				2
Wrong storage	Vaccine/ equipment failure			2
Wrong timing	Staff knowledge	Education and training		2
Wrong timing	Patient language			2
Wrong timing	Non-specific mistake	Failure to follow protocol		2
Wrong timing	Patient/ caregiver knowledge			2
Wrong timing	Failure to follow protocol	Working conditions		2
Wrong timing	Inadequate guidelines or protocols			2
Wrong timing	Continuity of care	Looked-after child		2
Wrong timing	Vaccine/ equipment failure			2
Wrong vaccine	Similar vaccine names	Vaccine/ equipment packaging	Vaccine/ equipment storage	2
Wrong vaccine	Misreading			2
Wrong vaccine	Staff knowledge			2
Wrong vaccine	Education and training			2
Wrong vaccine	Failure to follow protocol	Education and training		2
Access to care	Inadequate guidelines or protocols	Continuity of care		1
Adverse reaction	Abnormal coagulation			1
Adverse reaction	Failure to follow protocol			1
Appointment	Continuity of care			1

management				
Appointment management	Looked-after child			1
Communication with patient/ caregiver	Failure to follow protocol	Staff distraction		1
Communication with patient/ caregiver	Patient/ caregiver knowledge			1
Communication with patient/ caregiver	Working conditions			1
Communication with patient/ caregiver	Inadequate guidelines or protocols	Looked-after child		1
Contraindicated vaccine	Staff knowledge	Working conditions		1
Contraindicated vaccine	Immunocompromised patient	Failure to follow protocol		1
Contraindicated vaccine	Non-specific mistake	Immunocompromised patient		1
Contraindicated vaccine	Pregnancy	Patient/ caregiver knowledge		1
Contraindicated vaccine	Non-specific patient health			1
Contraindicated vaccine	Immunocompromised patient			1
Contraindicated vaccine	Abnormal coagulation			1
Contraindicated vaccine	Staff knowledge			1
Contraindicated vaccine	Failure to follow protocol			1
Contraindicated vaccine	Inattention			1
Inaccurate records	Working conditions			1
Inaccurate records	Looked-after child			1
Inaccurate records	Non-specific mistake			1
Insufficient supply				1
Medication error	Patient allergy	Failure to follow protocol	Working conditions	1
Non-specific	Inattention			1

administration error				
Non-specific administration error	Vaccine/ equipment storage			1
Non-specific administration error	Non-disclosure			1
Non-specific administration error	Failure to follow protocol	Looked-after child		1
Non-specific administration error	New to area			1
Non-specific administration error	Patient/ caregiver knowledge			1
Non-specific administration error	Vaccine/ equipment failure			1
Non-specific administrative error	Working conditions			1
Non-specific vaccine error	Vaccine/ equipment storage			1
Not administered	Other staff factors	Working conditions		1
Not administered	Working conditions			1
Not administered	Vaccine/ equipment packaging	Failure to follow protocol		1
Not administered	Inadequate guidelines or protocols	Vaccine/ equipment packaging		1
Not administered	Inadequate guidelines or protocols			1
Not administered	Working conditions			1
Not administered	Patient disability	Violence		1
Not administered	Failure to follow protocol			1
Not administered	Non-specific mistake	Working conditions		1
Out of date vaccine	Inattention			1
Out of date vaccine	Non-specific mistake	Failure to follow protocol	Vaccine/ equipment storage	1

Out of date vaccine	Failure to follow protocol	Non-specific mistake		1
Out of date vaccine				1
Out of date vaccine	Non-specific mistake	Vaccine/ equipment packaging	Vaccine/ equipment storage	1
Out of date vaccine	Non-specific mistake	Working conditions		1
Prescribing / dispensing error	Non-specific mistake			1
Prescribing / dispensing error	Similar vaccine names	Failure to follow protocol	Vaccine/ equipment storage	1
Prescribing / dispensing error	Similar vaccine names	Vaccine/ equipment storage	Working conditions	1
Prescribing / dispensing error	Vaccine/ equipment storage			1
Prescribing/ dispensing incident	Non-specific mistake			1
Procedural error	Staff knowledge	Working conditions		1
Professionalism				1
Professionalism	Other staff factors	Inadequate guidelines or protocols		1
Reconstitution error	Failure to follow protocol	Staff knowledge		1
Records not up to date	Inadequate guidelines or protocols			1
Records not up to date	New to area	Looked-after child		1
Records not up to date	Patient/ caregiver knowledge			1
Records not up to date	Continuity of care	New to area	Looked-after child	1
Records not up to date	Failure to follow protocol			1

Records not up to date	Inadequate guidelines or protocols			1
Records not up to date	Continuity of care			1
Transfer of records	New to area			1
Transport error	Patient allergy			1
Used needle	Non-compliance			1
Used needle	Failure to follow protocol	Non-compliance		1
Used needle	Non-specific mistake			1
Wrong dose	Staff knowledge			1
Wrong dose	Vaccine/ equipment failure	Non-compliance		1
Wrong dose	Inadequate guidelines or protocols			1
Wrong dose	Education and training	Inadequate guidelines or protocols		1
Wrong dose	Misreading	Working conditions		1
Wrong dose	Non-specific mistake	Failure to follow protocol		1
Wrong dose	Similar vaccine names			1
Wrong number of doses	Misreading	Looked-after child		1
Wrong number of doses	Vaccine/ equipment packaging	Failure to follow protocol		1
Wrong number of doses	Non-specific mistake	Failure to follow protocol	Working conditions	1
Wrong number of doses	Similar patient names	Working conditions		1
Wrong number of doses	Inadequate guidelines or protocols	Continuity of care		1
Wrong number of doses	Working conditions			1

Wrong number of doses	Similar patient names	Failure to follow protocol		1
Wrong number of doses	Non-specific mistake	Patient/ caregiver knowledge		1
Wrong number of doses	Non-specific mistake	Failure to follow protocol	Patient/ caregiver knowledge	1
Wrong number of doses	Non-specific mistake	Failure to follow protocol	Education and training	1
Wrong number of doses	Education and training			1
Wrong number of doses	New to area	Patient language	Failure to follow protocol	1
Wrong number of doses	New to area	Patient/ caregiver knowledge	Continuity of care	1
Wrong number of doses	Non-compliance			1
Wrong number of doses	Patient/ caregiver knowledge	Misreading		1
Wrong number of doses	Staff knowledge			1
Wrong number of doses	Staff knowledge	Education and training		1
Wrong number of doses	Failure to follow protocol			1
Wrong number of doses	Failure to follow protocol	Misreading		1
Wrong number of doses	Failure to follow protocol	Patient/ caregiver knowledge		1
Wrong number of doses	Failure to follow protocol	Patient/ caregiver knowledge	New to area	1
Wrong number of doses	Failure to follow protocol	Looked-after child		1
Wrong number of doses	Failure to follow protocol	Similar vaccine names		1
Wrong number of doses	Failure to follow	Other staff	Staff	1

	protocol	factors	knowledge	
Wrong number of doses	Inattention	Failure to follow protocol		1
Wrong number of doses	Patient/ caregiver knowledge	Working conditions		1
Wrong patient	Non-disclosure			1
Wrong patient	Failure to follow protocol			1
Wrong patient	Staff distraction			1
Wrong patient	Similar patient names	Patient disability		1
Wrong patient	Non-specific mistake	Patient disability		1
Wrong patient	Inadequate guidelines or protocols			1
Wrong patient	Working conditions			1
Wrong route				1
Wrong route	Failure to follow protocol			1
Wrong route	Misreading			1
Wrong site	Misreading	Working conditions	Vaccine/ equipment failure	1
Wrong site	Non-compliance			1
Wrong storage	Failure to follow protocol	Vaccine/ equipment failure		1
Wrong timing	Access difficulties			1
Wrong timing	Failure to follow protocol	Other staff factors		1
Wrong timing	Working conditions			1
Wrong timing	Patient disability			1
Wrong timing	Caregiver/ patient behaviour	Access difficulties		1
Wrong timing	Other staff factors	Staff knowledge	Education and training	1
Wrong timing	Inadequate guidelines or			1

	protocols			
Wrong timing	Continuity of care	Patient/ caregiver knowledge		1
Wrong timing	New to area			1
Wrong timing	Patient language	Failure to follow protocol		1
Wrong timing	Non-disclosure			1
Wrong timing	Failure to follow protocol	New to area		1
Wrong timing	Failure to follow protocol	Non-specific mistake		1
Wrong timing	Failure to follow protocol	Staff distraction		1
Wrong timing	Failure to follow protocol	Education and training		1
Wrong timing	Staff distraction	Working conditions		1
Wrong timing	Misreading			1
Wrong timing	Non-specific mistake	Patient language		1
Wrong timing	Non-specific mistake	Patient/ caregiver knowledge		1
Wrong timing	Non-specific mistake	Education and training	New to area	1
Wrong timing	Working conditions			1
Wrong timing	Education and training			1
Wrong timing	Education and training	Other staff factors		1
Wrong timing	Non-compliance			1
Wrong timing	Non-specific patient health			1
Wrong timing	Looked-after child			1
Wrong timing	Continuity of care	New to area		1
Wrong vaccine	Failure to follow protocol	Staff knowledge	Education and training	1
Wrong vaccine	Staff knowledge	Education and		1

		training		
Wrong vaccine	Other staff factors	Failure to follow protocol		1
Wrong vaccine	Staff fatigue/ stress			1
Wrong vaccine	Staff fatigue/ stress	Working conditions		1
Wrong vaccine	Failure to follow protocol	Other staff factors		1
Wrong vaccine	Vaccine/ equipment failure	Non-specific mistake	Failure to follow protocol	1
Wrong vaccine	Vaccine/ equipment packaging			1
Wrong vaccine	Working conditions			1
Wrong vaccine	Working conditions	Failure to follow protocol	Looked-after child	1
Wrong vaccine	Working conditions	Education and training		1
Wrong vaccine	Education and training	New to area	Similar vaccine names	1
Wrong vaccine	Vaccine/ equipment storage			1
Wrong vaccine	Failure to follow protocol	Staff knowledge		1
Wrong vaccine	Inattention	Staff distraction		1
Wrong vaccine	Similar vaccine names	Failure to follow protocol	Vaccine/ equipment storage	1
Wrong vaccine	Similar vaccine names	Staff fatigue/ stress		1
Wrong vaccine	Pregnancy			1
Wrong vaccine	Staff knowledge			1
Wrong vaccine	Failure to follow protocol	Non-specific mistake		1
Wrong vaccine	Failure to follow protocol	Inattention		1

Wrong vaccine	Failure to follow protocol	Working conditions	Education and training	1
Wrong vaccine	Inattention			1
Wrong vaccine	Inattention	Similar vaccine names		1
Wrong vaccine	Staff distraction	Staff fatigue/ stress	Staff fatigue/ stress	1
Wrong vaccine	Staff distraction	Working conditions		1
Wrong vaccine	Staff distraction	Working conditions	Education and training	1
Wrong vaccine	Similar vaccine names	Failure to follow protocol		1
Wrong vaccine	Similar vaccine names	Similar vaccine names		1
Total				**1745**

3.3 The frequency of each combination of incidents involving 'unwell' children

Primary incident	Contributory incidents				Frequency of combination
Medication dispensing					283
Transfer of information					88
Communication - patients / caregivers					87
Inadequate triaging					84
Treatment and procedures					82
Equipment					66
Medication prescribing					54
Inadequate triaging	Inadequate history				48
Documentation					45
Medication dispensing	Medication prescribing				44
Medication administration	Medication dispensing				35
Other					33
Investigations					32
Medication administration					32
Access to care					23
Incomplete referral					23
Transfer of patients					23
Medication dispensing	Medication dispensing				22
Treatment decision					22
Inadequate triaging	Communication - patients / caregivers				21
Delayed referral	Inadequate triaging				19
Communication between professionals					18

Treatment and procedures	Equipment				17
Inadequate triaging	Documentation				16
Delayed assessment					14
Diagnosis					14
Inadequate history					14
Other medication					14
Delayed referral	Inadequate triaging	Inadequate history			13
Inadequate triaging	Communication between professionals				13
Delayed referral					12
Inadequate triaging	Inadequate history	Communication - patients / caregivers			12
Medication administration	Communication - patients / caregivers				12
Delayed assessment	Inadequate triaging				11
Access to care	Transfer of information				10
Access to care	Documentation				10
Delayed assessment	Appointment management				10
Diagnosis	Investigations				10
Failure to refer when appropriate					10
Failure to refer when appropriate	Failure to identify at risk/ vulnerable child				10
Transfer of information	Documentation				10
Appointment management					8
Communication - patients / caregivers	Documentation				8
Delayed assessment	Access to care				8
Inadequate discharge					8

planning					
Referral administrative issues					8
Communication - patients / caregivers	Inadequate triaging				7
Delayed referral	Failure to identify at risk/ vulnerable child				7
Failure to refer when appropriate	Inadequate triaging				7
Insufficient assessment (non-specific)					7
Medication administration	Medication prescribing				7
Other medication	Medication dispensing				7
Communication - patients / caregivers	Inadequate history				6
Documentation	Inadequate history				6
Equipment	Equipment				6
Equipment	Other administrative				6
Failure to identify at risk/ vulnerable child					6
Inadequate triaging	Inadequate history	Documentation			6
Inadequate triaging	Failure to identify at risk/ vulnerable child				6
Transfer of information	Transfer of information				6
Treatment and procedures	Equipment				6
Access to care	Appointment management				5
Communication - patients / caregivers	Transfer of information				5
Communication -	Failure to				5

patients / caregivers	identify at risk/ vulnerable child				
Delayed assessment	Transfer of information				5
Delayed referral	Inadequate triaging	Inadequate history	Communication - patients / caregivers		5
Delayed referral	Inadequate triaging	Communication - patients / caregivers			5
Delayed referral	Delayed assessment				5
Documentation	Communication - patients / caregivers				5
Inadequate triaging	Documentation	Inadequate history			5
Incomplete referral	Inadequate triaging				5
Medication administration	Medication dispensing	Medication prescribing			5
Medication administration	Medication dispensing	Medication dispensing			5
Medication administration	Equipment				5
Medication dispensing	Communication - patients / caregivers				5
Other diagnosis and assessment					5
Transfer of information	Communication between professionals				5
Transfer of information	Equipment				5
Communication - patients / caregivers	Investigations				4
Delayed referral	Failure to identify at risk/				4

	vulnerable child				
Inadequate discharge planning	Failure to identify at risk/ vulnerable child				4
Inadequate history	Communication - patients / caregivers				4
Insufficient assessment (non-specific)	Documentation				4
Other	Equipment				4
Other	Treatment and procedures				4
Transfer of patients	Documentation				4
Treatment and procedures	Appointment management				4
Treatment and procedures	Transfer of information				4
Treatment decision	Other medication				4
Access to care	Documentation	Communication - patients / caregivers			3
Access to care	Communication - patients / caregivers				3
Communication - patients / caregivers	Treatment decision				3
Delayed assessment	Incomplete referral				3
Delayed assessment	Communication - patients / caregivers				3
Delayed referral	Inadequate triaging	Documentation			3
Delayed referral	Inadequate triaging				3
Failure to refer when appropriate	Investigations				3
Inadequate examination					3

Inadequate triaging	Documentation	Inadequate history	Communication - patients / caregivers		3
Insufficient assessment (non-specific)	Equipment				3
Investigations	Communication - patients / caregivers				3
Medication dispensing	Medication dispensing	Medication prescribing			3
Other administrative					3
Transfer of information	Communication between professionals				3
Transfer of information	Appointment management				3
Transfer of patients	Equipment				3
Transfer of patients	Insufficient assessment (non-specific)				3
Treatment and procedures	Treatment and procedures				3
Treatment decision	Medication dispensing				3
Treatment decision	Diagnosis				3
Access to care	Incomplete referral				2
Access to care	Other administrative				2
Access to care	Incomplete referral				2
Appointment management	Communication between professionals				2
Communication - patients / caregivers	Failure to refer when appropriate				2
Communication -	Incomplete				2

patients / caregivers	referral				
Communication - patients / caregivers	Diagnosis	Insufficient assessment (non-specific			2
Communication - patients / caregivers	Inadequate triaging	Inadequate history			2
Communication - patients / caregivers	Inadequate triaging	Communication between professionals			2
Delayed assessment	Documentation	Transfer of information			2
Delayed assessment	Referral administrative issues				2
Delayed assessment	Inadequate triaging	Communication - patients / caregivers			2
Delayed assessment	Inadequate discharge planning	Appointment management	Communication - patients / caregivers		2
Delayed referral	Transfer of information				2
Delayed referral	Inadequate triaging	Failure to identify at risk/ vulnerable child			2
Delayed referral	Communication between professionals				2
Delayed referral	Transfer of patients				2
Delayed referral	Documentation				2
Delayed referral	Communication - patients / caregivers				2
Delayed referral	Equipment				2
Diagnosis	Investigations	Failure to identify at risk/ vulnerable child			2

Documentation	Other administrative				2
Documentation	Investigations				2
Equipment	Inadequate discharge planning				2
Failure to refer when appropriate	Inadequate history				2
Failure to refer when appropriate	Transfer of information				2
Inadequate history	Failure to identify at risk/ vulnerable child				2
Inadequate triaging	Communication - patients / caregivers				2
Inadequate triaging	Inadequate history	Documentation	Communication - patients / caregivers		2
Inadequate triaging	Failure to identify at risk/ vulnerable child	Communication - patients / caregivers			2
Incomplete referral	Failure to identify at risk/ vulnerable child				2
Insufficient assessment (non-specific)	Treatment and procedures				2
Investigations	Transfer of information	Appointment management			2
Medication administration	Transfer of information				2
Medication dispensing	Communication between professionals				2
Medication dispensing	Communication between professionals				2
Medication monitoring	Appointment				2

	management				
Medication prescribing	Documentation				2
Other	Appointment management				2
Other	Other				2
Other	Transfer of information				2
Other	Access to care				2
Other medication	Equipment				2
Treatment decision	Communication - patients / caregivers				2
Treatment decision	Transfer of information				2
Treatment decision	Inadequate examination				2
Treatment decision	Medication prescribing				2
Access to care	Other administrative	Communication - patients / caregivers			1
Access to care	Transfer of information	Equipment			1
Access to care	Transfer of information	Transfer of information			1
Access to care	Transfer of information	Other			1
Access to care	Inadequate triaging	Inadequate history			1
Access to care	Communication - patients / caregivers	Documentation			1
Access to care	Appointment management	Inadequate triaging	Failure to identify at risk/ vulnerable child		1
Access to care	Equipment				1
Access to care	Transfer of	Transfer of			1

	information	information			
Access to care	Appointment management	Inadequate triaging			1
Access to care	Transfer of patients				1
Access to care	Appointment management	Failure to refer when appropriate			1
Access to care	Transfer of patients	Communication between professionals			1
Access to care	Referral administrative issues				1
Access to care	Inadequate triaging				1
Appointment management	Referral administrative issues				1
Appointment management	Failure to identify at risk/ vulnerable child	Inadequate triaging			1
Communication between professionals	Transfer of information	Inadequate discharge planning			1
Communication between professionals	Documentation				1
Communication between professionals	Inadequate history				1
Communication - patients / caregivers	Treatment decision				1
Communication - patients / caregivers	Medication prescribing				1
Communication - patients / caregivers	Inadequate triaging	Access to care	Appointment management		1
Communication - patients / caregivers	Other				1
Communication -	Other	Documentation			1

patients / caregivers					
Communication - patients / caregivers	Documentation	Inadequate history			1
Communication - patients / caregivers	Delayed referral	Inadequate triaging			1
Communication - patients / caregivers	Failure to refer when appropriate	Failure to identify at risk/ vulnerable child			1
Communication - patients / caregivers	Incomplete referral	Inadequate triaging			1
Communication - patients / caregivers	Diagnosis	Failure to identify at risk/ vulnerable child			1
Communication - patients / caregivers	Inadequate triaging	Inadequate history	Other		1
Communication - patients / caregivers	Failure to identify at risk/ vulnerable child	Equipment			1
Communication - patients / caregivers	Failure to identify at risk/ vulnerable child	Inadequate triaging			1
Communication - patients / caregivers	Insufficient assessment (non-specific	Access to care			1
Communication - patients / caregivers	Insufficient assessment (non-specific	Equipment	Equipment		1
Communication - patients / caregivers	Delayed assessment	Inadequate history			1
Communication - patients / caregivers	Treatment and procedures				1
Communication - patients / caregivers	Treatment decision	Inadequate examination			1
Communication - patients / caregivers	Equipment				1
Communication - patients / caregivers	Appointment management				1
Communication - patients / caregivers	Inadequate history				1

Delayed assessment	Other administrative				1
Delayed assessment	Appointment management	Transfer of information			1
Delayed assessment	Access to care	Appointment management			1
Delayed assessment	Access to care	Referral administrative issues			1
Delayed assessment	Access to care	Equipment			1
Delayed assessment	Access to care	Inadequate triaging			1
Delayed assessment	Other	Appointment management			1
Delayed assessment	Documentation				1
Delayed assessment	Delayed referral				1
Delayed assessment	Delayed referral	Failure to identify at risk/ vulnerable child			1
Delayed assessment	Failure to refer when appropriate				1
Delayed assessment	Referral administrative issues	Communication between professionals			1
Delayed assessment	Inadequate triaging	Documentation	Document ation		1
Delayed assessment	Inadequate triaging	Inadequate history			1
Delayed assessment	Inadequate triaging	Inadequate history	Communi cation - patients / caregivers		1
Delayed assessment	Inadequate triaging	Failure to identify at risk/ vulnerable child			1
Delayed assessment	Inadequate triaging	Communication between professionals			1

Delayed assessment	Inadequate triaging	Equipment			1
Delayed assessment	Failure to identify at risk/ vulnerable child				1
Delayed assessment	Failure to identify at risk/ vulnerable child	Communication between professionals			1
Delayed assessment	Investigations	Access to care			1
Delayed assessment	Communication - patients / caregivers	Inadequate triaging			1
Delayed assessment	Communication - patients / caregivers	Inadequate triaging	Inadequate triaging		1
Delayed assessment	Communication between professionals	Incomplete referral	Access to care	Appointment management	1
Delayed assessment	Communication between professionals	Incomplete referral	Failure to identify at risk/ vulnerable child		1
Delayed assessment	Equipment				1
Delayed referral	Failure to arrange follow up	Transfer of information			1
Delayed referral	Incomplete referral	Failure to identify at risk/ vulnerable child			1
Delayed referral	Diagnosis	Documentation			1
Delayed referral	Diagnosis	Diagnosis			1
Delayed referral	Access to care				1
Delayed referral	Other				1
Delayed referral	Diagnosis	Incomplete referral			1
Delayed referral	Insufficient assessment				1

	(non-specific)				
Delayed referral	Inadequate triaging	Access to care			1
Delayed referral	Inadequate triaging	Documentation	Inadequate history		1
Delayed referral	Inadequate triaging	Documentation	Inadequate history	Communication - patients / caregivers	1
Delayed referral	Inadequate triaging	Medication dispensing			1
Delayed referral	Inadequate history				1
Delayed referral	Inadequate examination	Failure to identify at risk/ vulnerable child	Communication - patients / caregivers		1
Delayed referral	Delayed assessment	Access to care			1
Delayed referral	Delayed assessment	Inadequate triaging			1
Delayed referral	Delayed assessment	Inadequate triaging	Documentation		1
Delayed referral	Delayed assessment	Inadequate triaging	Communication between professionals		1
Delayed referral	Treatment decision	Communication - patients / caregivers	Failure to identify at risk/ vulnerable child	Inadequate examination	1
Delayed referral	Investigations	Failure to identify at risk/ vulnerable child			1

Delayed referral	Communication - patients / caregivers	Inadequate triaging			1
Delayed referral	Communication - patients / caregivers	Inadequate triaging	Failure to identify at risk/ vulnerable child		1
Delayed referral	Inadequate triaging				1
Delayed referral	Communication - patients / caregivers				1
Delayed referral	Diagnosis	Documentation			1
Diagnosis	Failure to identify at risk/ vulnerable child				1
Diagnosis	Investigations	Communication between professionals			1
Diagnosis	Transfer of information				1
Diagnosis	Failure to identify at risk/ vulnerable child	Inadequate history	Transfer of information		1
Diagnosis	Failure to identify at risk/ vulnerable child	Investigations			1
Diagnosis	Delayed referral	Documentation			1
Diagnosis	Investigations	Diagnosis	Investigations		1
Diagnosis	Access to care				1
Diagnosis	Delayed referral	Failure to identify at risk/ vulnerable child			1
Diagnosis	Diagnosis				1
Diagnosis	Appointment management	Communication - patients /			1

		caregivers			
Diagnosis	Transfer of information	Other administrative	Other administrative		1
Diagnosis	Delayed referral				1
Diagnosis	Inadequate examination				1
Diagnosis	Failure to identify at risk/ vulnerable child				1
Diagnosis	Investigations	Inadequate history			1
Diagnosis	Investigations	Communication between professionals			1
Diagnosis	Investigations	Other administrative			1
Diagnosis	Communication - patients / caregivers				1
Documentation	Transfer of information				1
Documentation	Appointment management				1
Documentation	Equipment				1
Documentation	Communication between professionals	Transfer of information			1
Documentation	Investigations				1
Documentation	Other	Other			1
Documentation	Insufficient assessment (non-specific)				1
Documentation	Inadequate history	Communication - patients / caregivers			1
Documentation	Inadequate history	Communication - patients / caregivers	Communication - patients /		1

			caregivers		
Documentation	Inadequate examination				1
Documentation	Insufficient assessment (non-specific)	Appointment management			1
Documentation	Communication - patients / caregivers	Inadequate history			1
Equipment	Medication dispensing				1
Equipment	Equipment	Referral administrative issues	Incomplete referral		1
Equipment	Access to care	Transfer of information			1
Equipment	Failure to refer when appropriate				1
Equipment	Inadequate discharge planning	Transfer of information			1
Equipment	Medication prescribing				1
Equipment	Other medication				1
Equipment	Transfer of information				1
Equipment	Delayed assessment				1
Failure to arrange follow up	Delayed assessment				1
Failure to identify at risk/ vulnerable child	Inadequate triaging	Inadequate history			1
Failure to refer when appropriate	Investigations	Investigations			1
Failure to refer when appropriate	Access to care	Appointment management			1
Failure to refer when	Transfer of	Communication			1

appropriate	information	between professionals			
Failure to refer when appropriate	Inadequate triaging	Inadequate history	Communication - patients / caregivers		1
Failure to refer when appropriate	Inadequate triaging	Failure to identify at risk/ vulnerable child			1
Failure to refer when appropriate	Communication - patients / caregivers				1
Failure to refer when appropriate	Communication - patients / caregivers	Failure to identify at risk/ vulnerable child			1
Failure to refer when appropriate	Communication between professionals				1
Inadequate discharge planning	Transfer of information	Access to care			1
Inadequate discharge planning	Documentation				1
Inadequate discharge planning	Failure to refer when appropriate				1
Inadequate discharge planning	Incomplete referral				1
Inadequate discharge planning	Communication between professionals	Transfer of information			1
Inadequate discharge planning	Communication between professionals	Transfer of information			1
Inadequate discharge planning	Equipment				1
Inadequate discharge planning	Equipment	Medication dispensing	Communication - patients / caregivers		1

Inadequate examination	Transfer of information	Transfer of information			1
Inadequate examination	Documentation	Transfer of information			1
Inadequate examination	Equipment				1
Inadequate triaging	Other administrative				1
Inadequate triaging	Transfer of information				1
Inadequate triaging	Documentation	Inadequate history	Communication - patients / caregivers	Other	1
Inadequate triaging	Inadequate triaging				1
Inadequate triaging	Inadequate history	Transfer of information			1
Inadequate triaging	Inadequate history	Failure to identify at risk/ vulnerable child			1
Inadequate triaging	Inadequate history	Communication - patients / caregivers	Other		1
Inadequate triaging	Inadequate history	Communication - patients / caregivers	Documentation		1
Inadequate triaging	Inadequate history	Communication between professionals			1
Inadequate triaging	Medication dispensing				1
Inadequate triaging	Communication between professionals	Documentation			1
Inadequate triaging	Equipment				1
Incomplete referral	Appointment management				1
Incomplete referral	Insufficient assessment				1

	(non-specific)				
Incomplete referral	Inadequate examination				1
Incomplete referral	Communication - patients / caregivers	Inadequate history	Delayed assessment	Other	1
Incomplete referral	Incomplete referral				1
Incomplete referral	Incomplete referral	Treatment decision			1
Incomplete referral	Communication - patients / caregivers				1
Insufficient assessment (non-specific)	Transfer of information				1
Insufficient assessment (non-specific)	Transfer of patients				1
Insufficient assessment (non-specific)	Other				1
Insufficient assessment (non-specific)	Documentation	Documentation			1
Insufficient assessment (non-specific)	Documentation	Failure to identify at risk/ vulnerable child			1
Insufficient assessment (non-specific)	Medication prescribing				1
Insufficient assessment (non-specific)	Investigations				1
Insufficient assessment (non-specific)	Communication - patients / caregivers				1
Insufficient assessment (non-specific)	Communication between professionals				1
Investigations	Inadequate discharge planning				1
Investigations	Other administrative				1

Investigations	Transfer of information				1
Investigations	Investigations	Transfer of patients			1
Investigations	Communication - patients / caregivers	Documentation			1
Investigations	Transfer of information	Transfer of information			1
Investigations	Documentation	Equipment			1
Medication administration	Inadequate discharge planning				1
Medication administration	Other medication				1
Medication administration	Medication administration				1
Medication administration	Medication monitoring	Appointment management	Transfer of information		1
Medication administration	Communication - patients / caregivers	Medication dispensing	Medication prescribing		1
Medication administration	Communication - patients / caregivers	Communication - patients / caregivers			1
Medication administration	Communication - patients / caregivers	Equipment			1
Medication administration	Equipment	Communication - patients / caregivers			1
Medication administration	Documentation				1
Medication administration	Medication prescribing	Communication - patients / caregivers			1

Medication administration	Medication dispensing	Medication dispensing			1
Medication administration	Documentation	Communication - patients / caregivers			1
Medication administration	Access to care				1
Medication administration	Documentation	Transfer of information			1
Medication administration	Documentation				1
Medication administration	Other medication				1
Medication administration	Medication prescribing				1
Medication administration	Medication prescribing	Equipment	Communication - patients / caregivers		1
Medication administration	Medication dispensing	Medication prescribing			1
Medication administration	Communication between professionals				1
Medication dispensing	Medication dispensing	Equipment			1
Medication dispensing	Documentation				1
Medication dispensing	Other medication				1
Medication dispensing	Medication prescribing	Medication prescribing			1
Medication dispensing	Equipment				1
Medication dispensing	Other administrative				1
Medication monitoring					1
Medication monitoring	Transfer of information	Transfer of information			1
Medication monitoring	Inadequate discharge	Transfer of information			1

	planning				
Medication monitoring	Transfer of information				1
Medication monitoring	Insufficient assessment (non-specific	Documentation			1
Medication monitoring	Investigations				1
Medication prescribing	Transfer of information				1
Medication prescribing	Transfer of information	Inadequate discharge planning			1
Medication prescribing	Equipment				1
Medication prescribing	Inadequate history				1
Medication prescribing	Treatment decision	Communication between professionals			1
Medication prescribing	Medication prescribing				1
Medication prescribing	Medication monitoring	Access to care			1
Medication prescribing	Communication between professionals				1
Medication prescribing	Medication dispensing	Medication prescribing			1
Medication prescribing	Inadequate history	Documentation	Communication - patients / caregivers		1
Medication prescribing	Communication - patients / caregivers				1
Medication prescribing	Medication dispensing				1
Other	Communication - patients / caregivers				1

Other	Communication - patients / caregivers	Communication between professionals			1
Other	Communication between professionals				1
Other	Other administrative				1
Other	Access to care	Incomplete referral			1
Other	Other	Failure to refer when appropriate			1
Other	Other	Failure to refer when appropriate	Appointment management	Referral administrative issues	1
Other	Transfer of information	Other administrative			1
Other	Delayed referral	Documentation	Failure to identify at risk/ vulnerable child		1
Other	Delayed referral	Inadequate triaging	Inadequate history		1
Other	Failure to refer when appropriate				1
Other	Referral administrative issues				1
Other	Failure to identify at risk/ vulnerable child				1
Other	Inadequate discharge planning				1

Other	Treatment and procedures	Inadequate discharge planning	Failure to refer when appropriate		1
Other	Other medication	Other medication			1
Other administrative	Communication - patients / caregivers				1
Other administrative	Appointment management				1
Other administrative	Communication - patients / caregivers	Documentation			1
Other administrative	Communication between professionals				1
Other diagnosis and assessment	Delayed referral	Inadequate triaging	Failure to identify at risk/ vulnerable child	Inadequate examination	1
Other medication	Medication dispensing	Medication prescribing			1
Referral administrative issues	Other administrative				1
Referral administrative issues	Appointment management				1
Referral administrative issues	Transfer of information				1
Referral administrative issues	Communication - patients / caregivers				1
Referral administrative issues	Insufficient assessment (non-specific)	Communication between professionals			1
Referral administrative issues	Inadequate triaging				1

Transfer of information	Inadequate discharge planning				1
Transfer of information	Inadequate discharge planning	Communication - patients / caregivers			1
Transfer of information	Access to care	Documentation			1
Transfer of information	Referral administrative issues				1
Transfer of information	Inadequate discharge planning				1
Transfer of information	Communication between professionals	Transfer of information			1
Transfer of information	Inadequate triaging				1
Transfer of information	Inadequate history				1
Transfer of patients	Access to care	Appointment management			1
Transfer of patients	Transfer of information				1
Transfer of patients	Incomplete referral	Incomplete referral			1
Transfer of patients	Failure to identify at risk/ vulnerable child				1
Transfer of patients	Insufficient assessment (non-specific)	Communication between professionals			1
Transfer of patients	Delayed assessment				1
Transfer of patients	Communication - patients / caregivers				1
Transfer of patients	Incomplete referral				1

Transfer of patients	Communication between professionals				1
Transfer of patients	Diagnosis	Failure to identify at risk/ vulnerable child	Investigations		1
Treatment and procedures	Treatment and procedures	Communication - patients / caregivers			1
Treatment and procedures	Failure to refer when appropriate				1
Treatment and procedures	Diagnosis				1
Treatment and procedures	Insufficient assessment (non-specific)				1
Treatment and procedures	Other diagnosis and assessment	Failure to identify at risk/ vulnerable child			1
Treatment and procedures	Treatment and procedures	Treatment and procedures			1
Treatment and procedures	Medication dispensing	Medication dispensing			1
Treatment and procedures	Investigations	Equipment			1
Treatment and procedures	Inadequate history				1
Treatment and procedures	Appointment management	Treatment and procedures			1
Treatment and procedures	Access to care	Incomplete referral			1
Treatment and procedures	Transfer of information	Failure to refer when appropriate	Inadequate discharge planning		1
Treatment and procedures	Transfer of patients				1
Treatment and	Delayed referral				1

procedures					
Treatment and procedures	Incomplete referral				1
Treatment and procedures	Incomplete referral	Incomplete referral			1
Treatment and procedures	Referral administrative issues	Appointment management			1
Treatment and procedures	Diagnosis	Investigations	Investigations		1
Treatment and procedures	Diagnosis	Investigations			1
Treatment and procedures	Inadequate triaging	Inadequate history			1
Treatment and procedures	Delayed assessment	Transfer of information			1
Treatment and procedures	Delayed assessment	Inadequate triaging	Communication between professionals		1
Treatment and procedures	Delayed assessment	Inadequate discharge planning	Incomplete referral		1
Treatment and procedures	Treatment and procedures	Appointment management			1
Treatment and procedures	Medication dispensing				1
Treatment and procedures	Investigations	Transfer of information	Inadequate discharge planning		1
Treatment and procedures	Investigations	Communication between professionals			1
Treatment and procedures	Investigations	Equipment			1
Treatment and procedures	Investigations				1

Treatment and procedures	Equipment	Other administrative			1
Treatment decision	Access to care	Access to care			1
Treatment decision	Other diagnosis and assessment				1
Treatment decision	Appointment management				1
Treatment decision	Transfer of information				1
Treatment decision	Diagnosis	Transfer of information	Transfer of information		1
Treatment decision	Insufficient assessment (non-specific)				1
Treatment decision	Inadequate triaging	Inadequate history	Documentation		1
Treatment decision	Inadequate examination				1
Treatment decision	Medication dispensing	Equipment			1
Treatment decision	Other medication	Transfer of information	Failure to identify at risk/ vulnerable child		1
Treatment decision	Other medication	Access to care	Documentation		1
Treatment decision	Equipment				1
Treatment decision	Delayed referral				1
Treatment decision	Transfer of information	Incomplete referral	Delayed referral	Inadequate discharge planning	1
Treatment decision	Insufficient assessment				1

	(non-specific				
Treatment decision	Inadequate examination				1
Treatment decision	Failure to identify at risk/ vulnerable child	Diagnosis			1
Treatment decision	Inadequate discharge planning	Failure to identify at risk/ vulnerable child			1
Treatment decision	Other medication	Communication between professionals			1
Treatment decision	Investigations				1
Treatment decision	Investigations	Documentation			1
Treatment decision	Investigations	Transfer of information			1
Treatment decision	Communication between professionals	Communication - patients / caregivers			1
Treatment decision	Equipment	Transfer of information			1
Treatment decision	Equipment	Investigations			1
Treatment decision	Equipment	Transfer of information	Inadequate discharge planning		1
Grand Total					**2191**

3.4 The frequency of combinations of contributory factors for each primary incident type involving 'unwell' children

Primary incident	Contributory factors				Frequency of combination
Medication dispensing					144
Treatment and procedures					87
Medication dispensing	Mistakes				78
Communication - patients / caregivers					76
Transfer of patient information					68
Inadequate triaging	Failure to follow protocol				67
Equipment					65
Inadequate triaging					63
Documentation					49
Delayed referral					46
Medication administering					38
Other					35
Investigations					34
Access to care					31
Treatment decisions					29
Transfer of patient information	Continuity of care				27
Communication - patients / caregivers	Failure to follow protocol				26
Diagnostic issues					26
Medication dispensing	Mistake	Equipment/ medication factors			26
Delayed assessment					25
Transport/ transfer of patients					25
Inadequate triaging	Critical thinking				22
Failure to refer when appropriate					19
Medication prescribing					18

Other medication					18
Delayed referral	Failure to follow protocol				17
Incorrect/ incomplete referral					17
Inadequate triaging	Failure to follow protocol	Critical thinking			15
Medication administering	Mistakes				14
Medication dispensing	Mistakes	Working conditions			13
Medication dispensing	Failure to follow protocol				12
Appointment management					10
Delayed assessment	Failure to follow protocol				10
Medication prescribing	Mistakes				10
Access to care	Continuity of care				9
Delayed assessment	Continuity of care				9
Documentation	Failure to follow protocol				9
Inadequate discharge planning					8
Insufficient assessment (non-specific)					8
Medication administering	Patient age				8
Medication dispensing	Patient age				8
Medication prescribing	Patient age				8
Referral administrative issues					8
Treatment decisions	Working conditions				8
Delayed referral	Critical thinking				7
Failure to refer when appropriate	Failure to follow protocol				7

Medication dispensing	Equipment/ medication factors				7
Medication dispensing	Inadequate guidelines				7
Medication dispensing	Mistakes	Failure to follow protocol			7
Other	Failure to follow protocol				7
Access to care	Failure to follow protocol				6
Communication - patients / caregivers	Mistakes				6
Delayed assessment	Service availability				6
Inadequate history taking					6
Inadequate history taking	Failure to follow protocol				6
Inadequate triaging	Patient/ caregiver behaviour				6
Medication administering	Failure to follow protocol				6
Medication administering	Equipment/ medication factors	Working conditions			6
Medication dispensing	Mistakes	Working conditions	Working conditions		6
Transfer of patient information	Failure to follow protocol				6
Treatment and procedures	Patient/ caregiver behaviour				6

Treatment and procedures	Continuity of care				6
Communication between professionals					5
Delayed referral	Patient/ caregiver behaviour				5
Delayed referral	Failure to follow protocol	Critical thinking			5
Diagnostic issues	Failure to follow protocol				5
Other	Patient health				5
Other	Patient/ caregiver behaviour				5
Other diagnosis and assessment					5
Transfer of patient information	Continuity of care	Patient/ caregiver geography			5
Treatment decisions	Inadequate guidelines				5
Access to care	Working conditions				4
Communication between professionals	Failure to follow protocol				4
Communication - patients / caregivers	Patient age				4
Communication - patients / caregivers	Staff knowledge				4
Communication - patients / caregivers	Failure to follow protocol	Staff knowledg e			4
Delayed assessment	Inadequate guidelines				4
Delayed assessment	Working conditions				4
Delayed referral	Staff knowledge				4

Inadequate triaging	Mistakes				4
Inadequate triaging	Education and training				4
Medication administering	Patient/ caregiver behaviour				4
Medication administering	Patient/ caregiver knowledge				4
Medication dispensing	Working conditions				4
Medication dispensing	Mistake	Equipment/ medication factors	Working conditions		4
Medication prescribing	Failure to follow protocol	Patient age			4
Treatment and procedures	Patient age				4
Treatment decisions	Failure to follow protocol				4
Treatment decisions	Continuity of care				4
Access to care	Patient health				3
Access to care	Service availability				3
Access to care	Patient/ caregiver geography	Continuity of care			3
Communication between professionals	Continuity of care				3
Communication between professionals	Working conditions				3
Communication - patients / caregivers	Patient health				3
Communication - patients / caregivers	Patient/ caregiver knowledge				3
Communication - patients / caregivers	Inadequate				3

	guidelines				
Communication - patients / caregivers	Continuity of care				3
Communication - patients / caregivers	Failure to follow protocol	Patient age			3
Communication - patients / caregivers	Failure to follow protocol	Critical thinking			3
Delayed referral	Continuity of care				3
Delayed referral	Working conditions				3
Delayed referral	Failure to follow protocol	Staff knowledg e			3
Diagnostic issues	Patient health				3
Diagnostic issues	Staff knowledge	Education and training			3
Documentation	Mistakes				3
Equipment	Inadequate guidelines				3
Equipment	Education and training				3
Equipment	Working conditions				3
Failure to identify at risk child					3
Inadequate examination					3
Inadequate triaging	Staff knowledge				3
Inadequate triaging	Failure to follow protocol	Patient age			3
Incorrect/ incomplete referral	Failure to follow protocol				3
Insufficient assessment (non-specific)	Patient age				3
Medication dispensing	Staff				3

	knowledge				
Medication dispensing	Mistakes	Patient age			3
Medication dispensing	Mistake	Inadequate guidelines			3
Medication dispensing	Working conditions	Working conditions			3
Medication dispensing	Mistakes	Working conditions	Equipment/ medication		3
Medication dispensing	Mistake	Equipment/ medication factors	Working conditions	Working conditions	3
Medication prescribing	Staff knowledge				3
Other administrative					3
Other medication	Continuity of care				3
Transfer of patient information	Patient/ caregiver geography				3
Treatment and procedures	Patient health				3
Treatment and procedures	Equipment/ medication factors				3
Treatment and procedures	Working conditions				3
Communication between professionals	Mistake				2
Communication - patients / caregivers	Critical thinking				2
Communication - patients / caregivers	Education and training				2
Communication - patients / caregivers	Working conditions				2
Communication - patients / caregivers	Failure to follow	Patient/ caregiver			2

	protocol	geography			
Delayed assessment	Patient/ caregiver geography				2
Delayed assessment	Failure to follow protocol	Staff knowledge			2
Delayed assessment	Service availability	Inadequate guidelines			2
Delayed assessment	Service availability	Working conditions			2
Delayed assessment	Service availability	Working conditions			2
Delayed referral	Mistakes				2
Delayed referral	Inadequate guidelines				2
Documentation	Staff knowledge				2
Equipment	Non-specific organisational issues				2
Failure to refer when appropriate	Patient age				2
Failure to refer when appropriate	Staff knowledge				2
Inadequate discharge planning	Patient/ caregiver behaviour				2
Inadequate discharge planning	Failure to follow protocol				2
Inadequate history taking	Critical thinking				2
Inadequate triaging	Patient age				2
Inadequate triaging	Inadequate guidelines				2
Inadequate triaging	Failure to follow protocol	Patient health			2

Inadequate triaging	Critical thinking	Patient age			2
Inadequate triaging	Failure to follow protocol	Staff knowledge			2
Inadequate triaging	Patient health	Critical thinking			2
Inadequate triaging	Failure to follow protocol	Education and training			2
Incorrect/ incomplete referral	Patient age				2
Incorrect/ incomplete referral	Inadequate guidelines				2
Incorrect/ incomplete referral	Education and training				2
Incorrect/ incomplete referral	Failure to follow protocol	Education and training			2
Insufficient assessment (non-specific)	Failure to follow protocol				2
Insufficient assessment (non-specific)	Working conditions				2
Insufficient assessment (non-specific)	Patient age	Inadequate guidelines			2
Investigations	Inadequate guidelines				2
Medication administering	Equipment/ medication factors				2
Medication administering	Education and training				2
Medication administering	Continuity of care				2
Medication administering	Working conditions				2
Medication administering	Failure to follow	Patient/ caregiver			2

	protocol	knowledge			
Medication dispensing	Education and training				2
Medication dispensing	Mistake	Staff knowledge			2
Medication dispensing	Mistake	Mistake			2
Medication dispensing	Patient age	Mistake			2
Medication dispensing	Mistake	Other staff factors			2
Medication dispensing	Patient age	Working conditions			2
Medication dispensing	Staff knowledge	Education and training			2
Medication dispensing	Mistakes	Equipment/ medication factors	Failure to follow protocol		2
Medication dispensing	Mistake	Staff knowledge	Inadequate guidelines		2
Medication prescribing	Inadequate guidelines				2
Medication prescribing	Patient age	Failure to follow protocol			2
Medication prescribing	Mistakes	Equipment/ medication factors			2
Other medication	Inadequate guidelines				2
Transfer of patient information	Patient/ caregiver				2

	behaviour				
Transport/ transfer of patients	Patient/ caregiver geography				2
Transport/ transfer of patients	Failure to follow protocol				2
Transport/ transfer of patients	Service availability				2
Transport/ transfer of patients	Working conditions	Service availability			2
Treatment and procedures	Mistakes				2
Treatment and procedures	Staff knowledge				2
Treatment and procedures	Inadequate guidelines				2
Treatment and procedures	Education and training				2
Treatment and procedures	Service availability				2
Treatment and procedures	Mistakes	Patient/ caregiver behaviour			2
Treatment and procedures	Patient/ caregiver behaviour	Patient health			2
Treatment and procedures	Working conditions	Continuity of care			2
Treatment decisions	Equipment/ medication factors				2
Treatment decisions	Continuity of care	Inadequate guidelines			2
Access to care	Patient/ caregiver geography				1
Access to care	Patient/				1

	caregiver knowledge				
Access to care	Patient/ caregiver behaviour				1
Access to care	Critical thinking				1
Access to care	Education and training				1
Access to care	Continuity of care	Patient age			1
Access to care	Mistake	Failure to follow protocol			1
Access to care	Failure to follow protocol	Staff knowledge			1
Access to care	Patient health	Failure to follow protocol			1
Access to care	Service availability	Continuity of care			1
Access to care	Failure to follow protocol	Service availability			1
Access to care	Looked-after child	Patient/ caregiver geography	Inadequate guidelines		1
Appointment management	Patient/ caregiver geography				1
Appointment management	Patient age				1
Appointment management	Mistake				1
Appointment management	Service availability				1
Appointment management	Working conditions				1
Appointment management	Mistakes	Failure to			1

		follow protocol			
Communication between professionals	Continuity of care	Patient/ caregiver behaviour			1
Communication between professionals	Failure to follow protocol	Inadequate guidelines			1
Communication between professionals	Working conditions	Continuity of care			1
Communication between professionals	Critical thinking	Failure to follow protocol	Education and training		1
Communication - patients / caregivers	Equipment/ medication factors				1
Communication - patients / caregivers	Service availability				1
Communication - patients / caregivers	Patient/ caregiver knowledge	Patient/ caregiver knowledge			1
Communication - patients / caregivers	Failure to follow protocol	Patient health			1
Communication - patients / caregivers	Mistake	Patient age			1
Communication - patients / caregivers	Failure to follow protocol	Working conditions			1
Communication - patients / caregivers	Failure to follow protocol	Education and training			1
Communication - patients / caregivers	Failure to follow protocol	Staff knowledge	Patient health		1
Communication - patients / caregivers	Patient /caregiver language	Service availability	Working conditions		1

Communication - patients / caregivers	Failure to follow protocol	Patient age	Education and training		1
Communication - patients / caregivers	Failure to follow protocol	Critical thinking	Service availability		1
Communication - patients / caregivers	Patient health	Staff knowledge	Education and training	Failure to follow protocol	1
Delayed assessment	Looked-after child				1
Delayed assessment	Staff knowledge				1
Delayed assessment	Continuity of care	Patient/ caregiver geography			1
Delayed assessment	Service availability	Patient/ caregiver knowledge			1
Delayed assessment	Continuity of care	Patient health			1
Delayed assessment	Continuity of care	Patient age			1
Delayed assessment	Continuity of care	Failure to follow protocol			1
Delayed assessment	Service availability	Failure to follow protocol			1
Delayed assessment	Education and training	Failure to follow protocol			1
Delayed assessment	Patient age	Critical thinking			1
Delayed assessment	Continuity of care	Critical thinking			1

Delayed assessment	Patient /caregiver language	Service availability			1
Delayed assessment	Patient/ caregiver geography	Continuity of care			1
Delayed assessment	Patient health	Continuity of care			1
Delayed assessment	Continuity of care	Working conditions			1
Delayed assessment	Failure to follow protocol	Working conditions			1
Delayed assessment	Working conditions	Working conditions			1
Delayed assessment	Critical thinking	Education and training			1
Delayed assessment	Patient/ caregiver behaviour	Service availability			1
Delayed assessment	Failure to follow protocol	Staff knowledge	Education and training		1
Delayed referral	Patient /caregiver language				1
Delayed referral	Looked-after child				1
Delayed referral	Education and training				1
Delayed referral	Service availability				1
Delayed referral	Patient/ caregiver ethnicity	Inadequate guidelines			1
Delayed referral	Failure to follow protocol	Inadequate guidelines			1

Delayed referral	Mistakes	Inadequate guidelines			1
Delayed referral	Patient /caregiver language	Service availability			1
Delayed referral	Inadequate guidelines	Continuity of care			1
Delayed referral	Working conditions	Working conditions			1
Delayed referral	Failure to follow protocol	Education and training			1
Delayed referral	Critical thinking	Patient/ caregiver knowledge	Patient / caregiver geography		1
Delayed referral	Critical thinking	Education and training	Patient age		1
Delayed referral	Failure to follow protocol	Critical thinking	Staff knowledge		1
Delayed referral	Patient age	Failure to follow protocol	Inadequate guidelines		1
Delayed referral	Staff knowledge	Failure to follow protocol	Working conditions		1
Delayed referral	Failure to follow protocol	Staff knowledge	Education and training		1
Delayed referral	Service availability	Working conditions	Working conditions	Continuity of care	1
Diagnostic issues	Patient/				1

	caregiver behaviour				
Diagnostic issues	Patient age				1
Diagnostic issues	Staff knowledge				1
Diagnostic issues	Inadequate guidelines				1
Diagnostic issues	Patient health	Staff knowledge			1
Diagnostic issues	Failure to follow protocol	Staff knowledge			1
Diagnostic issues	Inadequate guidelines	Staff knowledge			1
Diagnostic issues	Patient/ caregiver knowledge	Working conditions			1
Documentation	Patient/ caregiver knowledge				1
Documentation	Critical thinking				1
Documentation	Continuity of care				1
Documentation	Service availability				1
Documentation	Failure to follow protocol	Staff knowledge			1
Documentation	Failure to follow protocol	Critical thinking			1
Documentation	Failure to follow protocol	Mistake			1
Documentation	Service availability	Continuity of care			1

Documentation	Mistakes	Continuity of care			1
Equipment	Patient/ caregiver geography				1
Equipment	Patient/ caregiver knowledge				1
Equipment	Patient health				1
Equipment	Mistakes				1
Equipment	Equipment/ medication factors				1
Equipment	Continuity of care				1
Equipment	Environmental				1
Equipment	Failure to follow protocol	Inadequate guidelines			1
Equipment	Continuity of care	Inadequate guidelines			1
Equipment	Patient age	Continuity of care			1
Equipment	Continuity of care	Working conditions			1
Equipment	Staff knowledge	Education and training			1
Equipment	Staff knowledge	Inadequate guidelines	Education and training		1
Failure to arrange follow up	Mistake	Continuity of care			1
Failure to identify at risk child	Critical thinking				1
Failure to identify at risk child	Failure to follow protocol	Critical thinking			1

Failure to identify at risk child	Inadequate guidelines	Education and training			1
Failure to identify at risk child	Failure to follow protocol	Staff knowledge	Education and training		1
Failure to refer when appropriate	Patient /caregiver language				1
Failure to refer when appropriate	Critical thinking				1
Failure to refer when appropriate	Education and training	Patient/ caregiver behaviour			1
Failure to refer when appropriate	Critical thinking	Patient/ caregiver behaviour			1
Failure to refer when appropriate	Failure to follow protocol	Patient age			1
Failure to refer when appropriate	Failure to follow protocol	Critical thinking			1
Failure to refer when appropriate	Continuity of care	Critical thinking			1
Failure to refer when appropriate	Failure to follow protocol	Mistake			1
Failure to refer when appropriate	Staff knowledge	Inadequate guidelines			1
Failure to refer when appropriate	Failure to follow protocol	Continuity of care			1
Failure to refer when appropriate	Service availability	Failure to follow protocol	Patient health		1
Failure to refer when appropriate	Critical thinking	Failure to follow	Staff knowle		1

		protocol	dge		
Inadequate discharge planning	Continuity of care				1
Inadequate discharge planning	Service availability				1
Inadequate discharge planning	Working conditions				1
Inadequate discharge planning	Continuity of care	Patient health			1
Inadequate discharge planning	Patient age	Inadequate guidelines			1
Inadequate discharge planning	Continuity of care	Inadequate guidelines			1
Inadequate discharge planning	Staff knowledge	Education and training			1
Inadequate discharge planning	Staff knowledge	Education and training	Working conditions		1
Inadequate examination	Patient/ caregiver geography				1
Inadequate examination	Continuity of care				1
Inadequate examination	Patient age	Failure to follow protocol	Staff knowledge		1
Inadequate history taking	Patient/ caregiver geography				1
Inadequate history taking	Service availability				1
Inadequate history taking	Environmental				1
Inadequate history taking	Patient age	Patient health			1
Inadequate history taking	Staff knowledge	Education and			1

		training			
Inadequate history taking	Failure to follow protocol	Working conditions	Patient / caregiver behaviour		1
Inadequate triaging	Patient health				1
Inadequate triaging	Patient/ caregiver knowledge				1
Inadequate triaging	Equipment/ medication factors				1
Inadequate triaging	Patient/ caregiver behaviour	Patient/ caregiver knowledge			1
Inadequate triaging	Failure to follow protocol	Patient/ caregiver behaviour			1
Inadequate triaging	Critical thinking	Patient health			1
Inadequate triaging	Critical thinking	Other staff factors			1
Inadequate triaging	Patient /caregiver language	Failure to follow protocol			1
Inadequate triaging	Patient health	Failure to follow protocol			1
Inadequate triaging	Failure to follow protocol	Failure to follow protocol			1
Inadequate triaging	Patient age	Failure to follow protocol			1
Inadequate triaging	Mistake	Failure to			1

		follow protocol			
Inadequate triaging	Critical thinking	Staff knowledge			1
Inadequate triaging	Patient/ caregiver behaviour	Critical thinking			1
Inadequate triaging	Mistake	Critical thinking			1
Inadequate triaging	Inadequate guidelines	Critical thinking			1
Inadequate triaging	Education and training	Critical thinking			1
Inadequate triaging	Service availability	Critical thinking			1
Inadequate triaging	Failure to follow protocol	Mistake			1
Inadequate triaging	Patient age	Inadequate guidelines			1
Inadequate triaging	Critical thinking	Inadequate guidelines			1
Inadequate triaging	Failure to follow protocol	Inadequate guidelines			1
Inadequate triaging	Inadequate guidelines	Continuity of care			1
Inadequate triaging	Continuity of care	Working conditions			1
Inadequate triaging	Failure to follow protocol	Service availability			1
Inadequate triaging	Inadequate guidelines	Service availability			1
Inadequate triaging	Failure to	Critical	Patient		1

	follow protocol	thinking	/ caregiver language		
Inadequate triaging	Failure to follow protocol	Critical thinking	Patient age		1
Inadequate triaging	Patient/ caregiver knowledge	Inadequate guidelines	Critical thinking		1
Inadequate triaging	Inadequate guidelines	Education and training	Critical thinking		1
Inadequate triaging	Failure to follow protocol	Patient age	Critical thinking	Education and training	1
Incorrect/ incomplete referral	Patient health				1
Incorrect/ incomplete referral	Critical thinking				1
Incorrect/ incomplete referral	Staff knowledge				1
Incorrect/ incomplete referral	Working conditions				1
Incorrect/ incomplete referral	Mistakes	Patient age			1
Incorrect/ incomplete referral	Continuity of care	Failure to follow protocol			1
Incorrect/ incomplete referral	Patient age	Mistake			1
Incorrect/ incomplete referral	Inadequate guidelines	Education and training			1
Incorrect/ incomplete referral	Patient/ caregiver behaviour	Patient health	Failure to follow protoco		1

			l		
Insufficient assessment (non-specific)	Critical thinking				1
Insufficient assessment (non-specific)	Mistake				1
Insufficient assessment (non-specific)	Continuity of care				1
Insufficient assessment (non-specific)	Education and training				1
Insufficient assessment (non-specific)	Continuity of care	Patient/ caregiver geography			1
Insufficient assessment (non-specific)	Failure to follow protocol	Patient age			1
Insufficient assessment (non-specific)	Working conditions	Working conditions			1
Insufficient assessment (non-specific)	Failure to follow protocol	Patient age	Patient / caregiver knowledge		1
Investigations	Patient health				1
Investigations	Patient/ caregiver behaviour				1
Investigations	Failure to follow protocol				1
Investigations	Mistakes				1
Investigations	Equipment/ medication factors				1
Investigations	Education and training				1
Investigations	Working conditions				1
Investigations	Mistake	Patient/ caregiver	Patient /		1

		knowledge	caregiver geography		
Medication administering	Inadequate guidelines				1
Medication administering	Continuity of care	Patient/ caregiver geography			1
Medication administering	Inadequate guidelines	Patient/ caregiver behaviour			1
Medication administering	Patient/ caregiver behaviour	Patient/ caregiver knowledge			1
Medication administering	Patient age	Patient/ caregiver knowledge			1
Medication administering	Patient/ caregiver behaviour	Patient/ caregiver knowledge			1
Medication administering	Mistakes	Patient age			1
Medication administering	Staff knowledge	Patient age			1
Medication administering	Patient/ caregiver knowledge	Patient age			1
Medication administering	Mistake	Failure to follow protocol			1
Medication administering	Mistake	Failure to follow protocol			1
Medication administering	Patient age	Mistake			1
Medication administering	Failure to	Failure to			1

	follow protocol	follow protocol			
Medication administering	Mistakes	Equipment/ medication factors			1
Medication administering	Mistake	Equipment/ medication factors			1
Medication administering	Inadequate guidelines	Continuity of care			1
Medication administering	Mistake	Working conditions			1
Medication administering	Mistakes	Working conditions			1
Medication administering	Mistake	Working conditions			1
Medication administering	Mistake	Working conditions			1
Medication administering	Working conditions	Working conditions			1
Medication administering	Inadequate guidelines	Education and training			1
Medication administering	Patient/ caregiver knowledge	Education and training			1
Medication administering	Patient age	Mistake	Staff knowledge		1
Medication administering	Patient health	Patient/ caregiver knowledge	Continuity of care		1
Medication administering	Mistake	Failure to follow protocol	Continuity of care		1
Medication administering	Failure to	Working	Working		1

	follow protocol	conditions	conditions		
Medication administering	Mistake	Working conditions	Working conditions		1
Medication administering	Mistakes	Failure to follow protocol	Working conditions		1
Medication administering	Patient age	Working conditions	Working conditions		1
Medication administering	Mistake	Working conditions	Education and training		1
Medication administering	Mistake	Patient health	Failure to follow protocol	Equipment/ medication	1
Medication administering	Continuity of care	Patient/ caregiver geography	Patient / caregiver knowledge	Inadequate protocols	1
Medication dispensing	Patient health				1
Medication dispensing	Patient/ caregiver behaviour				1
Medication dispensing	Failure to follow protocol	Patient health			1
Medication dispensing	Patient age	Failure to follow protocol			1
Medication dispensing	Working conditions	Staff knowledge			1
Medication dispensing	Equipment/	Mistake			1

	medication factors				
Medication dispensing	Staff knowledge	Equipment/ medication factors			1
Medication dispensing	Mistake	Service availability			1
Medication dispensing	Working conditions	Continuity of care			1
Medication dispensing	Mistakes	Working conditions			1
Medication dispensing	Staff knowledge	Working conditions			1
Medication dispensing	Failure to follow protocol	Education and training			1
Medication dispensing	Mistake	Education and training			1
Medication dispensing	Inadequate guidelines	Education and training			1
Medication dispensing	Patient age	Failure to follow protocol	Mistake		1
Medication dispensing	Mistake	Equipment/ medication factors	Mistake		1
Medication dispensing	Mistakes	Working conditions	Other staff factors		1
Medication dispensing	Mistake	Patient age	Equipment/ medication		1
Medication dispensing	Patient health	Mistake	Equipm		1

			ent/ medicat ion		
Medication dispensing	Mistakes	Patient age	Inadequ ate guidelin es		1
Medication dispensing	Equipment/ medication factors	Failure to follow protocol	Inadequ ate guidelin es		1
Medication dispensing	Failure to follow protocol	Staff knowledg e	Inadequ ate guidelin es		1
Medication dispensing	Mistake	Education and training	Working conditio ns		1
Medication dispensing	Patient age	Failure to follow protocol	Working conditio ns		1
Medication dispensing	Mistake	Failure to follow protocol	Working conditio ns		1
Medication dispensing	Mistake	Staff knowledg e	Working conditio ns		1
Medication dispensing	Mistake	Working conditions	Working conditio ns		1
Medication dispensing	Mistake	Mistake	Working conditio ns		1
Medication dispensing	Patient age	Staff knowledg e	Educati on and training		1
Medication dispensing	Failure to follow protocol	Equipmen t/ medicatio	Educati on and training		1

		n factors			
Medication dispensing	Inadequate guidelines	Continuity of care	Patient/ caregiver knowledge	Patient/ caregiver behaviour	1
Medication dispensing	Failure to follow protocol	Working conditions	Staff knowledge	Patient age	1
Medication dispensing	Mistake	Mistake	Working conditions	Working conditions	1
Medication dispensing	Mistakes	Patient age	Working conditions	Working conditions	1
Medication prescribing	Patient/ caregiver geography				1
Medication prescribing	Patient /caregiver language				1
Medication prescribing	Patient/ caregiver behaviour				1
Medication prescribing	Patient health				1
Medication prescribing	Failure to follow protocol				1
Medication prescribing	Patient/ caregiver geography	Patient/ caregiver knowledge			1
Medication prescribing	Patient/ caregiver behaviour	Patient/ caregiver knowledge			1

Medication prescribing	Mistake	Patient age			1
Medication prescribing	Patient/ caregiver behaviour	Failure to follow protocol			1
Medication prescribing	Mistake	Failure to follow protocol			1
Medication prescribing	Mistake	Staff knowledge			1
Medication prescribing	Patient health	Mistake			1
Medication prescribing	Patient age	Equipment/ medication factors			1
Medication prescribing	Failure to follow protocol	Inadequate guidelines			1
Medication prescribing	Continuity of care	Inadequate guidelines			1
Medication prescribing	Staff knowledge	Failure to follow protocol	Patient age		1
Medication prescribing	Mistakes	Staff knowledge	Patient age		1
Medication prescribing	Mistake	Staff knowledge	Patient age		1
Medication prescribing	Continuity of care	Inadequate guidelines	Patient age		1
Other	Patient/ caregiver geography				1
Other	Looked-after child				1

Other	Inadequate guidelines				1
Other	Continuity of care				1
Other	Working conditions				1
Other	Continuity of care	Patient/ caregiver geography			1
Other	Continuity of care	Patient health			1
Other	Inadequate guidelines	Looked-after child			1
Other	Continuity of care	Patient age			1
Other	Continuity of care	Failure to follow protocol			1
Other	Continuity of care	Inadequate guidelines			1
Other	Staff knowledge	Working conditions			1
Other	Failure to follow protocol	Staff knowledge	Education and training		1
Other administrative	Patient age				1
Other administrative	Failure to follow protocol				1
Other administrative	Mistake				1
Other administrative	Inadequate guidelines				1
Other diagnosis and assessment	Patient age	Staff knowledge			1
Other medication	Patient/ caregiver				1

	geography				
Other medication	Patient/ caregiver behaviour				1
Other medication	Mistakes				1
Other medication	Education and training				1
Other medication	Service availability	Patient/ caregiver behaviour			1
Other medication	Mistake	Staff knowledge			1
Other medication	Mistakes	Staff knowledge	Other staff factors		1
Other medication	Mistake	Staff knowledge	Education and training		1
Referral administrative issues	Mistake				1
Referral administrative issues	Service availability				1
Referral administrative issues	Failure to follow protocol	Patient health			1
Referral administrative issues	Continuity of care	Patient/ caregiver knowledge			1
Referral administrative issues	Continuity of care	Inadequate guidelines			1
Referral administrative issues	Education and training	Working conditions			1
Referral administrative issues	Looked-after child	Patient/ caregiver geography	Continuity of care		1
Transfer of patient information	Patient /caregiver				1

	language				
Transfer of patient information	Mistakes				1
Transfer of patient information	Working conditions				1
Transfer of patient information	Failure to follow protocol	Patient health			1
Transfer of patient information	Continuity of care	Patient health			1
Transfer of patient information	Failure to follow protocol	Critical thinking			1
Transfer of patient information	Mistakes	Equipment/ medication factors			1
Transfer of patient information	Looked-after child	Continuity of care			1
Transfer of patient information	Continuity of care	Continuity of care			1
Transfer of patient information	Failure to follow protocol	Continuity of care			1
Transfer of patient information	Working conditions	Working conditions			1
Transfer of patient information	Continuity of care	Education and training			1
Transfer of patient information	Failure to follow protocol	Failure to follow protocol	Working conditions		1
Transport/ transfer of patients	Patient/ caregiver behaviour				1
Transport/ transfer of patients	Staff knowledge				1
Transport/ transfer of patients	Inadequate guidelines				1
Transport/ transfer of patients	Environmental				1

Transport/ transfer of patients	Patient health	Staff knowledge			1
Transport/ transfer of patients	Service availability	Working conditions			1
Transport/ transfer of patients	Failure to follow protocol	Education and training			1
Transport/ transfer of patients	Failure to follow protocol	Service availability	Continuity of care		1
Transport/ transfer of patients	Service availability	Working conditions	Working conditions		1
Transport/ transfer of patients	Staff knowledge	Patient age	Inadequate guidelines	Education and training	1
Treatment and procedures	Patient /caregiver language				1
Treatment and procedures	Critical thinking	Patient health			1
Treatment and procedures	Continuity of care	Patient/ caregiver knowledge			1
Treatment and procedures	Inadequate guidelines	Staff knowledge			1
Treatment and procedures	Environmental	Inadequate guidelines			1
Treatment and procedures	Education and training	Working conditions			1
Treatment and procedures	Patient health	Working conditions			1
Treatment and procedures	Failure to	Working			1

	follow protocol	conditions			
Treatment and procedures	Equipment/ medication factors	Working conditions			1
Treatment and procedures	Working conditions	Working conditions			1
Treatment and procedures	Mistake	Working conditions			1
Treatment and procedures	Patient age	Education and training			1
Treatment and procedures	Equipment/ medication factors	Education and training			1
Treatment and procedures	Continuity of care	Looked-after child	Patient / caregiver geography		1
Treatment and procedures	Continuity of care	Failure to follow protocol	Patient health		1
Treatment and procedures	Mistake	Working conditions	Working conditions		1
Treatment and procedures	Failure to follow protocol	Working conditions	Education and training		1
Treatment and procedures	Patient age	Patient/ caregiver geography	Education and training	Continuity of care	1
Treatment decisions	Patient age				1
Treatment decisions	Staff knowledge				1
Treatment decisions	Mistake				1
Treatment decisions	Failure to follow	Failure to follow			1

	protocol	protocol			
Treatment decisions	Patient age	Inadequate guidelines			1
Treatment decisions	Patient/ caregiver behaviour	Inadequate guidelines			1
Treatment decisions	Staff knowledge	Inadequate guidelines			1
Treatment decisions	Patient age	Continuity of care			1
Treatment decisions	Inadequate guidelines	Continuity of care			1
Treatment decisions	Staff knowledge	Continuity of care			1
Treatment decisions	Failure to follow protocol	Staff knowledge	Patient age		1
Treatment decisions	Continuity of care	Inadequate guidelines	Working conditions		1
Grand Total					**2191**

3.5 Medline ovid search strategy for literature review

1. (Vaccin* adj3 error*).mp.
2. (Vaccin* adj3 program* error*).mp
3. (Immuni* adj3 error*).mp.
4. Immuni* safety.mp.
5. Vaccinat* safety.mp.
6. Medicat* error*.mp.
7. (triag* adj3 error*).
8. (triag* adj3 incident*).mp.
9. (clinical assessment adj3 error*).mp.
10. (patient assessment adj3 error*).mp.
11. (assessment adj3 safety incident).mp.
12. "diagnos* error*".mp.
13. diagnos* incident*.mp.
14. (patient* record* adj3 error*).mp.
15. (medical record* adj3 error*).mp.
16. (referral* adj3 error*).mp.
17. (referral* adj3 safety).mp.
18. (referral* adj3 incident*).mp.
19. (communicat* adj3 error*).mp.
20. (communicat* adj3 failure).mp.
21. communicat* incident*.mp.
22. (communicat* adj3 patient* safety).mp.
23. (1-22)/or
24. exp Child Health Services/ or exp Child, Preschool/ or exp Child/
25. Paediatri*.mp.
26. Pediatri*.mp.
27. exp Adolescent/ or exp Adolescent Health Services/
28. exp Infant/
29. exp Infant, Newborn/
30. (23-28)/or
31. (Improve* adj3 interven*).mp.
32. exp Quality Improvement/
33. (error* adj3 prevent*).mp.
34. (safety adj3 improve*).mp.
35. (error* adj3 reduc*).mp.
36. (31-35)/or
37. Animals/
38. animal stud*.mp.
39. 37 or 38
40. 23 AND 30 AND 36
41. 40 NOT 39