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PRIMARY CARE MEDICATION SAFETY INCIDENTS REPORTED TO THE NATIONAL REPORTING AND LEARNING SYSTEM (NRLS)

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Thesis submitted to the University Of Nottingham for the degree of Doctor of Philosophy

DECEMBER 2020

Abstract

Background: Medication-related safety incidents are a significant patient safety issue in healthcare. Despite more than 90% of UK patient healthcare interactions occurring in primary care, there is limited research to understand medication-related safety incidents in this setting. In 2003, the National Reporting and Learning System (NRLS) was created to collate patient safety reports in order to facilitate understanding and learning from incidents across England and Wales. The NRLS is a central reporting system for incidents occurring in healthcare settings and is the most comprehensive incident reporting system in the world. Medication safety incident reports in the NRLS that originate solely from primary care have never been systematically analysed.

This thesis aims to describe the nature, range and severity of primary care-based medication incidents reported to the NRLS between 2003 and 2013 in order to identify priority areas for interventions and to make recommendations for improvement.

Methods: Quantitative analysis methods, together with some qualitative analysis principles were utilised. A structured process for coding the free-text descriptions of medication incident reports and an exploratory descriptive analysis of the data was performed, followed by thematic analysis. Existing quality improvement interventions that could address the areas were additionally identified and informed the recommendations made.

Findings: A total of 83869 records relating to medication incidents in primary care were identified in the NRLS. All incidents classified by the reporter as having an outcome of death, severe harm and moderate harm were reviewed (n = 2556); additionally, 1500 reports resulting in mild harm and 1500 reports resulting in no harm yielded a total of 5556 reports that were reviewed in this study. After excluding non-valid records, 5017 incident reports were identified and analysed. Dispensing incidents were the most frequently reported medication safety issue (n = 3380, 67.4%); followed by administration incidents (n = 760, 15.1%); prescribing and clinical treatment decision incidents (n = 431, 8.6%); adverse drug reactions (n = 220, 4.4%); monitoring incidents (n = 36, 0.7%); and, “other” incidents (n = 190, 3.8%). The majority of the incidents (in which the severity of harm was clear) had a no harm or mild harm outcome (n = 2014/2664, 75%), followed by moderate harm (n = 573/2664, 22%), severe harm (n = 45/2664, 2%) and death (n = 32/2664, 1%).

Antidepressants (n = 477) were the most frequently reported medicines to be involved in the incidents overall, followed by opioid analgesics (n = 429), antiepileptics (n = 398), insulins (n = 373) and antithrombotic agents (n = 329).

Priority areas identified for improving medication safety in primary care included active failures due to insufficient protocols, workforce and equipment issues, inadequate procedures for implementing medication changes at transfer of care between settings, need for improved staff education and training, medication similarity (look-alike and sound-

alike) oversights, lack of adequate or implemented protocols, suboptimal working environment, inadequate administrative practices and insufficient communication of medicines information to patients. Suggested recommendations for improvement included various IT improvements, such as standardising patient electronic healthcare records across all care settings and using automation to allocate staff to a place of work.

Conclusions and recommendations: This study has identified priority areas and suggested important recommendations for interventions to improve medication safety. Priority areas included active failures due to insufficient protocols, workforce and equipment; inadequate procedures for implementing medication changes at transfer of care between settings; need for improved staff education and training; medication similarity (look-alike and sound-alike) oversights; lack of adequate or implemented protocols; suboptimal working environment; inadequate administrative practices; and insufficient communication of medicines information to patients. Recommendations included various IT improvements such as standardising patients' electronic healthcare records across all care settings and using automation to allocate staff to a place of work; direct personalised feedback to healthcare professionals; creation of distraction free zone in a dispensary; and providing medication cards to patients in easy to understand language. Further research on these recommendations should be carried out in order to develop, implement and evaluate them in clinical practice.

Publications and conference presentations

MUHAMMAD, K.W., AVERY, A.J., BOYD, M.J. and CARSON-STEVENS, A., 2016. Medication safety incidents reported to the National Reporting and Learning System in England and Wales: a review of primary care incidents classified as severe harm and death International Journal of Pharmacy Practice. 24 (Supplement 3), 0108

Abstract presented as a poster presentation at the Royal Pharmaceutical Society (RPS) annual conference in Birmingham, 4-5 September 2016.

MUHAMMAD, K.W., CARSON-STEVENS, A., AVERY, A.J. and BOYD, M.J., 2017. Community pharmacy medication safety incidents resulting in significant harm reported to the National Reporting and Learning System (NRLS). International Journal of Pharmacy Practice. 25 (Supplement 1), pp. 41-42

Abstract presented as a poster presentation at the Health Services Research and Pharmacy Practice (HSRPP) annual conference in Nottingham, 10-11 April 2017.

MUHAMMAD, K.W., CARSON-STEVENS, A., EVANS, H.P., AVERY, A.J. and BOYD, M.J., 2017. Medication prescribing safety incidents in primary care. Pharmacoepidemiology & Drug Safety. 26 (Supplement 1), pp. 13

Abstract presented as a poster presentation at the Prescribing and Research in Medicines Management (PRIMM) annual scientific meeting in London, 28 January 2017.

MUHAMMAD, K.W., CARSON-STEVENS, A., AVERY, A.J., EVANS, H.P. and BOYD, M.J., 2017. Medication-related safety incidents causing death in primary care: a mixed methods study. **(Safer Primary care conference in Manchester, 7-8 March 2017)**

Abstract presented as a poster presentation at the safer primary care conference in Manchester, 7-8 March 2017.

MUHAMMAD, K.W., CARSON-STEVENS, A., AVERY, A.J. and BOYD, M.J., 2018. What medication errors occur in community pharmacies and why do they occur? A national analysis of patient safety incidents. Research in Social and Administrative Pharmacy. 14(8): pp. e37

Abstract presented as an oral presentation at the International Social Pharmacy Workshop in Leuven, Belgium. 23-26 July 2018.

Acknowledgements

First of all, I would like to thank Allah (SWA) for giving me the opportunity to achieve a postgraduate doctoral degree at a prestigious University. I would like to express my deepest gratitude to my parents, Muhammad S. Wada (Baba) and Balaraba M. Wada (Hajiya) for their continued support, prayers and making sure I always had everything I needed. Especially to my father for financially supporting my decision to pursue this PhD study. Thank you Baba, for dedicating yourself to making sure we had the best of education, I will be forever grateful. To my beautiful wife Asma'u, you may not have started this journey with me, but your support and understanding made it easier to get to the finish line, thank you mon amour. Thank you to the rest of my family and friends for their unwavering love and prayers which has undoubtedly helped.

I would like to thank my supervisors: Dr Matthew Boyd, Professor Tony Avery and Dr Andy Carson-Stevens for their patience, detailed feedback and guidance over the course of my PhD study. Thank you Professor Avery for sponsoring some of my conferences and double coding which was expertly carried out by the excellent Gill Gookey.

I would also like to thank all my fellow PhD colleagues and staff within the division of Pharmacy Practice and Policy for their support and friendship throughout my time at the division. More thanks to my PISA colleagues at Cardiff University especially Huw Williams, Huw Evans

and Alison Cooper who have also provided me with support during my studies.

Finally I would like to give a special thank you to my squad who are always there whenever I need them, keeping me motivated and doing my proof reading, amongst other things. To Yasmin Karsan, Funmi Agbesanwa, Suha Alharbi, Shaz Ahmed and Franzi Stoeckel, thank you! A special shout out to Lydia Tutt for all the help, moral support and encouragements received. ALHAMDULILLAH

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Abbreviations

ADR	**A**dverse **D**rug **R**eaction
ATC	**A**natomical **T**herapeutic **C**hemical
CBSHA	**C**ommissioning **B**oard **S**pecial **H**ealth **A**uthority
CDS	**C**linical **D**ecision **S**upport
CPOE	**C**omputerised **P**rovider **O**rder **E**ntry
DH	**D**epartment of **H**ealth
EU	**E**uropean **U**nion
EMA	**E**uropean **M**edicines **A**gency
GMC	**G**eneral **M**edical **C**ouncil
GP	**G**eneral **P**ractitioner
GRADE	**G**rading of **R**ecommendations, **A**ssessment, **D**evelopment and **E**valuations
HCPs	**H**ealth **C**are **P**rofessional**s**
INR	**I**nternational **N**ormalised **R**atio
IT	**I**nformation **T**echnology
MAR	**M**edicines **A**dministration **R**ecord
MCCA	**M**ulti **C**ompartment **C**ompliance **A**id
MHRA	**M**edicines and **H**ealthcare products **R**egulatory **A**gency

NCC MERP	**N**ational **C**oordinating **C**ouncil for **M**edication **E**rror **R**eporting and **P**revention
NHS	**N**ational **H**ealth **S**ervice
NIHR	**N**ational **I**nstitute for **H**ealth **R**esearch
NPSA	**N**ational **P**atient **S**afety **A**gency
NRLS	**N**ational **R**eporting and **L**earning **S**ystem
OOH	**O**ut **O**f **H**ours
OWAM	An **O**rganisation **W**ith **A** **M**emory
PISA	**P**rimary care pat**I**ent **SA**fety
PMR	**P**atient **M**edication **R**ecord
RCTs	**R**andomised **C**ontrolled **T**rial**s**
UK	**U**nited **K**ingdom
USA	**U**nited **S**tates of **A**merica

Glossary

Adverse drug event (ADE) is a medication-related adverse event. Also, harm resulting from medical intervention related to a drug.

Adverse drug reaction (ADR) is an unexpected harm arising from a justified treatment with a drug.

Contributory factors are the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident.

Error is defined as a failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase.

Harmful incident (adverse event) is an incident that results in harm to a patient.

Healthcare-associated harm is harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.

Incident type is a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features and is a “parent” category under which many concepts may be grouped.

Intervention is an action or actions intended to interrupt the course of events that are in progress, so as to favourably modify them.

Medication error is any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible.

Medication safety is defined as freedom from accidental injury during the course of medication use; activities to avoid, prevent or correct adverse drug events which may result from the use of medications.

Medication safety incident is an event or circumstance relating to medicines that could have resulted, or did result, in unnecessary harm to a patient.

Near miss is an incident which did not reach the patient e.g. wrong medication being dispensed to a patient in a bag, but staff identified this before patient collected their medication bag.

No harm incident is an incident in which an event reached a patient but no discernible harm resulted.

Patient is a person who is a recipient of healthcare.

Patient outcome is the impact upon a patient which is wholly or partially attributed to an incident. Patient outcomes can be classified according to the type of harm, the degree of harm (none, low, moderate, severe and death), and any social and/or economic impact.

Patient safety is defined as the reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and

the context in which care was delivered weighed against the risk of non-treatment or other treatment.

Patient safety incident (or incident) is any unintended or unexpected event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

Primary care is the first point of contact in the healthcare system for members of the public seeking access to healthcare; it includes general practice, community pharmacy, dental and optometry.

Taxonomy is a system for naming and organising items into groups that share similar characteristics.

Chapter 1 Introduction and Background

1.1 Introduction

Medicines are at the forefront of therapeutic interventions offered by healthcare services in the UK and throughout the world. Since the early 2000s, patient safety has been a key public health priority worldwide following high profile failures during healthcare delivery to patients and the acknowledgement of human errors and system failures [1-4]. Furthermore, a large proportion of patient safety incidents are related to medications. Although the majority of these do not result in actual harm, some are fatal [5]. To tackle these issues, various patient safety initiatives - such as patient safety incident reporting and learning systems have been launched. Despite the progress in this area, most patient safety research to date has been conducted within the hospital setting [6-14]. Since more than 90% of healthcare services in UK are provided in primary care [15, 16], further research in this setting is important. Primary care refers to the first point of contact in the healthcare system for members of the public seeking access to healthcare; it includes general practice, community pharmacy, dentistry and optometry [17].

The global spending on medicines has steadily been on the increase with their role in improving people's health across the globe becoming increasingly significant. The global spend on medicines was approximately $1.1 trillion in 2016 and is expected to reach about $1.5

trillion by 2021 [18]. The United States of America (USA), United Kingdom (UK) and “pharmerging” countries (low income countries with high pharmaceutical growth) mostly China, Brazil and India lead the increase on spending [18]. In England, 1.11 billion prescription items were dispensed in 2017 (an increase of 0.2% from 2016 and 28% since 2007) whilst 80.4 million items were dispensed in Wales in the same year (an increase of 0.2% from 2016 and about 25% since 2007) costing the National Health Service (NHS) in England and Wales approximately £9.2 billion and £578.1 million respectively [19, 20]. Additionally, there has also been an increase in polypharmacy; for example the number of patients receiving five or more drugs in Scotland increased approximately two fold between 1995 and 2010 and the number of patients taking more than 10 medicines tripled [21]. This is compounded by the increasingly ageing population which often has the highest percentage of medicines prescribed due to increasing medical needs with age [21]. Similar trends were also shown in Sweden where there was a 15.7% increase in prescribing of 10 or more medicines in three years particularly in the elderly [22].

Increase in medication use increases the likelihood of medication-related safety incidents, which in turn increases the risk of harm to patients [23]. In England, a report on the prevalence and economic burden of medication errors in the NHS reported that avoidable Adverse Drug Reactions (ADRs) costs the NHS an estimated £98.5 million per year, causing 712 deaths nationally [24]. However, these estimates may not be an accurate representation because they have been

calculated on the assumption that avoidable ADRs are consistent with medication errors. Furthermore, studies involving one to two centres were used and extrapolated to the whole NHS. The assumed generalisation and the lack of consideration for longer term impact adds to the uncertainty around the estimated figures and suggest the figures could be higher or lower [24].

Whilst patient safety incident research in primary care setting is limited as discussed, factors associated with medication incidents occurring in primary care may differ from those in secondary care. For example, medication administration in primary care is largely performed outside the more controlled environment of a hospital setting by a non-healthcare professional; therefore, factors associated with medication administration incidents in this setting are likely to be different to that of secondary care settings. These differences highlight the need for further research into medication incidents in primary care, in order to develop solutions for the types of risks specific to this setting. One of the aims of patient safety research and improvement is to use retrospective or prospective analysis to identify and mitigate safety hazards at the microscopic level [25, 26].

In this chapter, I will review the background literature on medication-related patient safety in primary care. I will initially review some working definitions and describe the definitions used in this thesis. I will then provide an overview of relevant healthcare policy and the medication-related processes (including prescribing, dispensing, and medication administration) in primary care in the UK. Following this, I will go on to

explore the causes, classification and epidemiology of medication safety incidents within this setting and investigate existing interventions to reduce these incidents. Additionally, I will describe the various safety incident reporting systems - with particular emphasis on the National Reporting and Learning System (NRLS) used in England and Wales. Finally, I will summarise what has been learnt from patient safety incidents to date and outline the aims and objectives of my research.

When conducting the literature review for this study, literature searches were carried out using Web of Science, ScienceDirect and PubMed databases, which also incorporated other databases such as Medline and EMBASE. Search terms used included ‘primary care’, ‘patient or medication safety’, ‘medication incident(s) or error(s)’, ‘prescribing incident(s) or error(s)’, ‘dispensing incident(s) or error(s)’, ‘administration incident(s) or error(s)’ and ‘monitoring incident(s) or error(s)’, for example. Searches were conducted at the beginning of the study and updated periodically over the course of the study. Articles were screened to remove duplicates, followed by reading of the titles, abstracts and then the full body of the articles in order to include or exclude the identified literature from the review.

As the study developed, further literature searches were carried out to identify intervention studies to contextualise the findings (more information in Chapter 2) with respect to the study objectives. These searches were conducted using the same search and screening strategies described above with the addition of further key terms. These

include ‘intervention’, ‘improvement’, ‘improve’, ‘improving’, ‘reduce’, ‘quality’ and ‘reducing’.

1.2 Patient safety terms and definitions

1.2.1 Medication error definitions

There is a general lack of consensus regarding the definition of ‘medication error’ in the literature. Multiple definitions for ‘medication error’ have been reported to be used in medication error studies in the conceptual framework for the International Classification for Patient Safety (ICPS) published by WHO [27]. This demonstrate the level of heterogeneity of definitions and makes it challenging for studies to be compared with each other for the advancement of this field. Previous studies have used a variety of statements to define the term, as demonstrated in the systematic literature review conducted by Lisby and colleagues. Their findings highlighted that out of 203 relevant studies, 45 used a generic definition of ‘medication error’. Amongst these, 26 differed in wording and/or content [28]. This lack of consistency in defining medication errors likely affects the quality and consistency of medication error studies; this could be improved by standardising a clear-cut definition for the term, alongside other patient safety terms. Reducing variation in the definitions used in both clinical practice and research is important in helping researchers provide an accurate representation of medication errors in their studies, which in turn, will support in improving patient safety.

Lisby and colleagues then went on to develop and test a clear-cut definition for ‘medication error’ using Delphi process. They used information derived from their systematic literature review on ‘medication error’ definitions to come up with five representative definitions which were then put through a 2-stage Delphi process. The panel for the process consisted of physicians, pharmacists and nurses. The consensus definition was *“An error in the stages of the medication process – ordering, dispensing, administering and monitoring the effect – causing harm or implying a risk of harming the patient”* [29].

Another study by Ferner and Aronson reviewed and discussed potential problems with different definitions adopted in the literature, before proposing a new definition [30]. One of the definitions scrutinised was that of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP); an independent body comprising of 27 national organisations across the world. They provided a very broad and comprehensive definition, clearly showing the different levels at which errors could be avoidable*: "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use"* [31].

As Ferner and Aronson acknowledged, this definition is flawed in that it suggests that any preventable event leading to harm from a medication is an error. They pointed out that events could be preventable both when they result from an error, and when they are a consequence of a decision from careful consideration that causes unavoidable harm to patients. After reviewing many definitions used in the literature, the authors proposed a more succinct definition; eliminating the additional detail from the NCC MERP definition; *"A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient"* [30]. Whilst the authors cited several examples to support the use of their definition in clinical practice, it could be argued that their use of the word "treatment" may be construed as any medical care not necessarily involving medications.

The European Medicines Agency (EMA) uses a similar definition to the one proposed above, with the addition of two words; they define medication error as *"an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient"* [32]. However, in this definition, the word 'drug' has been inserted before 'treatment'; this addresses the ambiguity concern with the definition proposed by Ferner and Aronson.

Meanwhile, the National Patient Safety Association (NPSA) were more explicit with their definition; choosing to include a description of the points in the medication process where it could apply - similar to the definition proposed by Lisby and colleagues [29] but with more depth. They defined medication error as "*any incident where there has been*

an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible" [33]. This definition was adopted in this thesis because it establishes the scope of the medication process, identifying the various stages that need to be considered in medication safety studies. It is additionally advantageous since it refers to medication errors as 'incidents' - this is now the preferred term in patient safety research, which is starting to move away from the use of the term 'error'. This is to promote a no blame culture because 'error' could be associated with blame instead of the focus being on ways to prevent future occurrence.

Medication errors associated with the processes described in the NPSA definition have been further sub-defined in various studies (the medication use process is described further in section 1.4.1). These most commonly include prescribing, dispensing, administration and monitoring errors.

In one UK study of note, 'prescribing error' was given the definition of: *"a clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (i) reduction in the probability of treatment being timely and effective or (ii) increase in the risk of harm when compared with generally accepted practice"* [34]. This definition was developed using a two stage Delphi technique that used 34 healthcare professionals as judges which included doctors, pharmacist and nurses. Different examples of scenarios that can either be included or excluded

as a prescribing error accompanied the definition. Using different types of healthcare professionals as part of the expert panel provided the opportunity to incorporate ideas from different parts of the healthcare sector into the definition. This is now the most commonly adopted definition of prescribing errors used in current literature since it was developed [14]. However, the use of the term “clinically meaningful” in the definition suggests that only errors with clinical outcomes are of interest. It could be argued that errors with no clinical outcomes are also important to detect and analyse because they could still identify areas of weakness, which could produce further errors with clinical significance in the future. Furthermore, “generally accepted practice” may not always mean good practice which is of significance in patient safety. A defined standard achievable practice should be aimed for.

‘Dispensing error’ is another type of medication error that is very common. It was defined by Franklin and O’Grady following another Delphi technique as: *“any unintended deviation from an interpretable written prescription or medication order. Both content and labelling errors are included. Any unintended deviation from professional or regulatory references, or guidelines affecting dispensing procedures, is also considered a dispensing error”* [35]. This was adopted from a previous definition for a UK hospital setting study. It was altered to bear more relevance to the primary care setting and specifically, to describe the nature of dispensing errors in UK community pharmacies [36]. Although comprehensive, this definition - and the one it was adopted from - were both developed to be used in specific care settings; thereby

limiting their scope. Furthermore, this definition does not include errors made during the dispensing of medications not resulting from a written prescription or medication order; such as during recommendation and sale of over the counter medicines.

'Administration error' is another subtype of medication error and was defined in both a UK and a USA hospital study as *"…any dose administered (or omitted) that deviates from that prescribed; these can originate in the ordering or dispensing of medication as well as in administration itself"* [37, 38]. This definition was adopted and modified in a more recent study of UK care homes [39]. Barber and colleagues defined it in their prospective study as *"any deviation between the medication prescribed and that administered".* This simplified definition, although broader, could be used to identify administration errors irrespective of the care setting. Furthermore, it encompasses all medication administration; whether administered by a third party or self-administered.

'Monitoring error' was defined by Alldred and colleagues following a validated study examining the use of the definition in the UK care home setting: *"when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the frequency listed in the criteria for each medicine, with tolerance of +50%. This means, for example, that if a medicines requires liver function tests at 3-monthly intervals, an error would be classed if an error has not been conducted within 18 weeks"* [40]. A list of monitoring criteria for some medicines

was given in the study and the definition excluded cases where a patient would not consent to tests being carried out. This definition was developed for use in primary care; most of the criteria developed, related to medicines commonly found in primary care. Although the list of medicines was not exhaustive, the scope of the definition is limited. Moreover, the use of the phrase ‘acceptable in routine general practice’ in the definition could be regarded as ambiguous.

The definitions described above have been mostly developed specifically to help answer the research question(s) being asked in their various respective studies. There is, however, a need for a single definition for each of these terms to be developed, that is all-inclusive in spite of care settings or the research questions asked. This will aid the comparison of results between studies and the aggregation of data nationally to improve the safety of medication use. It is worth noting that many other terms used in the literature may also identify a medication error - such as adverse drug events, medication incidents, inappropriate prescribing and so on; these and other terms used in patient safety research are defined below.

1.2.2 Other terms and definitions

In this thesis, terms and definitions set out by the WHO through the conceptual framework for the ICPS [27] and NPSA [41] were adopted where applicable, unless otherwise stated. ICPS was commissioned by WHO to help standardise the definitions of the main terminologies used in patient safety research. The use of a variety of terms and definitions in patient safety makes it difficult to compare results among studies as

demonstrated in section 1.2.1 above. A literature review about the terms used in medication safety also demonstrate this [42]. Standardisation of terms and definitions is needed for the progression of patient safety research. In light of the above, the following terms and definitions (in alphabetical order) were used in this thesis.

Adverse drug event (ADE) is a medication-related adverse event. Also, harm resulting from medical intervention related to a drug [27].

Adverse drug reaction (ADR) is an unexpected harm arising from a justified drug treatment [27].

Contributory factors are the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident [27].

Error is defined as a failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase [27].

Harmful incident (adverse event) is an incident that results in harm to a patient [27].

Healthcare-associated harm is harm arising from, or associated with, plans or actions taken during the provision of healthcare, rather than an underlying disease or injury [27].

Incident type is a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features and

is a “parent” category under which many concepts may be grouped [27].

Intervention is an action or actions intended to interrupt the course of events that are in progress, so as to favourably modify them [27].

Medication error is any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible [41].

Medication safety is defined as freedom from accidental injury during the course of medication use; activities to avoid, prevent or correct adverse drug events which may result from the use of medications [27].

Medication safety incident is an event or circumstance relating to medicines that could have resulted, or did result, in unnecessary harm to a patient [27].

Near miss is an incident which did not reach the patient e.g. wrong medication being dispensed to a patient in a bag, but staff identified this before patient collected their medication bag [27].

No harm incident is an incident in which an event reached a patient but no discernible harm resulted [27].

Patient is a person who is a recipient of healthcare [27].

Patient outcome is the impact upon a patient which is wholly or partially attributed to an incident. Patient outcomes can be classified according to the type of harm, the degree of harm (none, low,

moderate, severe and death), and any social and/or economic impact [27].

Patient safety is the reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment [27].

Patient safety incident (or incident) is any unintended or unexpected event or circumstance which could have resulted, or did result, in unnecessary harm to a patient [27].

Primary care is the first point of contact in the healthcare system for members of the public seeking access to healthcare; it includes general practice, community pharmacy, dental and optometry [41].

Taxonomy is a system for naming and organising items into groups that share similar characteristics [27].

1.3 Healthcare policies underpinning patient and medication safety

Improving patient safety in healthcare delivery has become a global issue. The various policy documents on patient safety, published globally and here in the UK, are outlined hence forth.

In 1999, the Institute of Medicine in the United States of America (USA) released the report *To Err is Human*, which generated greater interest in patient safety [2]. This outlined the costs of errors in healthcare

delivery and highlighted the importance of improving patient safety, particularly with respect to medication. The report sought to address the lack of action against unsafe acts and preventable errors caused by healthcare professionals. Instead, it suggested a comprehensive approach to improving patient safety, including identifying and learning from errors through immediate and mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making the system safer for patients [2].

In 2000 the Department of Health published, *An Organisation With A Memory (OWAM),* which identified the need to prioritise improvements to patient safety in the NHS [1]. OWAM was commissioned following several high profile failings in the standards of NHS care during the 1990s, such as the widely publicised deaths of children following heart surgery at Bristol Royal Infirmary [43] and concerns about the conduct and competence of individual doctors [44]. OWAM acknowledged that the NHS does not always learn effectively from serious incidents in which patient harm or very poor outcomes of care result from avoidable failures in the system. These failures also contribute directly to increased costs for the NHS. While the report drew on experiences of adverse incidents almost entirely from secondary care - due to lack of knowledge of such incidents in primary care - its core recommendations were intended to encompass primary care. A total of 10 recommendations were generated from the report [1]:

1. Introduction of a mandatory reporting scheme for adverse healthcare events and specified near misses

2. Introduction of a scheme for confidential reporting by staff of adverse events and near misses
3. To encourage reporting and questioning culture in the NHS
4. Introduction of a single overall system for analysing and disseminating lessons from adverse healthcare events and near misses
5. To make better use of existing sources of information on adverse events
6. To improve the quality and relevance of NHS adverse event investigations and enquiries
7. To undertake a programme of basic research into adverse healthcare events in the NHS
8. To make full use of new NHS information systems to help staff access learning from adverse healthcare events and near misses
9. Act to ensure that important lessons are implemented quickly and consistently
10. To identify and address specific categories of serious recurring adverse healthcare events

Following the OWAM report, *Building a safer NHS for patients: Implementing an organisation with a memory* was published by the DH in 2001 [45]. This set out the Government's plans to promote patient safety through the implementation of the recommendations from the *OWAM* report. This, in turn, led to the creation of the National Patient Safety Agency (NPSA) in 2001 and the introduction of the National

Reporting and Learning System (NRLS) in 2003. The NPSA was established as a special health authority within the NHS to improve patient safety – one of its responsibilities was to create and maintain the NRLS [45].The NRLS was developed to be a national facility for healthcare professionals to self-report patient safety incidents in an open culture to then aid the development and implementation of solutions against preventable incidents.

The European Union (EU) also produced its own legislation in 2001 [46] (amended further in 2010 and 2012) on pharmacovigilance around the same time as the DH was producing its report on implementing the *OWAM* report. This had an influence on UK policy that was adopted such as the obligation to report any suspected adverse drug reactions to the EU database for adverse reactions. The EU legislation also required the need for EU member states to operate a pharmacovigilance system that would enable the mandatory collection and reporting of data on medication safety errors or incidents [32]. As a member of the EU, a provision was made for EU legislation to become law in the UK. Therefore, the 2001 EU legislation sets the foundation and the NRLS in England and Wales met this requirement, whilst the later legislations in 2010 and 2012 subsequently mandated reporting.

Building a safer NHS for patients: Implementing an organisation with a memory [45] also described the steps to be taken to establish the NRLS. This included creating agreed definitions for reporting incidents within the NHS, ultimately moving to agreed international standards. The NRLS collects information on patient safety incidents before being

analysed in order to learn lessons and disseminate back into practice. Section 1.7.2 provides detailed insight into the operation of the NRLS.

Finally, the report suggested future research strategies to be adopted in this emergent field. Experiences from research in other fields such as aviation, engineering and disaster prevention were used to help inform the future patient safety research questions and direction. Recommendations included understanding the factors which cause harm and assessing the efficacy of intervention strategies; developing and designing reporting systems to help ensure their good use; learning lessons and disseminating them [45].

In 2002, the World Health Organization (WHO), through World Health Assembly Resolution WHA55.18 recognised the need to promote patient safety as a fundamental principle of all healthcare systems [47]. This resulted from WHO's report *quality of care: patient safety* [3]; which identified the challenges to patient care such as human suffering and financial implications. The report built on the seminal reports described above to bring about awareness on the extent of the problem of patient safety and the lack of existing structure to tackle the problem.

Subsequently in the UK, the newly formed NPSA published an evidence based document in 2004 outlining seven steps to patient safety [41]. This introduced a checklist to ensure that the care provided to patients is as safe as possible: (1) Build a safety culture; (2) Lead and support your staff; (3) Integrate your risk management activity; (4) Promote reporting; (5) Involve and communicate with patients and the

public; (6) Learn and share safety lessons; and (7) Implement solutions to prevent harm [41].

World alliance for patient safety: WHO draft guidelines for adverse reporting and learning systems was subsequently published in 2005 [48]. This was a response to WHO's resolution WHA55.18, which identified patient safety as a challenge to patient care that needs to be addressed by both WHO's member states and the Director-General. This report contained guidelines to support member-countries to develop and improve their reporting and learning systems, which are fundamental to improving patient safety.

WHO later published *Conceptual Framework for the International Classification for Patient Safety (ICPS)* in 2009 [27]. As described in Section 1.2, this document was developed to standardise patient safety concepts and definitions across different systems internationally. Thereby, reducing the heterogeneity of patient safety research and promoting comparisons, analysis and interpretation of information to improve patient care across the world. The conceptual framework for the ICPS comprised of 10 high level classes for categorising patient safety events: (1) incident type; (2) patient outcomes; (3) patient characteristics; (4) incident characteristics; (5) contributing factors/hazards; (6) organisational outcomes; (7) detection; (8) mitigating factors; (9) ameliorating actions; and (10) actions taken to reduce risk. This aimed to provide a comprehensive understanding of the domain of patient safety through a cycle of continuous learning and improvement [27].

In 2007, the NPSA published the first of two documents on medication safety: *Safety in doses: improving the use of medicines in the NHS* [49]. In this first document, medication safety incidents (i.e.: the second most common type of patient safety incident) reported to the newly-created NRLS between January 2005 and June 2006 were analysed and reported so that learning could be achieved. This led to the identification of risks relating to medication safety, which informed the development of the Safe Medication Practice Work Programme for 2007 to 2008, the details of which are laid out in the document. The aim of the programme was to improve the safe use of medicines in the NHS and consisted of five patient safety alerts involving anticoagulant therapy, liquid medicines, injectable medicines, epidurals and hyponatraemia risk during intravenous infusions in children. The programme incorporated multiple strategies to minimise risk. These were described in the report alongside a suggested timeframe for implementation of each safety alert by the healthcare organisations with support from the NPSA (implementation of all actions required to be completed by 31 March 2018) [49].

The second document in the series, *Safety in doses: improving the use of medicines in the NHS – learning from national reporting 2007,* was published in 2009 [33]. Medication safety incidents submitted to the NRLS between January 2007 and December 2007 were analysed, with the aim of identifying risks and opportunities to improve medication safety throughout the NHS. Unlike the first document, this report did not develop a programme for implementation by healthcare organisations.

However, a wide range of areas such as acute settings, mental health, primary care and treatment of children or elderly patients were identified as requiring increased efforts to improve medication safety. Healthcare organisations could use this report to review the number, quality and usefulness of their medication incident reports. They could use the information and examples in this report to assess risks and generate initiatives and risk reduction strategies to reduce medication incidents [33]. The report also described the success of some previously issued NPSA guidance on safer medicines practice such as those for oral methotrexate and potassium chloride injection; but warned that effective implementation requires continued focus and action to be successful.

In summary, patient safety has been identified as a global priority in recent policies, both nationally and internationally. A key focus of which is improving medication safety. This is reflected in WHO's most recent initiative, their third Global Patient Safety Challenge: *Medication Without Harm* [50]. This was launched in March 2017 to reduce severe avoidable harm from medication-related errors in all countries by 50% over the subsequent five years. Three key action areas were identified as priority to achieve the target: polypharmacy, high-risk situations and transitions of care. In the UK, ongoing efforts to improve medication and patient safety include the development of new Patient Advocates for Safety and Patient Safety Specialist roles as well as the planned launch of the upgraded Patient Safety Incident Management System, which will replace the NRLS by 2020 [51]. In addition, ongoing research

(discussed throughout this thesis) aims to further address the issue of patient safety and drive future policy improvements.

1.4 Medication safety in primary care

1.4.1 Medication related processes in primary care

Medication related processes in primary care are the steps that are involved in the provision of medicines to patients [52]. Figure 1.1 shows the primary care medication related processes involved in patient care in the UK, adapted from Garfield et al. [52]. Garfield et al. conducted a systematic review of the literature to map out the processes of medicines use in UK primary care and errors associated with them. They used an iterative process to refine the map in light of findings from the literature review. They found 27 relevant papers that met their inclusion criteria which they used to produce a high-level process map based on established processes [52]. In most cases, medications are initiated in primary care by a general practitioner (GP); also, medications that are initiated in secondary care are likely to be continued in primary care, making primary care an important part of the healthcare system.

The prescribing stage after the patient has seen the GP, mostly in a general practice, is where the decisions about what appropriate medicine to prescribe is made if any is needed and where the patient is advised on the outcome of the consultation related to their health and wellbeing. If a prescription is produced by the GP, this is usually either given to the patient to take to a pharmacy or sent directly to a pharmacy

electronically for dispensing. The prescription is then dispensed by the pharmacy using a standard procedure and then the medicine(s) handed to the patient with appropriate advice about their medication. The patient or carer then administers the medicine and monitors the response. Where appropriate, the prescriber reviews and/or monitors the patient for therapeutic and adverse effects. Medication errors are common and could happen at any of the stages described in the related stages shown in Figure 1.1 (some of this will be described in Section 1.4.3). However, four main stages have been highlighted to have the most potential for error – the process of prescribing, monitoring, dispensing and administering [53]. Medication error classifications are discussed in the next Section (1.4.2).

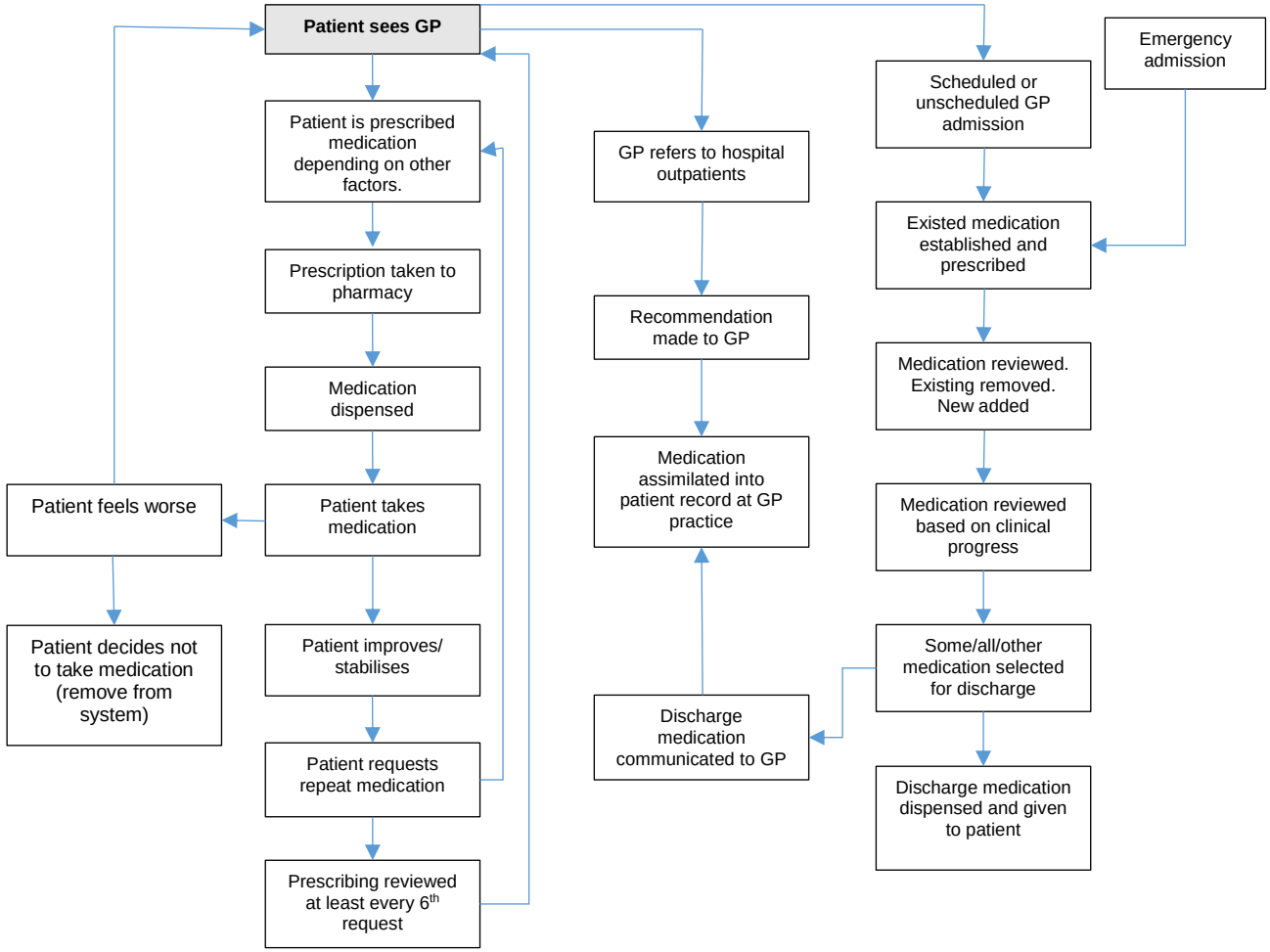


Figure 1.1 Medication related processes where potential errors that can affect the quality of medicines use in primary care occur. Figure adapted from Garfield et al. [52].

1.4.2 Medication error classification

When classifying medication errors, different approaches have been used in the literature. This usually depends on the purpose of the classification which could be of several types and/or subtypes. The definition and classification of medication errors are two different but related concepts; definition is established first before classification. Ferner and Aronson reviewed a few of the different approaches employed before proposing a classification founded on a psychological approach. This was on the basis that it was a more necessary preventative approach to medication errors, it explains why they happened rather than just describing them [30]. This approach classifies medication errors based on whether errors occur due to mistakes (knowledge-based or rule-based errors) or skill-based errors (action-based errors known as ‘slips’ or memory-based errors known as ‘lapses’) [54]. This approach is illustrated in Figure 1.2 below and Table 1.1 gives examples of errors in the different categories.

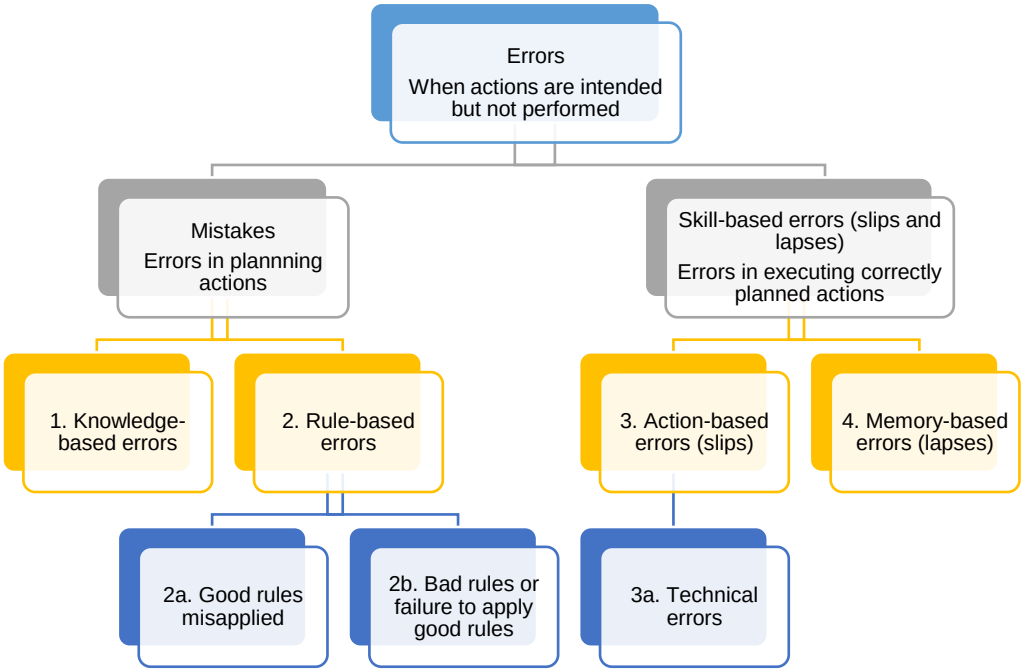


Figure 1.2 The classification of medication errors based on psychological approach. See table 1.1 for example of errors in each category type. Reproduced from Ferner and Aronson [30].

Table 1.1 Examples of medication errors according to categories based on the psychological classification of errors. Adapted from Ferner and Aronson [30]

Type of Error	Examples
Mistakes	
Knowledge-based	Giving a penicillin containing medicine without establishing whether the patient is allergic or not; Being unaware of interaction between simvastatin and amiodarone.
Rule-based	
Good rule misapplied	Injecting diclofenac into the lateral thigh (the usually preferred site for intramuscular injection) rather than the buttock (which is preferred for diclofenac).
Bad rule or failing to apply a good rule	Giving oral treatment to a patient who has difficulty swallowing (dysphagia).
Skill-based errors	
Action-based (slips)	Writing chlorpromazine instead of chlorpropramide; Picking a bottle containing 100mg/5ml of morphine solution when intending to pick the one containing 10mg/5ml; Misreading diltiazem for diazepam.
technical errors	Using the wrong amount of water to make up amoxicillin suspension; Putting the wrong amount of acetylcysteine in an infusion bottle.
Memory-based (lapses)	Giving penicillin containing medicine forgetting that the patient is allergic.

The NCC MERP adopted a different approach to classification using a medication error index which classifies medication errors based on severity of the outcome to one of nine categories. Figure 1.3 shows the NCC MERP index for classifying errors [55]. This classification is about the outcomes of the errors and not the causes, therefore, it may not be

very helpful in terms of future preventative measures. In Dean and Barber's study, they described and validated this approach using an expert panel to rate the severity of potential outcomes on a scale of 0 (no potential effect) to 10 (death) [56].

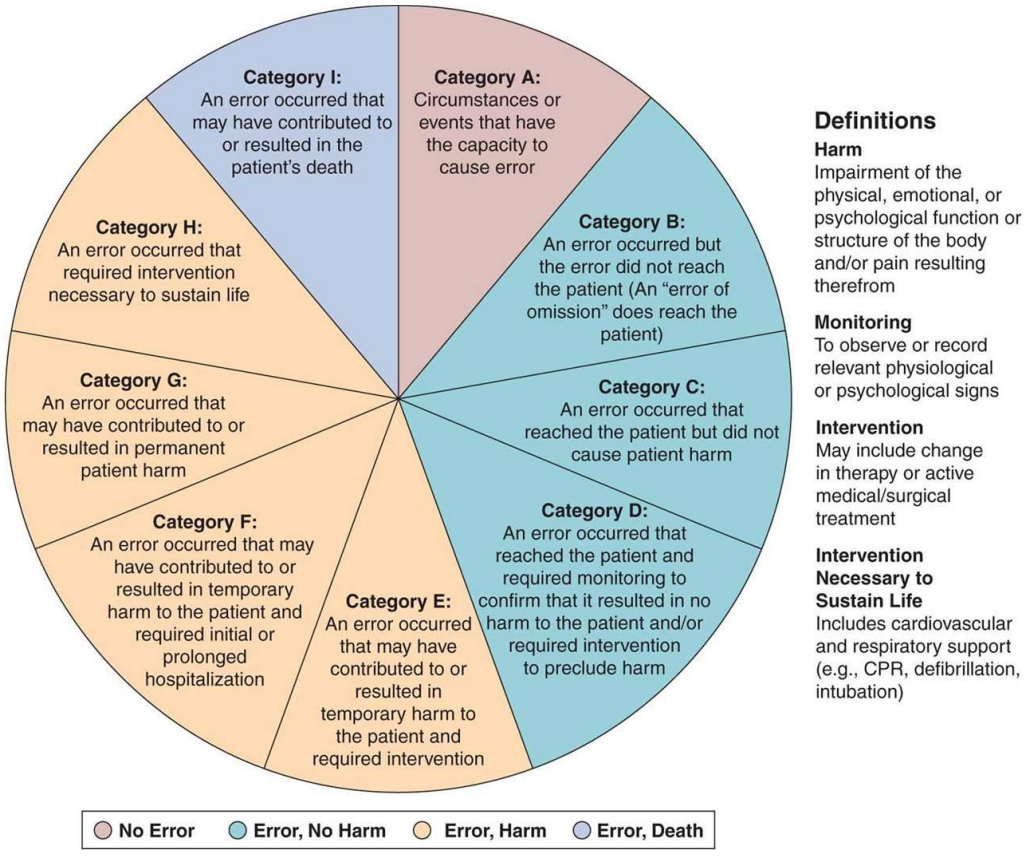


Figure 1.3 NCC MERP index for categorizing medication errors (Figure reproduced with permission from NCC MERP © 2001. All rights reserved)

In a more recent study, Cooper and colleagues reviewed the literature on patient safety research including medication in primary care and identified multiple approaches to harm severity classification [57]. Using the ICPS as a reference, they undertook a framework analysis of the various approaches and developed a new system for harm severity classification in primary care. The classification ranges from no, mild,

moderate, severe harm to death [57]. This is similar to the harm classification system used in the NRLS [41].

Another approach to classifying medication errors which is widely used in primary care is the one that follows medication related processes (e.g. prescribing, dispensing, administration and monitoring) (see section 1.4.1), which is similar to the classification used for the types of medication error defined earlier. An example of this approach is outlined in a study based in nursing homes and small hospitals by Barker et al. [58]. This follows from diagnosis, writing a prescription, prescription processed in the pharmacy, dispensing of medication, administration of medicine, to the patient getting well. This type of classification system was also proposed by Betz and Levy in a hospital setting to use three categories i.e. prescribing, dispensing and administration [59]. Although these were based in hospital settings, this approach could be extended to primary care and can be further classified within each category to have different types of error; for example, wrong timing, wrong drug, contraindication, etc. as shown in a study by Lesar and colleagues [60].

Some of the classification approaches described above are not very informative on their own in terms of informing plans for change that could be made to prevent errors. However, they could be important in combination with other approaches, such as the evaluation of causes (like in the psychological approach to classification described earlier), preventability and likelihood of recurrence to be able to inform possible

interventions to reduce medication errors or evaluate the effectiveness of the interventions being designed.

From the literature, it can be seen that the definition and classification of medication error in primary care or secondary care settings do not follow a universal method; although it is mostly generalizable between the two settings. Different studies have used different definitions and classification systems mostly based on the aims of study, type of analysis that is being looked at, preferences and the setting. It is however important to standardise definitions and classifications to assist literature comparison.

1.4.3 Medication errors and error causation

Researchers have studied medication errors as well as the causes of the errors previously but most of the studies were based in secondary care with a few in primary care [13, 61-65]. Table 1.2 shows example classifications of some types of medication errors as shown in the studies by Beso et al., Barber et al. and Avery et al. [36, 39, 66]. Beso and colleagues studied the frequency and potential reasons why dispensing errors occur in a UK hospital pharmacy through self-reporting by staff and staff interviews [36]. The study by Barber et al. was conducted in UK care homes and looked to determine the prevalence and potential harm of medication errors and their causes using a prospective study involving interviews, note reviews, observations and examinations of dispensed items [39]. The PRACtICe study by Avery et al. investigated the prevalence and causes of prescribing errors in UK general practice by systematic reviews,

retrospective review of medication items and interviews [66]. Although these three studies shared similar methods, they focused on three different areas of the healthcare system. Two of the studies [36, 66] had more emphasis on particular stages of the medication related processes (dispensing, prescribing and monitoring) whilst the other study explored errors at all the stages with the focus on the care setting (care homes) [39]. Some similar error types were found between the studies where applicable.

Table 1.2 Examples of different classifications of different types of medication errors. Sourced from [36, 39, 66]

Prescribing errors	**Dispensing errors**	**Administration errors**	**Monitoring errors**
Incorrect drug Allergy error Interaction error Contraindication error Dose/strength error Formulation error Frequency error Timing error Quantity error Duration error	Content error such as incorrect drug/strength/form, missing doses, etc. Labelling error such as incorrect name of patient/drug, incorrect quantity, date, strength etc. Documentation error such as incorrect controlled drug documentation	Wrong dose Errors of omissions	Monitoring not requested Requested but not done Results not available Results not acted upon

In a study by Lu and Roughead that looked at the factors that contribute to medication errors, a comparison across seven countries was conducted using a cross-sectional survey. They conducted a secondary

analysis on the 2007 Commonwealth Fund international Health Policy Survey data. The survey was conducted via phone conversations and focused on four issues: access, primary care, coordination and safety, to understand adults' healthcare experiences in the countries. They found poor coordination of care (most common), cost-related hurdles to medical services/medicines, multiple chronic conditions and hospitalisation to be among the common risk factors amongst the countries [67]. A Spanish study conducted in community pharmacy over a 13-month period looking at prescribing errors, dispensing near misses and errors, found illegible handwriting to be the most common cause of error [68]. Although the Spanish study was conducted in a single location, the finding is likely to be true in most parts of the developing world. However, this may not be a large problem in the UK and other developed countries where most prescriptions are printed or issued electronically. In the UK hospital pharmacy study by Beso and colleagues, 106 conditions that could lead to dispensing errors were reported and classified under the following: workload, environment, drug design, protocols, communication, organisation, stressors and, skill and knowledge. The most frequent reported factors were being too busy, lack of staff, time restraints and fitness condition (whether or not the individual is weary or not feeling too well). Interruptions and look-alike or sound-alike medicines also featured prominently [36]. Sound- and look-alike medicines have been established to be a key factor contributing to medication errors in practice especially during the dispensing process [69].

Another prospective study had a similar aim of identifying causes in a UK community pharmacy [70]. Pharmacists recorded details of incidents that occurred during the dispensing process. It reported the perceived causes of dispensing errors and near misses as well as the conditions associated with the incidents that were reported. Some of the common causes reported were similar drug names, misread prescriptions and using previous drug or dose listed on the Patient's Medication Record (PMR) in the dispensary computer. Most of the causes reported were found to be similar for both errors and near misses. The conditions commonly reported in which the incidents occurred were: busier than normal, telephone interruptions and not having the usual dispenser [70]. Although the two studies discussed above [36, 70] were conducted in a secondary care and primary care respectively, it is clear that some of the causes of errors in the two settings were similar, but there were also notable differences such as the PMR being an issue in the community pharmacy but not the hospital pharmacy.

In the General Medical Council's PRACtICe Study, risk of errors was found to be associated with polypharmacy, old age, male gender and specific medicines or class of medicines independently [66]. Comparable relations between risk of errors and the factors described in the PRACtICe Study were also identified in a USA study about adverse drug events in outpatient setting using a retrospective national data, except the risk was higher for female gender in this study [71]. The cross-sectional study by Guthrie and colleagues about high risk

prescribing in Scottish primary care also showed that inappropriate prescribing of drugs is more likely with polypharmacy and age. The study also showed female gender to have a positive smaller association with inappropriate prescribing as well [72]. In the PRACtICe study, error-producing conditions that increases the susceptibility of medication errors were identified following a qualitative study and classified into seven key conditions, these conditions with examples of some of the important factors given are highlighted in Table 1.3 [66]. In the study by Barber et al. about care homes' use of medicines which looked at prescribing, dispensing, administration and monitoring errors, error-producing conditions were categorised in a similar way and similar contributing factors to the PRACtICe study were identified [39].

Whilst the heterogeneity of studies is wide, most of the causes and contributory factors to medication errors seem to be similar across primary care and secondary care. However, studies focussing on understanding the context of the underlying contributory factors to medication errors in primary care are lacking.

Table 1.3 Error producing conditions and examples of factors that influence the conditions to make an error as identified by the PRACTiCe Study [66]

Error-producing conditions	Factors influencing errors
The prescriber	Drug knowledge and experience Therapeutic training Knowledge of the patient Perception of risk Physical and emotional health
The patient	Personality Literacy issues Language barrier
The team	Poor communication Nurses' quasi-autonomous role
The working environment	High workload Time pressures Associated stress
The task	Failure of proper patient review Repeat prescribing systems Patient monitoring
The computer system	Selecting the wrong drug or dosage from drop down menu Overriding important drug-drug interaction alerts Unnecessary/inappropriate alerts Too much reliability by staff
The primary secondary care interface	Quality of correspondence

1.4.4 Swiss cheese model of error causation

Reason developed an accident causation model referred to as the Swiss cheese model, which is a systems-focused model aimed at reducing errors in an organisation by looking at many different factors including the organisation and its policies [54, 73]. It is used in risk analysis and risk management in different sectors such as aviation, engineering and healthcare. This model is widely used in patient safety research to put into context how the structure and process (system) is implicated in patient safety incidents [74]. It promotes focus on the conditions and situations in which incidents occur rather than apportioning blame. The model shows a trajectory of accident opportunity (medication incidents) penetrating several defensive barriers designed to prevent such incidents (Figure 1.4). Each slice of cheese represents a defensive layer against errors and like Swiss cheese, may have many holes. However unlike in the cheese, the holes are continually opening, closing and moving positions. The presence of holes in a single “slice” does not usually produce an adverse outcome, this only happens when the holes in many layers line up briefly to allow a trajectory of accident opportunity. Reason identified two causes for these holes in the defences: active failures and latent conditions. Most errors are likely to involve a combination of these two factors. Active failures are defined as unsafe acts committed by people who are in direct contact with the patient or system, whilst latent conditions are the inevitable “resident pathogens” within the system (defensive weaknesses) [54, 73]. These factors are mostly referred to as

'contributory factors' in this thesis and have been defined in Section 1.2 of this chapter. The potential to identify the contributory factors of medication incidents, represents an opportunity for the development of improvement ideas to strengthen system defences. The Swiss cheese model was used in this study to inform the understanding of the causes of medication safety incidents in primary care.

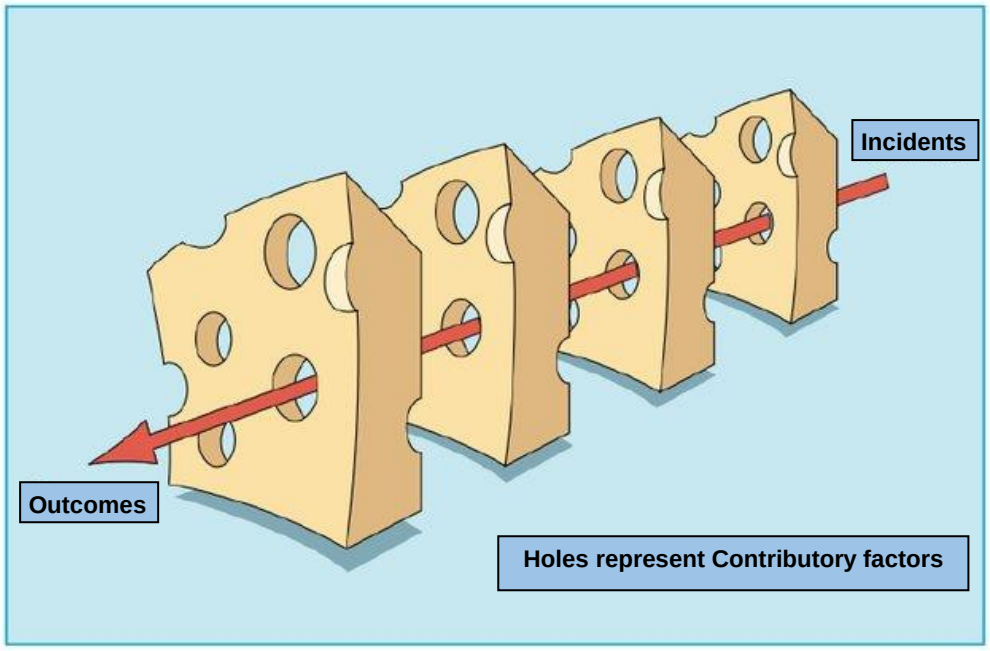


Figure 1.4 Swiss cheese model of how defences, barriers and safeguards may be penetrated to cause medication errors (taken from Reason [73])

As previously mentioned, Reason's model of error causation has since been adapted for application in the healthcare context. The approach was appealing since its use in aviation and nuclear power industries supported an organised way of understanding risk in complex systems, and how catastrophic outcomes could be avoided [73]. It has also been specifically adapted to healthcare by Vincent and colleagues [74]. Whilst Reason's model contains a general framework not specific to

any particular industry, the Vincent and colleagues' framework developed the inherent concepts from Reason's framework and contextualised these for the healthcare context. For example, Vincent's framework identifies seven major key components or factors (with sub-levels) which may influence clinical practice, including: institutional context; organisational and management factors; work environment; team factors; individual (staff) factors; task factors; and patient characteristics [74]. Each sub-level of the major factors could be analysed further to provide a more detailed specification or information on the major factor. For example, staffing levels and skills mix was a sub-factor under the 'work environment' component. Therefore, the framework can provide a structured approach for understanding the various, and sometimes simultaneous, influences and interactions of the different components on clinical practice. In reviewing these factors, and considering the context in which they occur, it is possible to identify opportunities for intervention including error reducing strategies.

Although this framework has been used in patient safety studies [75-78], Vincent and colleagues acknowledged that further work needed to be done to standardise procedures for using the framework to structure data gathering and analysis [74].

In the context of investigating patient safety in primary care, classification systems such as the International Taxonomy of Medical Errors in Primary Care (LINNEAUS) [79], NCC MERP classification [55], NRLS classification [41] and the Eindhoven Classification Model for System Failure [80] have been commonly used approaches for

organising findings. Some of these classification systems were described earlier in Section 1.4.2 and more will be discussed in the next chapter. Classification systems are important descriptive tools in the analysis of patient safety incidents. Most recently, a classification system (PISA patient safety classification system) was empirically derived from the analysis of patient safety incident reports from primary care. The framework is aligned ontologically to the WHO International Classification for Patient Safety.

A review conducted by WHO in 2003 [81] identified the lack of classification systems (including Reason's and Vincent's frameworks) appropriate for the primary care setting. Although most patients receive healthcare in the primary care setting, the majority of patient safety research is conducted in secondary care. However, results from secondary care may not easily be extrapolated to primary care due to differences that exist between the settings. These may include the relationships between patients and healthcare professionals, organisational structures, environmental factors and patient characteristics. Therefore, it was important and necessary to consider these factors when classifying primary care based incidents. The review also concluded that most classification systems in use had theoretical and methodological flaws. Following the review in 2003, WHO developed the International Classification for Patient Safety (ICPS) to help standardise the definitions of the main terminologies used in order to make sense of patient safety research and promote the comparison of findings [27]. Subsequently, the WHO Safer Primary Care Expert

group identified a universal need for the development of methodological approaches for understanding the nature of healthcare associated harm in primary care [82]. The PISA patient safety classification system has been empirically derived in response to this dearth of research and development, and therefore tools to assess and investigate patient safety in primary care. I adopted this tool in my study.

However, unlike the development of other prior approaches for classifying incidents, by the very nature of its development through a constant comparative approach [15] which exclusively uses the content of incident reports to develop and update its codebook, it does risk omitting factors included in other frameworks such as Vincent's, NRLS's, and NCC MERP's. However, the strength of the PISA classification could arguably be that it has been developed by health services researchers with training in modern patient safety theory. Whilst the developers do not specify which theories, the developers of PISA have conceptually and theoretically based their design on the ontology outlined in WHO ICPS [27] which directly acknowledges the influence of systems thinking [54, 74], inclusive of the approaches advocated by Reason (1990) and then Vincent (1998). The PISA patient safety classification system will be discussed further in the next chapter (see Section 2.7.1) [83].

1.5 Epidemiology of medication incidents in primary care

Much of the current literature on medication error has described the epidemiology in a secondary care setting, although whilst literature in

the primary care setting is available, it is limited [14, 60, 70, 84-89]. The various definitions and classifications discussed in Sections 1.2.1 and 1.4.2, used in different studies makes it impossible to make a definitive estimate of the prevalence of medication errors. The incidence also vary due to the different denominators used to calculate the rates in different studies, i.e. patients, prescriptions or individual item. The heterogeneity of methods for learning from errors (e.g. self-reporting and medical records review) or reporting systems in different countries, which could be employed in a medication error study are also likely to compound the variations associated with estimating the frequencies of medication errors [89-91].

These issues are reflected in widely differing values reported for error rates which I will now look at for studies conducted in different areas of primary care which is the focus of this study.

1.5.1 General practice

In UK, the general practice setting mostly provides the first point of contact with doctors and other prescribers to members of the public, this therefore provides a source of prescribing errors. A study set out to classify and measure the frequency of prescribing errors in this setting; data was collected by retrospectively reviewing prescriptions presented in three pharmacies from three general practices over two months. From 37,821 reviewed prescription items, they found an overall error rate of 7.46 for every 100 items, with the most common error relating to the direction of use (with an error rate of 2.8 per 100 items) [92]. In the PRACtICe study, a 2% random sample of patient records in 15 general

practices were selected and reviewed by pharmacists to identify prescribing and monitoring errors retrospectively. They found that 12% of all patients (one in eight) were affected by an error in prescribing or monitoring in a period of one year. This figure was higher in some patient groups; 17.8% in patients who received at least one medicine, 30.1% in those who received five or more medicines, 38% in those aged at least 75 years who had at least one medicine and 47% in all patients that had at least 10 medicines [66]. The overall prevalence of prescription items with errors of prescribing or monitoring in the study was found to be 4.9% with 0.18% of the prescription items associated with severe error. The study also showed that the medicines most associated with errors are the ones most frequently prescribed, such as simvastatin, ramipril and amoxicillin. The general practices involved in this study were similar to other practices in England in terms of size, number of GPs, and Quality and Outcome Framework scores which provides good representative sample for the population being studied [66]. Another Austrian study also found the frequency of medication errors in primary care to be high in patients with polypharmacy (patients taking multiple medicines), mostly being the elderly [93]. The authors wanted to examine the frequency of medication errors in patients with polypharmacy treated in general practice. Data was collected through filling of a case report form for each patient recruited by a GP. The form included details of medicines the patients are taking; indication, appropriateness, dosing and interaction information were checked against evidence to identify any errors. The study found a medication

dosing error in at least 56% of the 169 patients included in the study taking five or more medicines. This study was limited by its size; a higher number of participants could have provided stronger evidence. The selection of known GPs to recruit patients could also have introduced the risk of selection bias to the study which might affect the representativeness of the population. Finally, although analysis was conducted by three researchers independently, no measure of inter-rater reliability was reported. However, they indicated that discrepancies were easily resolved by consensus and arbitration if necessary [93]. In the systematic review by Garfield et al., error rates were assessed using a different approach which involved mapping the primary care medication related processes (see Section 1.4.1) in UK based on the literature and found error rates at different stages of the process. They found an error rate of 7.5% at the prescribing stage and 77.4% at the crossing point between primary and secondary care where recommendations were made to the GP by secondary care [52].

Studies from non-western nations about medication error in general practice are very scarce and the majority of them were based in secondary care. This was demonstrated in a systematic review of the literature on medication errors in the Middle Eastern countries where only 9 (20%) of the 45 included studies originated from primary care [94]. Twenty-one of 45 included studies assessed prescribing errors with seven based in primary care. Again, due to the different definitions and methods used in the different studies included in the review, the authors found it difficult to make any comparisons between the studies

because error rates were expressed differently. The most frequent prescribing errors found were incorrect dose, wrong frequency and wrong strength [94]. One of the seven primary care based studies reviewed was in Saudi Arabia's primary healthcare system and found prescribing error rate of 18.7% (990 of 5299 prescriptions sampled contained prescribing errors) but the potentially serious errors were a lot lower at a rate of 0.15% (8 of 5299 prescriptions) [95]. Another of the seven studies evaluated the primary care prescribing errors in Bahrain and found 7.7% of prescriptions to contain errors with error of omission accounting for almost 94% [96]. Three of the remaining five studies originated from Bahrain and reported error rates of 88%, 90.5%, and 34.8% of prescriptions containing errors. The other two studies were from Saudi Arabia; one reported that 72% of physicians were writing low-quality prescriptions whilst the other did not report on error rates but explored the factors influencing prescribing. The authors assessed the quality of studies using a quality assessment criteria and concluded that the studies were of poor quality [94].

In Malaysia, 41.1% of primary care medical records were found to contain medication errors after randomly selecting the records and reviewing them for medical errors by two specialists, independently in 12 government primary care clinics. The possibility of error prevention was also assessed based on the opinion of the two expert panel reviewers. A total of 93.5% of all the errors identified in the study were considered to be preventable [97].

A Brazilian study looked at the prevalence and factors associated with potentially inappropriate medication use by the elderly in the primary care setting and found almost 35% of medicines used to be inappropriate with polypharmacy as one of the factors influencing this. Data was collected prospectively using a survey to document the medications used by the elderly following random sampling [98].

1.5.2 Community pharmacy

The majority of prescriptions issued in primary care are dispensed to patients by community pharmacies. Therefore, dispensing incidents are most likely to occur here, and studies are conducted in this setting to find out more on these incidents. However, these studies sometimes provide information on other types of incidents. For example, a study conducted in 2002 in the UK about the interventions recorded during dispensing in community pharmacies showed that 0.69% of items required an intervention by a pharmacist, with 0.08% classified as potentially serious. This could be used to give an indication on prescribing error rates. Data was collected through data collection forms distributed to the community pharmacies involved [99].

Ashcroft and colleagues looked, in 2001, at the incidence of dispensing incidents in community pharmacies prospectively using incident reporting and found a near-miss error rate of 22.33 and a dispensing error rate of 3.99 per 10,000 items. They defined ‘near-miss’ as any incident that was detected up to and including the point at which the medication was handed over to the patient or their representative. Those detected after medication is in possession of the patient or their

representative were classed as ‘dispensing errors’. Selection errors were found to be the most common cause of dispensing incidents in the study [70]. The systematic literature review by Garfield et al. also found an error rate of 3.3% at the dispensing stage in the pharmacy [52]. Another study by Franklin and colleagues looked at the prevalence of different types of dispensing errors in English community pharmacies when they compared the three different forms of NHS prescriptions (a printed form, a printed form with barcode and an electronically transmitted form) that are presented to the pharmacies using a non-randomised stepped wedge study design. They found 5.4% of items to contain labelling errors (errors concerning the dispensing label) and 1.4% to contain content errors (errors relating to the dispensed item itself or other consumables), electronically transmitted prescriptions were found to have a higher prevalence of labelling error (7.4%) compared to other forms (4.8%) which disagreed with the anticipated results [100]. However, this study was conducted during the roll out of the electronic transmission system. Users were still getting to grips with understanding the most effective ways of using the system which may have contributed to the increased prevalence of labelling error detected for this system.

A number of USA studies have reported a wide range of dispensing error rates in community pharmacy from 1.7% (77 errors among 4,481 prescription items dispensed) [101] up to 24% (24 dispensing errors detected in an analysis of 100 prescription orders dispensed) [102]. A small percentage of these errors were deemed clinically important in

these studies. Again, a wide variation in definitions and methods were used which does not aid comparison and may have contributed to the disparities in error rates.

As previously mentioned, community pharmacy based studies do not only focus on dispensing stage of the medication related processes but also other stages such as prescribing stage. In a study conducted in Danish community pharmacies using incident self-reporting, prescription corrections (prescribing errors), dispensing near-misses and dispensing errors were found to occur at a rate of 0.2%, 0.02% and 0.01% of prescriptions respectively. The number of prescriptions was used to calculate the rates in this study [103]. These are considerably lower rates than for other countries described. The researchers also reported that the differences could be due to differences in study design, methods and definitions used. It could also be due to improved system used in Denmark such as electronic prescribing which was implemented a lot earlier than other countries [103]. A similar study was conducted in a Spanish community pharmacy and found an overall medication error rate of 5% of prescriptions (2.7% prescribing errors; 1.8% dispensing near-misses; and 0.5% dispensing errors). Of this, prescribing, dispensing near-misses and dispensing errors corresponded to 53.2%, 36.6% and 10.2% of the errors identified respectively [68]. An older Swedish study of community and hospital pharmacies reported a prescription error rate of 42%. This rate was however, boosted by the fact that ‘omission of the purpose of therapy’ was considered an error and represented 64% of the total errors

identified. Errors of commission which could potentially be harmful to the patient accounted for only 1% of the reported errors [104].

1.5.3 Community nursing

In the UK, community nursing is any nursing care provided outside of an acute hospital. This includes healthcare provided at home, within general practice, care home, school, community hospital or under police custody [105]. Community nursing is mostly associated with administration medication error studies due to the nature of the patient care they provide. This was shown in a study by Alrwisan and colleagues, where medication incidents were studied using an online reporting system in Scotland, one of their aims was to quantify the proportion of reported incidents based on the reporters' profession. Nurses and midwifes reported more than 80% of the incidents with more than 87% of the incidents being administration incidents. Only 6% of the reports however, originated from primary care which is the lowest number among the healthcare facilities that reported and these were not elucidated further [85].

In 2011, Cousins et al. reviewed the medication incidents reported to the NRLS over 6 years (2005 – 2010), this review played a pivotal role in informing the direction of my PhD study [5]. The study reviewed all medication incidents reported in both primary and secondary care together but did not explore the factors contributing to the incidents. Furthermore, the majority of incidents reported (91.5%) were from secondary care which could skew the findings of the study. The authors described how serious medication incident reports were still being

received even after issuance of guidance to help minimise the medication incidents. Therefore, understanding the contributory factors and the context of occurrence could be key in informing effective change ideas for the future.

Table 1.4 shows the number of incidents and the corresponding number of medication incidents of primary care sectors reported in that review. Again, community nursing had the highest number of medication incident reports followed by community pharmacy and general practice. Community and general dental service and optometry/optician service had the lowest numbers with the later having only four medication incident reports in six years [5].

Table 1.4 Number of patient safety incident reports and medication incidents in primary care sectors received by NRLS from 2005-2010. (adapted from Cousins et al. [5])

Primary care sector	**Total number of incident reports**	**Number of medication incident reports**	**Medication incidents as a percentage of total incident reports**
General practice	22,587	5,358	23.72
Community pharmacy	19,696	19,245	97.71
Community nursing, medical and therapy service	542,323	48,594	8.96
Community and general dental service	2,560	133	5.20
Community optometry/optician service	82	4	4.88
Total	**587,248**	**73,334**	**12.5**

1.5.4 Care homes

Care homes are places where older people are being accommodated and cared for in the community when they cannot look after themselves anymore, this include nursing homes where community nursing care is also provided. Patients in care homes are usually weak and frail with multiple medications due to multiple morbidities they experience. Patients in these homes usually have their medicines prescribed on site and administered to them by a team of carers or nurses, therefore, raising issues of medication errors. The majority of literature on community nursing (introduced earlier) were found to be based in care homes. Multiple types of medication errors could be studied in care homes as demonstrated below.

A prospective study in the UK about Care Homes' Use of Medicine (CHUM) found 69.5% of residents to be affected by at least one medication error. Errors were identified through patient interviews, note reviews, observation of practice and examination of dispensed items. Of the total number of residents recruited for the study (n = 256), 39.1% (n = 100) experienced prescribing errors with an error rate of 8.3%; 36.7% (n = 94) experienced dispensing errors with an error rate of 9.8%; 22.3% (n = 57) experienced administration errors with an error rate of 8.4%; and, 10.5% (n = 27) experienced monitoring errors with an error rate of 14.7% [39]. The prevalence of prescribing errors was comparable to general practice [92] while the dispensing error rate was a lot higher than what was found in community pharmacy (1.7% for content error and 1.6% for labelling error) [35]. Although the CHUM

study considered the whole system of medication use in care homes, sampling was not random. However, sample was taken from three geographic and diverse areas in the UK to promote getting a varied sample. Also, subjective judgements were sometimes used due to lack of evidence. The presence of researchers on site may have also affected the prevalence or rate of administration errors by the staff during observation of practice.

Medication error rate was evaluated in a sample of long term care facilities in the USA and found an error rate of 12.2% following observations of practice (administration of medicines) by researchers. The error rate in this study was calculated using an approach of the proportion of errors in total opportunity-for-error (OE). OE was defined as the total number of doses authorised in addition to any unauthorised doses given to the patient [58]. Another USA cohort study about the incidence of adverse drug events in long-term care facilities found 42% of the 815 events to be preventable, where preventable meant any adverse event that was as a result of a medication error and could have been avoided by any means available [106]. The rate of preventable adverse events was found to be 4.1 per 100 resident-months with 61% of the serious or more harmful events being preventable compared to 34% of the less serious events. Most of the preventable adverse events occurred mostly during ordering and monitoring stages of the care homes' medication process [106].

Some of the studies discussed have shown that medication errors in care homes are likely to have more consequences due to other patient

factors such as multi-morbidity, age and polypharmacy and therefore, it is imperative that more studies in this area are conducted to tackle the harm caused by medication errors.

1.5.5 Other community services

The literature on medication errors in the remaining disciplines of community health services that make up primary care are very scarce. This could be due to the fact that the majority of patients are exposed to medicines in primary care through general practices and pharmacies. One study from Brazil looked at dental prescribing errors in primary care and found similar types of errors as general practice prescribing errors. Errors of omission and/or inadequacies were the most common errors detected, e.g. errors of route, dosage, frequency, directions, authorisation stamp and legibility [107]. Although there is a much lower chance of a medication incidents occurring in dental and optician services due to medicines exposure not being as high as other settings described above, it could still be beneficial to study these settings as well, especially dental service because medication incidents in this setting could potentially cause a high severity of harm to patients, up to death from the use of anaesthetics for example [108]. Literature on medication errors in optometry/optician services is virtually non-existent.

1.6 Interventions to reduce medication safety incidents

There are not many studies that have looked at interventions designed to reduce or prevent medication errors systematically, by aiming to plug

all the holes in the medication related processes that lead to a medication incident in both primary and secondary care. However, studies exist that have designed interventions for a particular stage of the medication related processes, such as to improve prescribing in the primary care setting. Some have looked at specific clinical areas such as antibiotic use. Most interventions have been conducted in individual countries with different healthcare systems, and therefore may not be generalizable, although important lessons could still be carried across.

A systematic review conducted in 2006 aimed to recognize and assess intervention studies in primary care that targeted lowering adverse events due to medication [109]; they used the outcomes of morbidity, hospital admission and/or death as a measure of adverse events. Data extraction and quality assessment of included studies was done using the Cochrane Effective Practice and Organisation of Care (EPOC) data collection checklist and template. Meta-analysis was also performed following data extraction. Thirty eight studies were identified with majority coming from the USA (18), UK (8), the rest of Europe (8), three from Australia and one from New Zealand. Seventeen of the studies were pharmacist-led, eight were led by other healthcare professionals and thirteen involved complex interventions. The pharmacist-led interventions involved medication review by the pharmacist with most of them using hospital admission as a measure of outcome, the other healthcare professional-led used preventable drug related morbidity as a measure of outcome while the complex interventions involved an element of medication review to reduce falls in the ageing population

(outcome measure being falls). Following meta-analysis, the pharmacist-led interventions were shown to be significantly effective in lowering hospital admissions; this is not true however, when only Randomised Controlled Trial (RCT) studies were included in the analysis. No evidence of significant effectiveness of the other two types of interventions was seen in the meta-analysis. The authors concluded that more studies are needed to evaluate whether the better understanding of the causes of medication incidents can be translated into meaningful improvements in patient safety [109].

A 2009 study however, conducted a pooled analysis of two RCTs in outpatients with hypertension to determine the effect of pharmacist intervention on adverse drug events and medication errors. The pharmacist intervention involved regular and ongoing oral and written instructions to patients following dispensing of their medications which was compared to the usual care patients received without follow ups. They found that the pharmacist intervention was effective in reducing adverse drug incidents and errors of medication [110]. Furthermore, a Malaysian controlled trial study used a pragmatic complex intervention to reduce medical errors in primary care; the intervention included educational training, structured process change, methods of review and educating the patients. They found this to be significantly effective in reducing medication error rates from 43.2% to 25.2% within the intervention group [111].

Another systematic review by Lainer et al. looked at the effects of Information Technology (IT) intervention RCTs on medication safety in

primary care. The interventions identified were Computerised Provider Order Entry (CPOE) with Clinical Decision Support (CDS), pharmacist-led IT interventions (such as Pharmacy Information Management System, PIMS) and telemedicine (use of medical information derived from one site to another via electronic communications such as web program and TeleWatch system intervention). They found half of the ten included studies to be effective in reducing medication errors which included two pharmacist-led interventions on inappropriate prescribing in older patients and pregnancy [112]. The authors suggested that IT interventions could be successful in reducing medication errors but limited to clearly defined medications and target groups or when pharmacists and physicians work together. However, they may also be associated with other possible safety hazards [112]. A pharmacist-led IT intervention for medication errors (PINCER) which was included in the review by Lainer et al. was conducted using a multicentre clustered RCT in UK general practice to compare its effectiveness to the normal simple feedback system (computer generated) when it comes to reducing medication errors. The intervention included educational outreach and dedicated support as well as the computer generated feedback led by a pharmacist. A significant reduction in all three prescribing errors measured as primary outcomes was seen in the intervention group [113].

A Cochrane review by Alldred and colleagues looked at prescribing interventions for older people (>65) in care homes and examined the efficacy of the eight included diverse randomised interventions which

included educational, clinical decision support and multidisciplinary case-conferencing; with seven of the RCTs having a piece on medication review. They found no evidence of any effect on the primary outcomes (mortality, hospital admissions and adverse drug events) of the review in all of the interventions but there was evidence of the interventions leading to the identification and resolution of medication-related problems, mostly medication errors [114]. Another Cochrane review reviewed the literature on interventions to improve the appropriateness of polypharmacy in older patients (>65) and hence, reduce medication-related problems such as errors [115]. Eleven of the 12 included studies were complex multi-faceted interventions whilst the other was a computerised decision support intervention, all of which were conveyed by healthcare professionals, for example; physicians and pharmacists. The interventions appear to reduce inappropriate prescribing overall but it is unclear whether they improve appropriate prescribing [115].

Rinke et al. systematically reviewed the literature on interventions to reduce paediatric medication errors and found almost all of the included studies (n = 63) to reduce all types of medication errors (by 17% to 99%); prescribing errors were reduced by 27% to 87% [116]. CPOE with or without CDS was the most common type of intervention identified in the review (n = 26), followed by education and training (n = 20), preprinted order sheet (n = 9), protocol implementation (n = 8), publicising/reporting error rates (n = 7) and increased pharmacist participation in medication ordering (n = 5). They concluded that

medication errors in paediatrics can be reduced by aiming to improve multiple stages of the medication-related process through different forms of interventions. However, understanding of the optimal interventions is still hindered mostly because of heterogeneity of studies.

Looking at a specific clinical area, a systematic review of educational interventions to improve prescription and dispensing of antibiotics was conducted. Forty-seven studies were identified in primary care with outcome measures of adherence to guidelines and number of antibiotics prescribed used by the reviewers. Mostly, adherence to guidelines was improved and the number of antibiotics prescribed was reduced but no medication error was specifically looked at. This intervention was mostly used in multi-faceted type interventions [117].

1.7 Patient safety incident reporting systems

Increased priority given to patient safety in recent years have seen patient safety incident reporting systems being created around the world. However, as reported by various studies, different methods have been used to study medication errors; for example, self-reports, surveys, observation of practice, interviews and note reviews. This contributes to the varying rate of incidents attributed to medication errors. A literature review by James and colleagues found the reported incidence of dispensing errors to vary according to many factors, one of which was the research method used [89]. Patient safety incident reporting systems allows healthcare professionals and patients or

carers to describe in detail safety incidents that have occurred so learnings can be obtained and prevent future occurrences. Reducing preventable medication incidents has become a major concern in healthcare. Therefore, a national level incident reporting system is a very important tool which could promote and improve incident reporting and hence, seek to improve patient safety by learning from experience. It could also address some of the heterogeneity amongst the literature on medication incidents through its national coverage.

1.7.1 Types of incident reporting systems

According to WHO, there are two main types of systems that can be used to report incidents: learning systems and accountability systems. Learning system reporting is usually voluntary and has a wider context of incidents that can be reported while the accountability system reporting is usually compulsory and has a specific list of incidents that must be reported [48]. A successful reporting system must be able to produce appropriate information that can be used to improve patient safety. In a health policy report, Leape identified the characteristics of a successful reporting system shown in Table 1.5.

Countries such as USA, England and Wales, Ireland, Czech, Denmark, Australia, Netherlands, Slovenia, Sweden and Japan all have national reporting systems, some of which were developed by governmental agencies and others by private or non-governmental sectors [48]. The purpose of these reporting systems is to allow for learning from incidents to be achieved and promoted across healthcare systems, thereby improving patient safety. This should be achieved through their

rich descriptions and context about incidents. Current systems are not fully utilised with millions of reports not being analysed, as they have an important role in identifying weaknesses in the system and interventions to improve them [15].

Table1.5 Characteristics of successful reporting systems (reproduced from Leap [118])

Characteristics	Explanation
Nonpunitive	Reporters are free of fear of retaliation or punishment from others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed to a third party.
Independent	The program is independent of any authority with power to punish the reporter or organisation.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and who are trained to recognise underlying systems causes.
Timely	Reports are analysed promptly, and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than on individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations, and participating organisations agree to implement recommendations when possible.

1.7.2 National Reporting and Learning System (NRLS)

In the UK, a report called “Building a safer NHS for patients” set out the Government’s plans for improving patient safety following *An Organisation With A Memory’s* (OWAM’s) recommendations which led to the establishment of National Patient Safety Agency (NPSA) and the development of NRLS by the NPSA [45]. NRLS was developed for England and Wales to ensure that lessons are learnt across the whole

NHS from patient safety incidents when they occur in any part of the NHS through the promotion of an open, no-blame reporting culture from local to national level. The main function of the system was to learn from patient safety incidents through identification of themes and patterns of the incidents and near misses before developing and implementing solutions to tackle the incidents through root cause analysis. The necessary guidance needed for the system was also discussed in the report which included the definition of patient safety incident (and near misses) that was used as a guide to identifying incidents that should be reported. For the purpose of reporting, NPSA defined patient safety incident as *"….any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare"* [5]. The stakeholders responsible for reporting such incidents to the system are healthcare staff members; the patients and the members of the public are also able to report incidents directly to the NRLS electronically using an e-form via the NHS Improvement website [119]. Healthcare professionals are able to submit reports either directly to the NRLS or through local reporting system of their healthcare facility which then upload these to the NRLS system. Each report is uploaded using a structured and detailed form containing categorical information about patient demographics, where, when, what occurred and severity of harm as perceived by the reporter. The form also contains sections for free-text narrative which gives the reporter a chance to describe the incident, possible contributory factors (apparent causes) and planned actions to prevent re-occurrence of the

incident. See Appendix 1 for a list of NRLS fields required to be filled in the form. Although the reports are not all completed to the same level, the free-text narratives offers a rich body of data which can be used to describe, evaluate and analyse patient safety incidents. They can also be used to identify areas of patient safety that can be improved.

Reports are then aggregated and analysed before lessons are disseminated back into practice through various outputs. Since the creation of NRLS, various outputs have been released such as patient safety alerts, safer practice notices, data summaries (The National patient safety incident reports, NaPSIRs) and various reports. The majority of these outputs have focused on improving patient safety in secondary care settings.

Today, the NRLS is the largest and most comprehensive patient safety incident reporting system in the world. It receives more than two million reports per year in England and Wales. Medication incident reports are among the top four incident categories being consistently reported (~ 11% of total reports) [5, 120]. The majority of this originates from secondary care. However medication incident reports are the top category in most primary care settings such as general practice and community pharmacy [5].

Since the abolition of NPSA in June 2012, the responsibility for the NRLS was transferred to Commissioning Board Special Health Authority (CBSHA) before being moved to NHS Improvement in April 2016. A new upgraded reporting system called Patient Safety Incident

Management System (PSIMS) is currently being developed by NHS improvement to replace the NRLS and is expected to go live in 2020.

Data from the NRLS database of patient safety incident reports in England and Wales is the subject of analysis in this thesis.

1.8 Learning from patient safety incidents

After the essential gathering and analysis of the information on patient safety incidents, improvement should be achieved through dissemination of lessons and the development of good models for practice. As regards to the NRLS, this was part of the function of the NPSA [45] which NHS improvement is now responsible for. This is done through the development and publication of the outputs described earlier. They cover a wide range of topics identified through the NRLS and other sources of information [33]. The NPSA published two reports namely: "*Safety in doses: improving the use of medicines in the NHS*" in 2007 and "*Safety in doses: improving the use of medicines in the NHS. Learning from national reporting 2007*" in 2009 [33, 49]. These publications reported the analysis of the patient safety incidents related to medications. The reports identified patterns of reporting and what lessons can be garnered together with the patient safety alerts related to medication being published. Example of areas covered in the safety alerts published by NPSA included anticoagulant therapy, injectable medicines, epidural injections and infusions and hyponatraemia in children administered intravenous infusions [121]. The review about medication incidents reported to the NRLS over 6 years was done in

anticipation of the handover of NRLS's responsibility to the NHS CBSHA [5]. There was a consistent and significant increase in medication incidents every year and they were the second highest category of incidents reported in that period; however, most of the reports came from hospitals (75%). Primary care was responsible for less than 9% of the medication incident reports described in the review, even though the majority of medication use happens in primary care. Although the proportion of reports from primary care may be considered to be low, there are nevertheless a large number of reports and the information in these reports from the NRLS is still potentially valuable in terms of learning and improvement.

Patient safety alerts and notices, rapid response reports, patient safety booklets and themed reviews have been published since the NRLS was created, however, literature evaluating these publications to ensure the learning from them are affecting patient safety in a positive way are very scarce. A study by Lankshear and colleagues assessed the quality and impact of NPSA's medication safety outputs qualitatively in 2011 and found the respondents to agree that the outputs have had a major impact on patient safety since their introduction [122]. However, despite the large volume of reports being submitted to the NRLS, the data are not being more effectively used in informing systems changes for improvement of patient safety [123]. The sheer volume of reports could be one of the reasons for this. Best methods for optimising such data effectively is needed. Analysis of patient safety incident reports have

been shown to be used to generate learning and inform the prevention of medication errors [124, 125].

Reports on medication safety incidents solely from primary care collected by the NRLS have not been previously systematically analysed to generate such learning. Understanding the contributory factors and the context of occurrence of primary care incidents could be key in informing effective change ideas for improving the safety of medication use in primary care.

1.9 Aim and objectives of PhD

1.9.1 Aim

The aim of my PhD is to describe the nature, range and severity of primary care medication safety incidents reported to the National Reporting and Learning System (NRLS) between 2003 and 2013; to identify priority areas for interventions and to make recommendations for improvement.

1.9.2 Objectives

The objectives are to:

1. Describe the characteristics of medication incident reports in primary care such as location or care setting of occurrence, patients' age and gender, healthcare professional involved, types and frequency of incidents and contributory factors.
2. Determine the medicines or medicinal classes that are most frequently involved and associated with what degrees of patient harm.

3. Determine which characteristics are associated with what degree of patient harm.
4. Identify potential priority areas for intervention by mapping relationships between themes e.g. incident types vs contributory factors and understanding the contextual factors.
5. Make recommendations and identify areas for quality improvement projects and future research.

Chapter 2 Methods

2.1 Overview

Research is a process which is systematically achieved to understand a problem or answer questions of interest [126]. There are various ways research is conducted, one of which is known as social research. This is a systematic process of investigating a social problem or issue and identifying potential solutions to that problem or issue through understanding the reasons behind them [127]. Therefore, social research targets undesirable social conditions or behaviours that needs to be addressed. Such research may be driven by developments and changes in society, for example, climate change or binge-drinking [127, 128]. Methods are described as the techniques and/or procedures that are used to collect and analyse data [129, 130]. In this chapter, I will present the methods, including the research design used in my PhD study, which is of a social nature.

This study used data from the National Reporting and Learning System (NRLS) database (described in chapter 1.7.2), which collects patient safety incidents in England and Wales. Medication safety incidents was the subject of interest in this study and these were extracted and analysed.

2.2 Types of methods

2.2.1 Quantitative methods

Quantitative methods follow empirical laws to study phenomena such as incidence and prevalence studies or the study of association between important factors (independent variables) and outcomes (dependent variables) [131]. Quantitative methods use large sets of numerical data to provide a broad and, ideally, generalisable analysis. A deductive approach enables the testing of theories [128]. Examples of quantitative research methods include randomised control trials, surveys and statistical analyses.

2.2.2 Qualitative methods

Qualitative methods on the other hand, rely on words and experiences rather than numerical data collection and analysis. Traditionally adopting an inductive approach, they focus on the generation of theories as opposed to testing them. Qualitative data can be analysed using thematic analysis, which organises excerpts of data into themes using codes. Qualitative data provides a more in-depth analysis of a smaller sample size, and is less concerned with generalisability and more so with understanding. It is therefore a more favoured approach in social sciences [128]. Examples of qualitative data methods include interviews, focus groups or observations.

2.2.3 Mixed methods

Mixed methods research is an approach that integrates both quantitative and qualitative methods in order to combine their strengths

and compensate for their limitations. Mixed methods studies may use any combination of the two methodologies as required to best address the research question [128, 131]. For example, they may rely more heavily on either qualitative or qualitative approaches. Similarly, each phase may be conducted either sequentially or concurrently. However, the mixed methods approach is characterised by the integration of qualitative and quantitative data. This is the way in which the findings from each phase of a study are drawn together to form a more complete picture. Triangulation of data is also important here; for example, using the findings from one approach to confirm the findings of another [128].

2.3 Ontological and epistemological considerations

In social research, it is important for the researcher to be aware of ontology and epistemology as they are important elements of the philosophy of knowledge. Ontology denotes what the reality or nature of being is; while epistemology refers to the theory of knowledge and how it can be obtained with justification and rationality of belief [132]. Both of these elements are important in social research because the ontological and epistemological assumptions employed influence the choice of methods to be used in the research. This leads to the development of different research paradigms.

A research paradigm is “the set of common beliefs and agreement shared between scientists about how problems should be understood and addressed”. Research paradigms are usually characterised by their

ontology, epistemology and methodology [133]. Methodology refers to the general principles behind research methods used to address research questions [129]. This helps the researcher to identify the best choice of methods which aligns most with their ontological and epistemological perspective. The most common research paradigms used in social science research include positivism, constructivism or interpretivism and pragmatism.

Positivists believe that there is a single reality which can be measured and known objectively without any bias using a deductive approach. The positivists believe there is a universal truth that is always true under certain conditions [134]. Therefore, they use quantitative methods to measure this reality.

In constructivism or interpretivism, no single reality or truth exists, but rather depends on subjective observation and interpretation. This means that people perceive reality in different ways due to other factors such as experience and knowledge [132, 134]. Therefore, qualitative methods are used here to ascertain those multiple realities and understand them better. Constructivists usually propose a theoretical model in the absence of an existing one, i.e. an inductive or exploratory approach. For example, generating theories using grounded theory, which is the emergence of theories from the data after collection, using an inductive methodology that provides systematic guidelines for gathering, synthesising, analysing and conceptualising qualitative data [131].

Pragmatists believe that the reality is constantly changing based on existing conditions and the best method to know the reality is one that best solves the problem. Mixed methods are mostly used here [131, 135]. The idea of mixed methods comes from epistemological debates between two competing paradigms, i.e. advocates of quantitative methods and those of qualitative methods. Other paradigms such as constructionism [136], critical theory [137] and critical realism [138] are also associated with mixed methods research.

The research paradigm adopted for this research was strongly influenced by the nature of the data, which was extracted from an incident reporting system, the NRLS. This system contains a large volume of data with unstructured free-text descriptions full of jargon. To achieve the aim and objectives of my thesis, a reliable process was required to classify the data and be able to interpret the free-text descriptions to generate better understanding of the context.

A positivist view of analysing incident report would mean coding what is explicitly stated in the reports without subjective interference. This is appealing because it provides a reliable and auditable process which will minimise subjective variations before identifying priority areas. On the other hand, a constructivist view of analysing incident reports would mean using the knowledge and experience of the researcher to interpret and make sense of the data. This could provide a better understanding of the meaning and context of the reports.

Therefore, in this project, I took a pragmatic approach to combine both the positivist view and the constructivist view to be able to achieve the aim and objectives of this study in the study design. Given the nature of the data, I feel this approach will give me a better understanding of medication incidents (phenomenon) and assess their causes, effects and trends.

2.4 Study design

There are three main phases involved in social research according to Blaikie (2010), including: planning, execution and reporting [139]. They can either be completed in order or merged with each other depending on the type of research being conducted. I used this concept to underpin the logic for my study design and related research purpose, strategies and methods.

I used the study's aim and objectives described in Chapter 1.9 to guide the planning, execution and reporting of this study. The objectives were developed from initial research questions set out from the beginning of this study to fill a knowledge gap. The purpose of research is usually to identify how the knowledge gap can be filled such as to describe, explore, explain, identify, understand or evaluate a phenomenon of interest [139, 140]. One or more of these can be pursued in the same research project.

Research strategies are ways in which new knowledge can be sought to answer research questions and fill the knowledge gap [139, 140].

There are four research strategies used in social research, namely: inductive, deductive, retroductive and abductive [139].

Research design provides the framework for how the data is to be collected and analysed. The nature of the data being analysed in this research (secondary analysis of a dataset) and the epistemological considerations described earlier limits the research design to be adopted. Therefore, a retrospective cross-sectional study of incident reports was carried out in this study. This study design was used as opposed to other study designs due to the data being sampled from a large database for a particular time period. Quantitative analysis methods were used for this research using some qualitative analysis principles to analyse the free-text data in this study. This included exploratory descriptive and thematic analyses [141, 142].

Different methods have been used by health services researchers to understand medication patient safety in primary care in the past. These include record reviews, observations, surveys, interviews, focus groups and incident reports. Record reviews evaluates either written or electronic records for patient safety incidents and is conducted by trained personnel not directly involved in the care of the patient. Observation is a prospective method of incident identification by trained observers. Interviews, surveys and focus groups of patients or healthcare professionals may be used to gather information or data after a patient safety incident has occurred or in order to improve existing processes in a prospective way. Incident reporting is a retrospective detection method used to identify safety incidents and is

dependent on healthcare professional or patient recognition as well as reporting of actual and potential (i.e., near miss) incidents.

The method(s) or approaches adopted will be associated with different advantages compared to the others depending on the aim of the research. For example, incident reports do contain insights about contributory factors, which are predominantly not possible to identify from reviews in isolation without follow up inquiries [143]. Furthermore, observation might be considered a ‘gold standard’ for understanding contributory factors in real-time but it has labour and resource intensive costs [144]. Therefore, an initial analysis of national-level data to inform observational type activities might be a more prudent approach to take.

The NRLS was created in order to learn from patient safety incidents to help prevent future occurrence of similar incidents, it has grown to be one of the largest and most comprehensive patient safety incident reporting systems in the world. As yet, thousands of medication incident reports from primary care, situated in the database have not been critically analysed. The opportunity to learn lessons and identify national-level priorities for medication safety support the ideas proposed in the *OWAM* report [1] about learning from unsafe care and validates the purpose(s) of incident reporting systems.

Furthermore, secondary analysis offers the possibility of having access to data for a small fraction of the time and resources it will take one to collect the data themselves, thereby saving cost and time. This is a very important factor because of the limited time and resources associated

with a PhD study. Also, secondary analysis provides the opportunity for more time to consider and carry out the necessary analysis required to answer research questions which may not have otherwise been possible.

Therefore, to address the aim and objectives of this study (Chapter 1.9), a secondary analysis of NRLS data was conducted to answer the research questions. Additionally, the data was readily available for this research and in large quantities.

In my research, I have used an inductive approach to make sense of the data, typically used in qualitative research, due to the nature of my data (incident reports) and the aim and objectives of the study. This is described as building explanations based on the data, from the ground up. It is usually exploratory in nature and aims to establish descriptions of characteristics and patterns [134]. I used this strategy to describe the nature of medication safety incidents in primary care. The findings alongside evidence from the literature were linked back to my aims and objectives to answer my research questions.

2.5 Inclusion criteria

Those reports classified as medication incidents from primary care locations such as general practices, community pharmacies, dental practices, opticians, nursing homes and private residence in England and Wales were included in this study.

2.6 Sample selection

All reports identified as medication incidents reported to the NRLS from primary care since its inception in 2003 to 2013 were considered to be the full dataset (83,869 incident reports). In the PISA study [83], where NRLS reports from general practice were analysed using similar methods as this study, 75.9% of incidents that were coded by the PISA team as medication incidents were also coded as medication incidents in the NRLS database (sensitivity of about 76%). This information was used in deciding how the full dataset was drawn from the NRLS database using NRLS taxonomy. This was achieved by using the taxonomy code of 'Medication' to filter out medication incidents from the primary care incident report data between 2003 and 2013. A total of 83,869 reports were identified. Given the nature of the study and time constraints, it was not possible for all the incidents in the full dataset to be analysed. The data needed to be coded as part of the analysis and, depending on the length of report, each record took anywhere between three and twenty minutes to code. This time-consuming process meant that a representative sample was required for this time limited PhD project.

To get a feel of the data, an initial exploratory search of the full dataset was conducted to gain an overview of the data using the NRLS taxonomy to help with sample selection, given the inductive and exploratory nature of this research.

To ensure my sample population was current, weighting by year of report was considered in order to accommodate for more recent reports. However, in the exploratory search of the full dataset, incidents reported to the NRLS were found to be already weighted as number of reports significantly increased every year, with about a quarter of the incidents reported in 2013. Therefore, there was no need to incorporate weighting in the sampling strategy to be adopted.

Medication incidents with harmful outcomes are detrimental to both patients and healthcare service providers both economically and otherwise as described in Chapter 1.1. It is important that these are studied and understood to learn lessons and ensure prevention of future occurrences. Therefore, from the full dataset, all incidents classified by the reporter as moderate harm (n = 2285), severe harm (n = 226) and death (n = 45) were included in the study sample.

From the remaining mild harm (n = 7,061) and no harm (n = 74,217) incidents, an initial random sample of 100 reports were taken from each category to get a feel of the no and mild harm incidents before deciding on further sampling. These were read and double checked against their harm severity allocations before taking a final sample from these categories to make up the study sample. After confirming the consistency of the harm severities allocated to the reports, I then took a random sample of 1,500 reports from each of the mild and no harm incidents to make up the remainder of my study sample with consensus agreement with my supervision team. Including the mild and no harm reports in the sample was important to ensure learning was achieved

from the vast majority of reported incidents. Although these have not caused much harm, future reoccurrence may likely cause a higher degree of harm to patients. Due to the inductive and exploratory nature of this study, it was better to have a fair representation of the mild and no harm incidents. Taking a combined random sample of the remaining mild and no harm incident reports would have left a small number of incidents causing mild harm in the sample, as this makes up less than 9% of the remaining reports.

Overall, this process resulted in a total study sample of 5,556 incident reports to be processed and analysed using the PISA patient safety classification system (see Section 2.7.1). Table 2.1 shows the summary of the study population taken from the NRLS by reported harm severity.

Table 2.1 ***Overview of study population (n=5,556)***

	Pre-allocated harm severity				
	No	**Mild**	**Moderate**	**Severe**	**Death**
Sample taken	1500/74,217 (2%)	1500/7,061 (21%)	2285/2285 (100%)	226/226 (100%)	45/45 (100%)

2.7 Data Analysis

Four stages were proposed for the analysis of the free-text data in this study, I adopted the principles used in the original PISA study [15]. This approach was appropriately suited given the objectives of my study, limited time and resources, predetermined retrospective sample

population, and the sheer volume of the data. The data analysis plan developed to achieve the aim and objectives of this study was based on a sequential exploratory approach to analysing data [145]. In summary, the four stages of analysis were:

- Stage 1: Data classification – data familiarisation and coding
- Stage 2: Generation of data summaries – using Exploratory Data Analysis (EDA),
- Stage 3: interpretation of codes and theme generation – Seeking to understand the most commonly identified medication safety themes, events leading up to it and reported contributory factors, and the contexts within which they occurred – thematic analysis,
- Stage 4: Recommendations for interventions – using findings from stage 3 and the literature to identify risk reduction approaches for identified areas to improve medication patient safety in primary care.

Each stage will now be discussed in more detail.

2.7.1 Data classification – familiarisation and coding

Analysis of the free text descriptions of safety incident reports has largely been done through various safety classification systems commonly called taxonomies given the unstructured nature of the free-text data in reports. This is where factors with similarities are grouped together to aid in identifying relationships between them. Many safety classification systems have been developed in the past to deconstruct patient safety incidents to aid the understanding of the factors responsible for such incidents and to inform system improvements;

some of which were discussed in Chapter 1 [79, 146-156]. These include the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [55], the Australian Incident Monitoring System (AIMS) [157], the National Reporting and Learning System (NRLS) [41], the Eindhoven Classification Model for System Failure [80], the International Classification for Patient Safety (ICPS) [27], the International Taxonomy of Medical Errors in Primary Care [158], and the PISA patient safety classification system [83]. Authors of research papers have also developed (or adopted) and named other classification systems such as International Taxonomy for Errors in General Practice [153] and Medical Event Reporting System for Transfusion Medicine [159] specifically for use in their respective studies. All these different classification systems used in patient safety research limit comparisons between studies making it difficult to maximise the learning from patient safety incidents. The Conceptual Framework for ICPS was developed by WHO to tackle this issue and bring about international consensus to classifying patient safety incidents using preferred terminologies and concepts.

In terms of the validity and reliability of the various classification systems when deciding the most appropriate classification system to use, a review conducted by WHO in 2003 provided an overview of the status of patient safety incident classification systems in healthcare and concluded that most classification systems' validity was inadequate and their reliability was not being reported [81]. These were mostly developed empirically or based on a theoretical framework or model.

However, few classification systems have been adopted and used in research since their development. A further systematic review conducted in 2013 identified 40 different classification tools from 61 included studies [160]. As part of the review, acceptable reliability and criterion validity were assessed from the studies included. Of the 61 studies, only two tools were found to have met this criteria, one of which was NCC MERP discussed previously and Dean and Barber's tool [56].

Given that incident report data is highly variable in quality, and given what WHO Safer Primary Care recognised in 2013 as a limited field with poorly developed research tools, as discussed in Chapter 1 [82]. I intend to advance a relatively new and existing empirical approach developed post 2013, using the same data (NRLS) but with a more focus on medication incidents. In doing so, there is an opportunity to add value by updating and refining an existing system used in a NIHR Health Services and Delivery Research study which has been developed using the constant comparative approach [15].

Although the PISA classification system is relatively new compared to other existing classification systems, it was developed by qualitative research and multi and mixed methods health services researchers. It has been reviewed by multiple leading health services researchers for NIHR. The PISA classification methods and papers that have used the classification system have been peer reviewed extensively at major international journals [161-165].

In this study, I adopted this recently developed PISA patient safety classification system, which is aligned to WHO ICPS [15, 123]. In addition, this classification system accounts for some of the complex incident reports which involve a sequence of events culminating and contributing to an incident, which the other taxonomies do not. It allows for detailed coding of complex incident trajectories whilst able to preserve the meaning and understanding about the sequence of events culminating to the patient safety incident. It was also developed using NRLS data, the same source of data as for this study.

Therefore, data was coded using the PISA classification system which allows for comparison of similar studies and also extends the learning opportunity to a wider audience than England and Wales. The PISA classification system was developed to include multiple coding frameworks (see Appendix 2 for coding frameworks used) to help characterise the sequence of events in a patient safety incident report by applying codes. Free-text entries of each report were read, and then codes were applied to describe the primary incident type (i.e. the incident with the most direct effect on the patient), other possible subsequent incident(s), potential contributory factors (apparent causes) and patient outcomes. Where no existing codes were available to appropriately describe an incident, new codes were developed and the coding frameworks reiterated with permission from PISA.

Before coding of the study sample started, I received training from the PISA team at Cardiff University. This involved incident report classification, root cause analysis and human factors in healthcare. This

was augmented by coding a training dataset of 401 incident reports and having it double checked by an experienced coder for accuracy and consistency. I coded the study sample after completion of training. Full details on the methods used in the coding process using the PISA classification system are described below.

2.7.1.1 Data coding process

To code an incident report, I first orientate myself to the free-text elements of the report as well as some of the categorical information being reported before going through the process of coding which is explained further below.

Free-text entries of the incident reports were read and coded using the PISA classification system. After getting familiar with the content of a report, codes were selected from the PISA coding frameworks in a systematic way to show the trajectory of the incident. Multiple codes from the coding frameworks could be used to represent the incident type(s), contributory factor(s) and incident outcome(s). Codes were selected and applied to each report objectively, ensuring codes represent what was explicitly stated in the report only. No assumptions were made, nor any details inferred from what was stated in the narrative. Primary incidents were those closest to the patient's outcome whereas contributory incidents included those that contributed to the occurrence of another incident. This meant the steps preceding and leading to a primary incident in a report could be modelled and the narrative reconstructed whilst retaining its original meaning based on acknowledged semantic relationships between codes and classes. This

was done iteratively and re-classification of previously classified reports was done if necessary. Figure 2.1 shows a flow chart of the coding process.

The PISA classification system uses rules to define the way codes are assigned to reports which were modelled based on the recursive model of incident analysis developed by the Australian Patient Safety Foundation (see Appendix 3 for examples of rules applied) [166]. This allowed modelling of the sequence of events leading to the primary incident type and to the patient outcomes causing patient harm. It also allowed for multiple incidents or contributory factors from one report to be coded in a structured way, with the incident closest to the patient being the primary incident type and then working backwards, giving a rich description of the report.

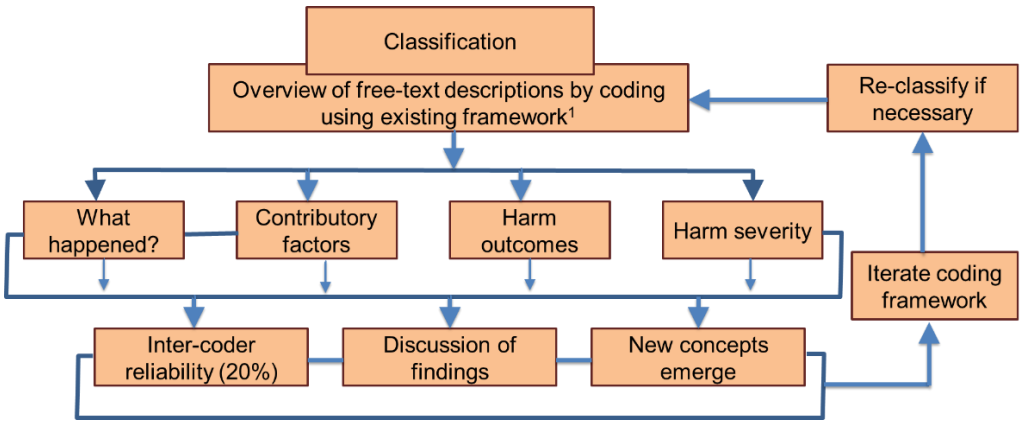


Figure 2. 1 A flow chart representation of the coding process

Perceived harm severity of incidents were already assigned in the reports by the reporters; however, during coding of the training dataset, it was observed that harm severity allocated to some of the reports

were wrongly classified, with most of the wrong classifications being overestimations. Therefore, severity of harm was re-classified after reading the free-text content of the reports and gaining an insight on the patient outcomes in the study sample. This was also coded during the process of allocating codes from the PISA frameworks described above. However, this reclassification was achieved using a recently developed harm severity classification specific to primary care which was aligned to the WHO ICPS [57]. Although harm severity for the data was ought to have been classified by the reporter using the NRLS taxonomy [41], this recently developed harm severity classification system was used instead, again to promote comparison and generate maximum learning. Furthermore, the harm classifications for the two systems were similar; however, the classification system used for this study contained more detail in its descriptions of the different harm classifications, which covers the descriptions used by the NRLS. The decision to recode the harm severity following evidence of miss-classification of the data was to prevent systematic error. Overestimation creates an inaccurate picture that would not be appropriate to publish.

The overriding principle influencing this process was that harm severity could only be recoded where there was explicit evidence in the reports submitted to the NRLS which corresponded to a less or more severe harm level. Without this firm stance, where no implicit assumptions were made or actually possible, reports without that extra detail to confirm or contradict the assigned harm severity were left as unclear.

This is one limitation of using these data to identify priorities based on harm severity.

Potential reasons for misclassification could include the reporter was not aware of the criteria (or definitions) for each severity level, or the outcome for the patient was unclear at the time of reporting. Related, where an incident has been investigated following a report being filed, or where there is now a clearer understanding about patient outcomes, some organisations will update the harm severity to retain a more accurate log for this variable. Therefore, it is important to remember that each contributing organisation to the NRLS will have different procedures for quality assuring and maintaining the accuracy of their data. In this regard, an additional review of report content, and where there is explicit and clear evidence which supports reclassification, I recognise this is an added value step which I can adopt whilst coding these data.

Despite this structured approach to re-classification, it must be recognised that despite explicit evidence being required to justify the changes, there is a risk of compromising the precision of harm severity results. This include the potential loss of the number of incident reports included in further analysis of the harm severity variable; thereby decreasing the precision of the sample in regard to harm severity results. Furthermore, there is a chance for wrongful recoding of the incident report which may be due to the fact that the reporter, may not have included all of the information available to them in the report, to be able to accurately code the severity of harm. Also, there is the potential

of a reported incident being amended at a later date following the initial submission; this may also lead to wrongful recoding of the incident's harm severity due to the lack of further information added to the report which may have led to the original harm severity allocation.

Overall, on balance, harm severity is one variable of several for informing judgements for identifying patient safety priorities. In addition, modern patient safety theories acknowledge that the same incidents and contributory factors can result in a no harm or near miss in one context and a catastrophic death in another.

Further, some of the information in the reports were also re-coded and corrected wherever possible after reading the free-text due to the information not being recorded appropriately in the reports. These included 'medicine names' and 'care setting of occurrence'. New variables not in the NRLS taxonomy were also added and coded for this study. These included 'gender of patient' and 'reported staff member involved' with the incident. Gender was recorded where the patient's gender was eluded to in the free-text description and left blank where it was not. Reported staff member referred to the staff member who was fully or partly responsible for the occurrence of the incident or made the error where applicable. The majority of reports, however, did not specifically mention the role of the healthcare professional or staff member involved with the incident. Therefore, where this was the case, it was recorded under the grouped categories formed based on the care setting of occurrence, e.g. community pharmacy or general

practice staff. Each of the aforementioned variables were considered for each report before moving on to review the next incident report.

2.7.1.2 Double coding

To ensure validity, reliability and improved accuracy of coding, a random sample of 20% of reports was double coded by a second coder Gill Gookey, an experienced general practice pharmacist and a researcher who received similar coding training delivered by the PISA team. These were done at specific coding intervals to check the discordance of the primary incident type and harm severity allocation to ensure consistent application of the coding frameworks. Both Gill and I met regularly to discuss discrepancies from 50 double coded reports after every 250 reports coded by myself. Resolved discrepancies were amended and lessons learnt for future reference. Where discrepancies in coding could not be resolved between the two of us, a third person arbitration was sought (Matthew Boyd).

In total, 1113 reports were coded by Gill Gookey. Of these, we agreed on the coding for 890 reports (80%), and we were able to resolve the discrepancies from 221 of the 223 discordant reports through discussion. However, on two occasions, a third person arbitration was sought before an agreement was reached.

2.7.1.3 Coding management system

The coding process was managed through a bespoke management system developed by Huw Evans, a member of the PISA group with experience in information technology. This provided secure access to

the data based at Cardiff University regardless of geographical location, which other existing qualitative data analysis management software tools do not. The system comprised of a backend database system and a web-based portal. The backend database was built on Microsoft SQL Server 2014, with custom SQL algorithms to provide, for example, live concordance checks between the primary coder and the double coder. The web front end was produced using a customised version of Portofino 4.1.1, an open source web framework written in Java.

2.7.2 Exploratory data analysis, EDA (descriptive statistics) – Quantitative analysis

EDA is a type of quantitative analysis that aims to summarise the main characteristics of a data often visually [145]. This can be used to explore what data can reveal beyond formal modelling or hypothesis testing. Given the nature of the data (incident reports) and the inherent biases associated with it such as under-reporting, incomplete reporting, selective reporting and not being able to detect an incident; most statistical tests (e.g. Chi-squared test, Spearman's rho, Fisher's exact test, t-test, odds ratios, logistic regression) to evaluate relationships between variables would be of limited value when trying to identify priority areas and making recommendations for improvement. It would be more beneficial to identify clusters of like phenomena and analyse them further in terms of their contributory factors and context to achieve said objectives. Therefore, for the purpose of my thesis, EDA analysis approach was used to address some of my objectives set out in Chapter 1.9.

For this stage of the data analysis, EDA was used to describe and summarise the basic characteristics of medication incident reports in primary care. This included identifying the most frequently reported incidents, harm and contributory factors associated with them; and to help identify potential areas that would benefit from interventions or further research and development as will be discussed later on in subsequent chapters. This was achieved inductively and was guided by clinical expertise.

Descriptive statistics in the form of frequency tables and bar charts were used to describe the characteristics of the incident reports which included country of origin, care setting of occurrence, age of patients, gender of patients, staff members involved, incident types, contributory factors, medicines associated with incidents, medication incidents categories and harm severity associations (Objectives 1-3). Medication incident categories were created from clusters of incident type codes of similar origin forming a higher-level category.

The incident category that made up Adverse Drug Reactions (ADRs) were excluded for further analysis past this stage because they were mostly not preventable. In the UK, ADRs are already reported and monitored through the yellow card scheme, this is a reporting system of ADRs to the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA records and reviews the information submitted so that important safety issues can be detected [167]. These included allergic reactions to new medications and undesired side effects

experienced for the first time. Reports from my sample with incidents not fitting any of the reported categories were categorised as other.

When describing the country of origin of reports and reported age of patients, comparisons were made to the populations of England and Wales in 2013 (census sourced from UK - Office for National Statistics) [168].

The Anatomical Therapeutic Chemical (ATC) classification system recommended by WHO for drug utilisation studies was used to classify medicines that were reported to be involved in the incidents. Medicines were classified in a hierarchy with five different levels based on anatomy, therapeutics, pharmacology and chemical substance [169].

An exploratory approach informed by descriptive statistics, through frequency tables and cross tabulations of variables, were used to explore relationships between variables in a sequential way (e.g. incident type vs contributory factors, incident type vs medicines, incident type vs age group, age group vs harm severity, etc.). Further, interpretation was guided by expert clinical guidance which led to the identification of potential priority areas (Objective 4). This was done to first identify the most frequent incidents and the harm severity associated with them and then to identify the nature of the incidents through their relationships with other reported variables. This helped indicate potential areas for improvement through identification of clusters of reports or contributory factors and other factors which could all be potential targets for improvement. The identified clusters of

incident reports were further explored using thematic analysis in stage three of the data analysis for more insights.

All descriptive statistical analyses were conducted using Microsoft Excel 2016.

2.7.3 Interpretation of codes and theme generation (thematic analysis)

Following stages one and two of the data analysis, which identified patterns in the data. I needed to maximise insight from the descriptive analysis by interpretation of codes and understanding of the context, thereby identifying the most important areas involved in medication patient safety incidents in primary care to effect changes. The purpose of this stage of the analysis was to develop a coherent synthesis of the data by identifying the categories and concepts evident from stage 2. This additional process allowed the identification and description of themes in the form of priority areas that could be targeted for interventions to reduce future medication safety incidents.

Exploratory data analysis (stage 2) allowed collation of important medication safety incident codes and investigate the relationships between these codes and other variables such as contributory factors to identify important clusters of incident reports. Identified clusters were examined further and provided an opportunity to identify issues within the context of each subset of data (e.g. incident reports describing deaths as a result of wrong dose being dispensed or administered). The subsets of reports were re-examined by me and sought to identify

any relevant issues (context) that might not have been clearly expressed in stage 2 of the analysis which could help to understand the relationships identified in that analysis in more detail. Themes could be generated with additional contextual understanding of the categories generated in stage 2. For example, ‘inadequate procedures for implementing medication changes resulting in poor transfer of care between settings’. Transfer of care between settings being the category identified in stage 2 with additional information generated in stage 3 providing a better understanding of the context.

From the reports used for further examination, only reports with more information i.e. containing at least one contributory factor or contributory incident were re-examined and thematically analysed. Reports lacking depth about the reasons behind the occurrence of incidents were left out of this stage of the analysis.

During this stage, similar coded data could be grouped together to form a new category due to characteristics that they share together beyond parent-child relationships of the coding framework, which was mostly the outcome of the previous stage. Insights from the themes identified were combined with that of stage 2 within the data to identify priority areas and help formulate hypotheses for improvement which I will show in subsequent chapters of this thesis.

2.7.4 Recommendations for intervention

Stages 1 – 3 of the analysis allowed the emergence of themes from the data through categorisation of reports formed by grouping codes with

similar characteristics and understanding the context [170] as discussed previously.

This allowed me to identify potential priority areas which could be targeted for improvement strategies and further research to help mitigate medication safety incidents. These potential priority areas were discussed by myself and my supervision team to identify the key priority areas where an intervention will be of most benefit in reducing patient safety incidents involving medication.

Following identification of the areas, recommendations of interventions were made and informed by existing literature on medication safety intervention studies. Synthesis of these interventions through literature reviews (as described in Chapter 1.1) alongside reading of the incident reports, informed the change ideas for addressing the priority areas. Grading of Recommendations, Assessment, Development and Evaluations (GRADE) rating was used to assess the quality of the studies identified where possible [171].

GRADE is a framework that is used to assess, develop and present summaries of evidence in a systematic way which helps to make clinical practice recommendations. It is one of the most widely used grading tool for assessing the quality of evidence and for making recommendations [172, 173]. The purpose of using GRADE in this study was to assess the quality and strength of intervention studies that have been identified from the literature searches (described in Chapter 1), in order to guide judgements about the strength of evidence (where

applicable) for existing interventions that could improve safety. This will help determine the strength of the recommendations provided, which is the extent to which one can be confident that the given recommendation is likely to be effective. GRADE consists of four ratings: very low (the true effect is probably markedly different from the estimated effect), low (the true effect might be markedly different from the estimated effect), moderate (it is believed that the true effect is probably close to the estimated effect) and high (it is believed with a lot of confidence that the true effect is similar to the estimated effect) [171]. Although GRADE follows a systematic way to determine the level of evidence, there is a considerable amount of subjectivity involved, this could be a limitation to using this framework.

To assess the rating of evidence, an initial rating is given to each evidence which is determined by the type of evidence, i.e. randomised trials (high), observational studies (low) and any other evidence (very low). This rating is then downgraded if required after assessing the risk of bias, imprecision, inconsistency, indirectness and publication bias. The rate could also be upgraded if there is a very strong evidence of association, when there is a clear dose-response gradient or when the confounding factors are likely to have reduced the effect size where this is applicable [171].

A driver diagram, which is a quality improvement tool, was used to visualise the key concepts and ideas for improvement that emerged from the analysis. The driver diagram graphically mapped potential interventions to the concepts. In doing so, healthcare teams that

identify the problem summarised by the concept (such as, need for improved staff education and training), could then review the intervention(s) that have been developed to minimise / improve this concept in practice [174, 175]. For example, where there is evidence of studies describing an intervention which tackled the change concepts, these were reported under the 'evidence of efficacy' column. The GRADE rating is colour coded and the colours correspond to the strength of the study in the 'strength of evidence' column. Where no evidence was found, the phrase 'No evidence' was used to describe this due to the fact that the review conducted was not a systematic review of all literature.

2.8 Ethical considerations

The Aneurin Bevan University Health Board research risk review committee waived the need for ethical review due to the anonymised nature of the data (ABHB R and D reference number: SA/410/13) – see Appendix 4. Ethical considerations for the use of this data was made through Cardiff University as part of a bigger project involving the NRLS data by the PISA group.

Although this study was considered a research involving NHS patients' data, the health board waived the need for ethical review because the NRLS data was anonymised and the application for access to the data was deemed by NHS England to fully adhere to Caldicott principles. A Data Sharing Agreement was signed between Cardiff University and NHS England.

The NRLS data had already been anonymised by NHS England with no method to contact the original reporter, this made it impossible to obtain consent from patients. Patients or healthcare organisations could not be identified without contacting NHS Improvement. No additional data about NHS patients were collected during or after the study. Where patient safety concerns were raised from information derived from a report, provisions were made to relay this information to the relevant leads at English NHS Clinical Commissioning Groups (CCGs) or NHS Wales Boards to appropriately deal with such concerns.

While reports were anonymised according to NHS England's information governance policies, the PISA team added additional level of security to reduce the risk of identifying a patient, staff or healthcare organisations. This included clinical details of rare cases which could become identifiable because of its rare occurrence.

In terms of data security, the Data Sharing Agreement specified the security measures needed throughout the lifecycle of the data especially during storage, transmission and destruction. The SQL database was stored on a designated computing cluster that was housed securely in the Division of Population Medicine at Cardiff University. The cluster had full NHS Information Governance Toolkit for secondary use of data. The security requirements were scrutinised further by the University's Informatics Services Team where they performed monthly tests to ensure compliance with all policies. Data were backed up every 15 minutes to local storage and encrypted tapes

overnight which were kept in fireproof safe in the Informatics Service Team's data centre.

All coding work was completed via the computing cluster with access only granted to PISA team members. I was part of the PISA team for three years following my appointment by Cardiff University as a Research Associate with the University, a privilege which provided me with access to the data. I was able to gain access to the data from offsite via a secure Virtual Private Network (VPN) connection which connected me to the cluster whilst maintaining security and access requirements which is provided through Cardiff University, the gatekeepers of the data.

Chapter 3 Results: Descriptive analysis – characterisation of primary care medication safety incident reports

3.1 Overview of chapter

This chapter will present the overall descriptive analysis of the sample taken from the medication related safety incidents reported to the NRLS in England and Wales. This analysis describes the characteristics of the primary care incident reports in terms of the following variables: incident types or categories, their frequencies, countries of origin, care settings involved, staff members involved, patients' age and gender, medicines involved and contributory factors (Objective 1). The analysis also explores which characteristics are associated with different levels of harm severity (Objective 2: determine the medicines or medicinal classes most frequently involved and associated with what degree of patient harm; and, Objective 3: determine which characteristics described in Objective 1 are associated with what degree of patient harm). A total of 5,556 incident reports were sampled and coded for this study (details described in Sections 2.6 and 2.7).

3.2 Reports excluded from the analysis

In total, 539 (9.7%) of the 5,556 reports were excluded from analysis. Most of the excluded reports were either not from primary care (i.e. incidents originated from secondary care) or did not describe a patient safety incident, so were deemed irrelevant (n = 312, 5.6%). A number

of reports lacked the necessary information to ascertain what had happened and were also excluded (n = 154, 2.8%). Further, although some reports described safety incidents, they were not medication-related (for example, one incident report described how a patient refused to let nurses have a look at their pressure areas) (n = 66, 1.2%). Table 3.1 shows the summary of reports excluded from the analysis.

Table 3.1 Incidents not included in the analysis (n = 539)

Excluded incidents	**Frequency (%)**
No harm from primary care or irrelevant	312 (57.9)
No details or insufficient detail	154 (28.6)
Not a medication incident	66 (12.2)
Defensive reporting e.g. when a patient is refusing care	2 (0.4)
Reporting issues not related to healthcare – relating to vulnerable adults	3 (0.6)
Use of the reporting system to report patient suicides or attempted suicide	1 (0.2)
Patient self-harmed	1 (0.2)
Total	**539 (100.0)**

3.3 Analysed incident reports

3.3.1 Overview

A total of 5,017 incident reports were included in the analysis in this study. Harm severity could only be established in 53.1% (n=2,664) of these reports; it was not clear in the remaining 46.9% (n=2,353) due to lack of information on the incident outcome in the reports' free-text. Table 3.2 shows the correlation between reported harm severity and re-

classified harm severity. Only 30.5% of the reports (n = 1,528) retained the harm severity allocated to them by the reporter following the re-classification process. The remaining reports were either unclear (as stated above) or were re-classified into other harm severity categories (n = 1,136, 22.6%) - see Table 3.2. Of the incidents that were classified into one of the five harm severity categories (excluding unclear), 57.4% (n = 1528/2664) retained the original harm severity allocation. Table 3.3 shows examples of incidents with different levels of harm as coded in this study. It also shows the percentage of analysed reports that have caused each level of harm severity.

Table 3.2 Correlation between NRLS and re-coded harm severity (n = 5017)

NRLS pre-allocated harm severity	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
No	539 (39.0)	64 (4.6)	4 (0.3)	0 (0.0)	0 (0.0)	776 (56.1)	**1383 (27.6)**
Mild	115 (8.4)	486 (35.6)	45 (3.3)	0 (0.0)	0 (0.0)	719 (52.7)	**1365 (27.2)**
Moderate	97 (4.7)	656 (32.0)	460 (22.5)	26 (1.3)	4 (0.2)	804 (39.3)	**2047 (40.8)**
Severe	12 (6.5)	41 (22.0)	63 (33.9)	19 (10.2)	4 (2.1)	47 (25.3)	**186 (3.7)**
Death	1 (2.8)	3 (8.3)	1 (2.8)	0 (0.0)	24 (66.7)	7 (19.4)	**36 (0.7)**
Total	**764** (15.2)	**1250** (24.9)	**573** (11.4)	**45** (0.9)	**32** (0.6)	**2353** (46.9)	**5017 (100.0)**

Table 3.3 Descriptions, examples and number of reports by harm severity (n = 5017)

Harm severity	Description of outcome	Example	No of reports, n (%)
None	Patient has no symptoms or injury and does not require any treatment as a result	Patient given a higher dose of medication in error but did not experience any side effects	**764 (15.2)**
Mild	Patient has mild symptoms. Loss of function is minimal or intermediate but short term and no or minimal intervention is required e.g. review, additional investigations, observations or minor treatment	Patient given a higher dose of medication in error which resulted in patient experiencing side effects which required minimal intervention	**1250 (24.9)**
Moderate	Patient has symptoms which require interventions such as therapeutic treatment or surgical interventions. They may also cause increased length of stay or causing permanent or long-term loss of function	Patient given the wrong medication in error which led to the patient being admitted to the hospital for a minor surgical intervention as a result	**573 (11.4)**
Severe	Patient has symptoms which requires a life-saving intervention or major surgical or medical intervention. They may also cause major permanent or long-term loss of function and shortening life expectancy	Patient given half the dose of their medication in error and subsequently deteriorated and admitted to the hospital with the diagnosis of stroke and heart failure	**45 (0.9)**
Death	Patient's death being caused or brought forward in the short term by the incident on the balance of probability	Patient given four times the dose of their medication, subsequently collapsed and died as a result of the overdose taken	**32 (0.6)**
Unclear	Outcome is not described or clear from the free-text description as to what level of harm has occurred	Patient given the wrong dose of their medication but no mention of the outcome as a result of the error	**2353 (46.9)**

Of the total incident reports from the sample, only 0.4% (20 reports) were confirmed to be near miss incidents. Near misses were defined as patient safety incidents that may or may not have resulted in unwanted harm to patients but were detected either by chance or through timely intervention before reaching the patient, thereby preventing a

potentially harmful outcome. All other reports (n = 4,997, 99.6%) were identified to be incidents that had occurred and reached the patient.

3.3.2 Country

The country from which each incident originated was provided in 91.5% (4,592) of the total reports, see Table 3.4. Using the population of England (53.9 million) and Wales (3.1 million) in 2013, the relative percentage of reports to the population were 0.008% for both England and Wales. This implies that incident reports from my sample were an accurate representation of the two countries that populated the database.

Table 3.4 Country of origin of reports (n = 5017)

Country	England	Wales	Missing or unidentifiable	Total
No of reports (%)	4352 (86.7)	240 (4.8)	425 (8.5)	5017 (100)

3.3.3 Care setting of occurrence

Reported medication incidents occurred in various care settings in primary care and this was evident in 98.5% (4,943) of reports. It was not possible to identify the care setting of occurrence in 74 reports (1.5%). Table 3.5 provides a summary of reported care setting of occurrence with harm severity.

Table 3.5 Reported care setting of occurrence and harm severity (n = 5017)

Reported care setting of occurrence	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Community pharmacy	550 (16.4)	748 (22.3)	311 (9.3)	22 (0.7)	5 (0.1)	1714 (51.2)	**3350 (66.8)**
Community nursing, medical and therapy service	91 (11.0)	283 (34.1)	111 (13.4)	5 (0.6)	11 (1.3)	329 (39.6)	**831 (16.5)**
General practice	106 (14.5)	183 (25.0)	137 (18.7)	18 (2.5)	14 (1.9)	275 (37.5)	**733 (14.6)**
Community and general dental service	2 (6.7)	17 (56.7)	7 (23.3)	0 (0.0)	2 (6.7)	2 (6.7)	**30 (0.6)**
Not known	15 (20.3)	19 (25.7)	7 (9.5)	0 (0.0)	0 (0.0)	33 (44.6)	**74 (1.5)**
Total	764 (15.2)	1250 (24.9)	573 (11.4)	45 (0.9)	32 (0.6)	2353 (46.9)	**5017 (100.0)**

More than two thirds of the incidents occurred in community pharmacy with harm severity of more than half of these unclear. Of the remaining community pharmacy incidents in which harm severity could be established, almost 80% resulted in no or mild harm. Community nursing, medical and therapy services were the second most common areas where medication incidents occurred. These included areas such as care and nursing homes, patient's own accommodation and schools. Although general practice incidents were the third most common, they had the highest number of incidents resulting in severe harm or death (n = 32 of 77 reports, 41.6%). However, two of the 30 incidents (6.7%) that occurred in dental services resulted in an outcome of death; a higher proportion compared to other primary care settings (<2%).

In total, 92.8% (n = 3108) of the community pharmacy incidents were reported from the community pharmacy and 58.4% (n = 428) of general practice incidents were reported from the general practice, with the remainder being reported from elsewhere in the healthcare system. For example, a prescribing incident that occurred in a general practice surgery being reported by a community pharmacy and vice versa. General practice and community nursing reported most of the remaining community pharmacy incidents whilst the community pharmacy, community nursing and the hospital reported most of the remaining general practice incidents.

3.3.4 Reported staff members involved

The groups of staff members that were involved included pharmacy staff, GP staff and dispensary staff in dispensing practices. In the reports that stated which particular healthcare professional or staff member was involved, the most commonly described staff member was a nurse, followed by a doctor and a pharmacist. Of the 335 reports that indicated the involvement of a doctor in the incident, 25 (7.5%) resulted in an outcome of severe harm or death. This was a higher proportion than for any other implicated healthcare professional or staff member and was responsible for at least 32% (n = 25 of 77) of the total incidents causing severe harm or death from the sample. Other healthcare professionals or staff indicated in reports included prescription clerks, pre-registration students, health visitors and dispensers.

Table 3.6 Staff members most commonly involved in incident reports and harm severity (n = 5017)

Identified staff member involved	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Pharmacy staff (not specified)	497 (16.1)	695 (22.5)	287 (9.3)	18 (0.6)	7 (0.2)	1587 (51.3)	**3091 (61.6)**
Nurse	70 (13.3)	149 (28.2)	34 (6.4)	3 (0.6)	2 (0.4)	270 (51.1)	**528 (10.5)**
Doctor	48 (14.3)	105 (31.3)	77 (23.0)	11 (3.3)	14 (4.2)	80 (23.9)	**335 (6.7)**
GP staff (not specific)	47 (17.3)	60 (22.1)	34 (12.5)	5 (1.8)	3 (1.1)	122 (45.0)	**271 (5.4)**
Pharmacist	41 (19.3)	44 (20.8)	22 (10.4)	2 (0.9)	0 (0.0)	103 (48.6)	**212 (4.2)**
Dispensary staff (GP practice)	5 (11.1)	13 (28.9)	10 (22.2)	0 (0.0)	0 (0.0)	17 (37.8)	**45 (0.9)**
Carers	5 (12.8)	16 (41.0)	1 (2.6)	0 (0.0)	0 (0.0)	17 (43.6)	**39 (0.8)**
Delivery driver	9 (32.1)	3 (10.7)	2 (7.1)	0 (0.0)	0 (0.0)	14 (50.0)	**28 (0.6)**
Dentist	1 (9.1)	3 (27.3)	4 (36.4)	0 (0.0)	1 (9.1)	2 (18.2)	**11 (0.2)**
Healthcare assistant	2 (28.6)	1 (14.3)	2 (28.6)	0 (0.0)	0 (0.0)	2 (28.6)	**7 (0.1)**
Out Of Hours staff	0 (0.0)	1 (14.3)	3 (42.9)	0 (0.0)	0 (0.0)	3 (42.9)	**7 (0.1)**
Receptionist	1 (14.3)	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42.9)	**7 (0.1)**
Others	5 (18.5)	6 (22.2)	1 (3.7)	0 (0.0)	0 (0.0)	15 (55.6)	**27 (0.5)**
Not applicable or unknown	33 (8.1)	152 (37.2)	95 (23.2)	6 (1.5)	5 (1.2)	118 (28.9)	**409 (8.2)**
Total	**764 (15.2)**	**1250 (24.9)**	**573 (11.4)**	**45 (0.9)**	**32 (0.6)**	**2353 (46.9)**	**5017 (100.0)**

Table 3.6 shows the healthcare professionals or staff members most commonly indicated in reports and the harm severity attributed to incidents involving them.

3.3.5 Gender of patients

Patient gender was categorised in 1,865 (37.2%) of the total incident reports. Table 3.7 demonstrate the frequency of harm severity by gender. Although female patients were more commonly involved in the overall patient safety incidents, male patients were more likely involved in reported incidents that have resulted in severe harm or death (table 3.7).

Table 3.7 Reported gender of patients and associated harm severity proportions (n = 1865)

Gender	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Female	187 (16)	497 (43)	190 (16)	10 (1)	5 (0.4)	273 (24)	**1162 (62.3)**
Male	120 (17)	267 (38)	103 (15)	16 (2)	9 (1)	188 (27)	**703 (37.7)**
Total	**307 (16)**	**764 (41)**	**293 (16)**	**26 (1)**	**14 (1)**	**461 (25)**	**1865 (100.0)**

3.3.6 Reported age of patients

Patient age was included in 51.8% (n = 2598) of the total incident reports. Figure 3.1 shows the number of reports by age group. The number of incidents mostly increased along with age from 18 years to 85 years, before decreasing for patients of over 85 years. However, a higher proportion of the population of over 85 years (0.03%) experienced an incident compared to 85 years and under (0.004%). The 76 – 85 years age group had the highest frequency of incidents with 20.2% of reports and those patients under one month had the

lowest frequency with just 0.2% of reports. More than 74% (n = 1927) of the reports involved a patient of at least 46 years.

Both the age and level of harm were apparent in 1264 (25.2%) of the total reports. This is demonstrated in Figure 3.2 where a stacked bar chart shows the number and proportion of incidents for each harm severity outcome by age group. Patients aged 46 years and over were shown to be most commonly involved with incidents resulting in an outcome of moderate and severe harm or death.

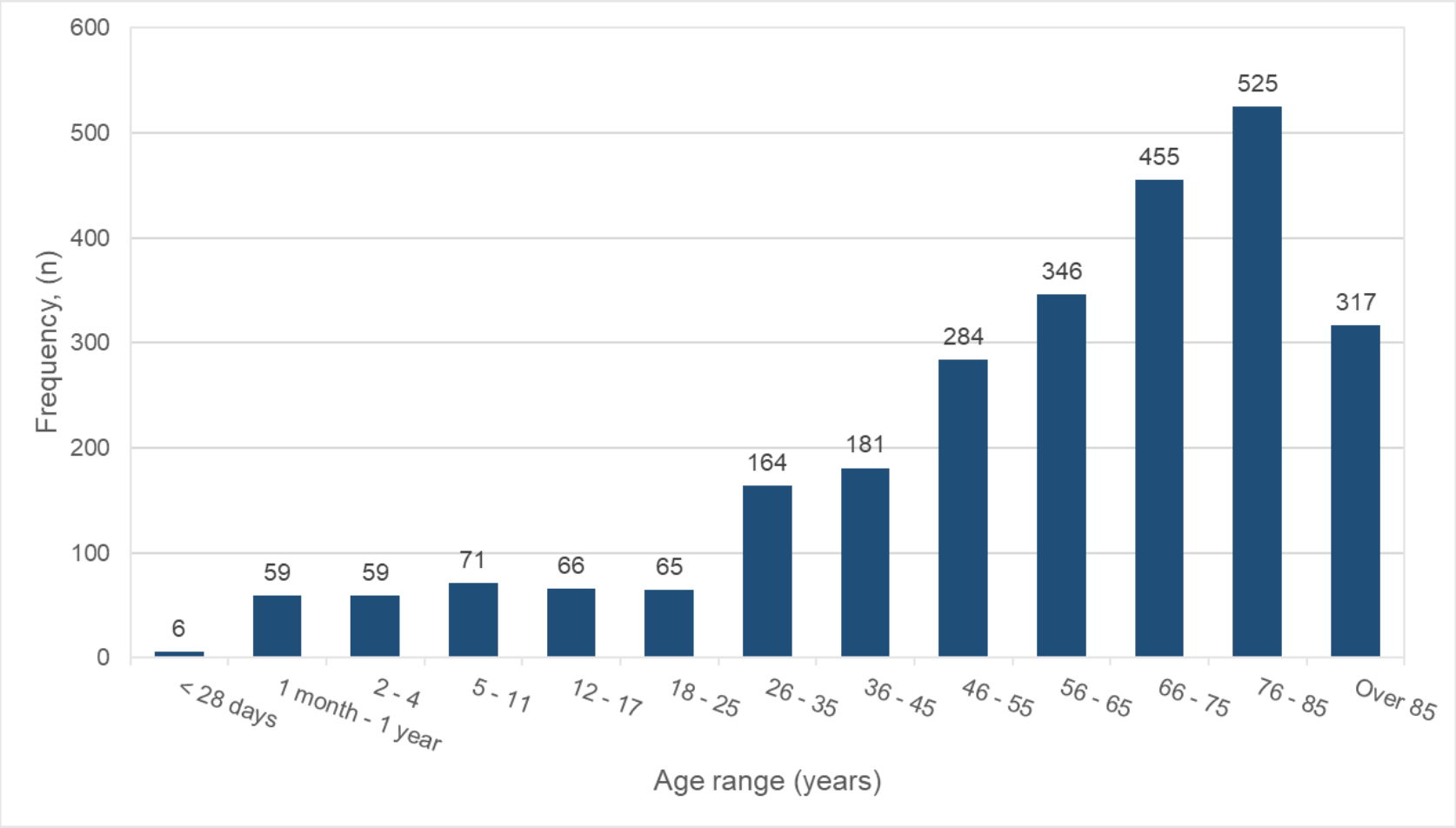
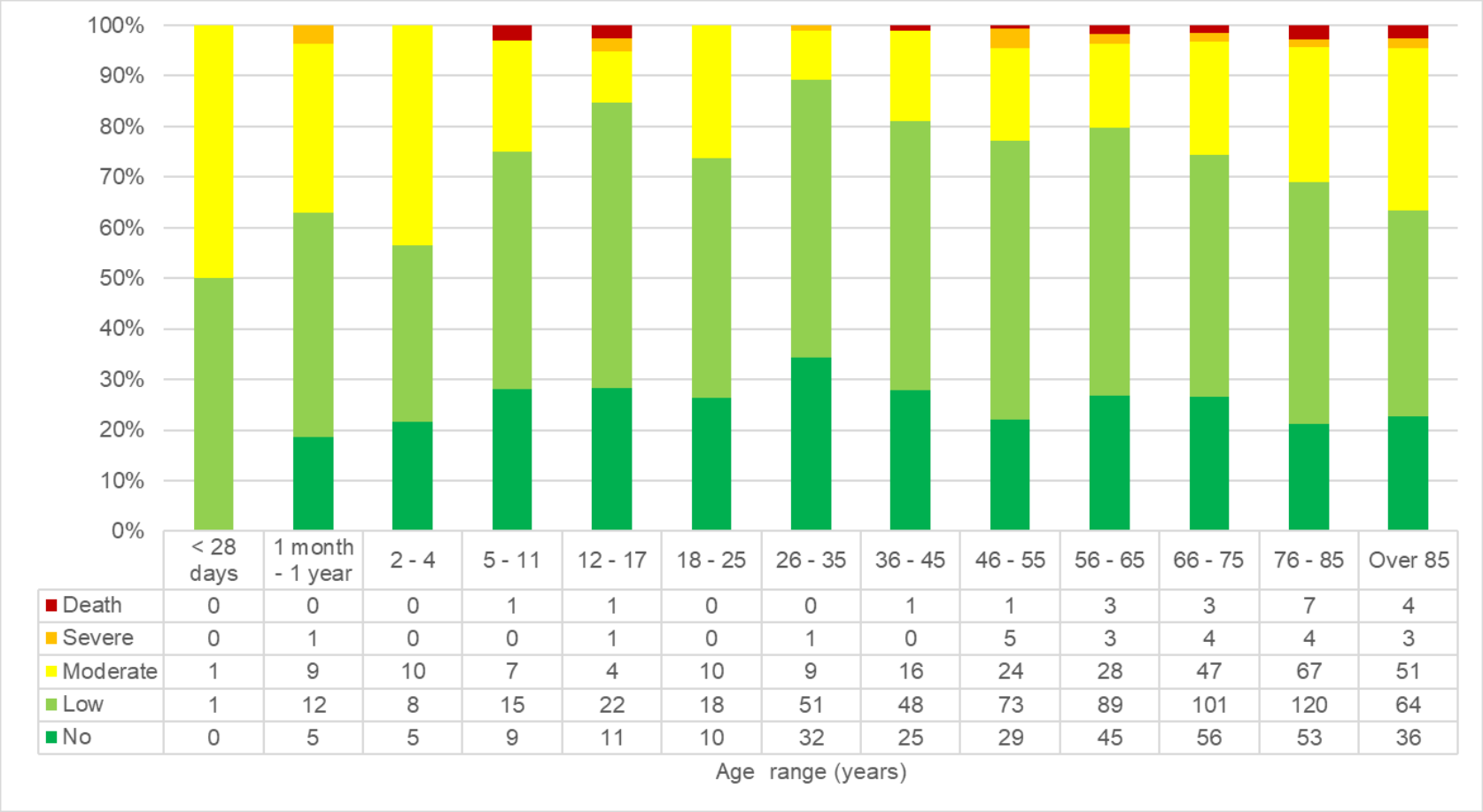


Figure 3. 1 Frequency of reports by age group (n = 2598)



	< 28 days	1 month - 1 year	2 - 4	5 - 11	12 - 17	18 - 25	26 - 35	36 - 45	46 - 55	56 - 65	66 - 75	76 - 85	Over 85
Death	0	0	0	1	1	0	0	1	1	3	3	7	4
Severe	0	1	0	0	1	0	1	0	5	3	4	4	3
Moderate	1	9	10	7	4	10	9	16	24	28	47	67	51
Low	1	12	8	15	22	18	51	48	73	89	101	120	64
No	0	5	5	9	11	10	32	25	29	45	56	53	36

Figure 3. 2 Proportions of level of harm severity per age group (n = 1,264)

3.4 Medication incident categories and harm severities

Table 3.8 shows the range of medication safety incidents and their reported harm severities.

Dispensing incidents were the most frequently reported safety issues by more than two-thirds of the total reports, followed by administration incidents and prescribing and clinical treatment decision incidents. Adverse drug reactions and monitoring incidents had the lowest number of reports. The majority of reported dispensing incidents (where the severity of harm was clear) had a no or mild harm outcome (n = 1298/1651, 78.6%). However, 47.0% (n = 102) of adverse drug reactions, although not due to errors, resulted in serious harm to patients - defined as incidents that have caused a moderate, severe harm or death; derived from a previous NIHR study [83]. Prescribing and clinical treatment decision incidents were the third most common category with medication errors, however, these, along with the monitoring incidents had the highest proportion of incidents resulting in serious harm (where severity of harm was clear) (n = 96/311, 30.9%). This was followed by dispensing incidents (n = 353/1651, 21.4%) and administration incidents (n = 74/369, 20.1%). These incident categories will be elucidated further in the next chapter of this thesis (Chapter 4). ‘Adverse drug reaction’ and ‘Other’ incidents were excluded from further analysis. A total of 190 (3.8%) incidents were classified as ‘Other’ (see Appendix 5 for the full list of the incident types).

Table 3.8 Incident categories by harm severity (n = 5017)

Incident Categories	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Prescribing and clinical treatment decision incidents	84 (19.5)	120 (27.8)	66 (15.3)	9 (2.1)	7 (1.6)	145 (33.6)	**431 (8.6)**
Dispensing incidents	547 (16.2)	751 (22.2)	325 (9.6)	21 (0.6)	7 (0.2)	1729 (51.2)	**3380 (67.4)**
Administration incidents	86 (11.3)	209 (27.5)	65 (8.6)	3 (0.4)	6 (0.8)	391 (51.4)	**760 (15.1)**
Monitoring incidents	0 (0.0)	11 (30.6)	12 (33.3)	0 (0.0)	2 (5.6)	11 (30.6)	**36 (0.7)**
Adverse drug reactions	2 (0.9)	113 (51.4)	85 (38.6)	9 (4.1)	8 (3.6)	3 (1.4)	**220 (4.4)**
Others	45 (23.7)	46 (24.2)	20 (10.5)	3 (1.6)	2 (1.1)	74 (38.9)	**190 (3.8)**
Total	764 (15.2)	1250 (24.9)	573 (11.4)	45 (0.9)	32 (0.6)	2353 (46.9)	**5017 (100.0)**

3.5 Reported contributory factors

In total, 6,688 contributory factors were identified from the included incident reports. These were defined as circumstances, actions or influences thought to have either played a part in the origin or development of an incident, or increased the risk of an incident without directly causing it [27]. Just under 70% (n = 3,490) of the reports described at least one contributory factor while more than a quarter of the reports failed to mention any factors that may have contributed to the occurrence. These factors were categorised from the PISA classification system into staff-related factors, which were the most commonly identified; followed by service-related; patient-related; and

equipment-related factors. A summary of these factors is shown in Table 3.9 below.

The most common staff-related factors involved mistakes, slips and lapses, mostly relating to similarity of medication names or appearances, followed by those resulting from distractions or oversight. WHO's definitions, based on Reason's human error definitions, were used to define mistakes, slips and lapses. A mistake was defined as "a deficiency or failure in the judgement and/or inferential processes involved in the selection of an objective or in the specifications of the means to achieve it, irrespective of whether or not the actions directed by this decision-scheme run according to plan (commissions and omissions)"; errors of conscious. A slip was defined as "an unintended error or execution of a correctly intended action" (errors of action); whilst a lapse was defined as "an error resulting from some failure in the execution and/or storage stage of an action sequence, which may not manifest as an actual behaviour but may only be apparent to the person experiencing them" (failures of memory) [27, 54]. Although further information relating to these were described in most reports, a considerable number only mentioned mistakes (n = 231). Other common staff-related factors included those that described failures in staff decision making processes; mostly violations (such as failure to follow protocols and the lack of knowledge or skill set).

Table 3.9 Principal contributory factors identified

Contributory factor theme (number and percentage of total contributory factors, n=6,688)	Contributory factor subtheme (number and percentage of contributory factor theme)	Most common examples of contributory factors	Frequency (number and percentage of N: contributory factor theme)
Patient-related factors (N = 748, 11.2%)	Patient characteristics (n = 422/748, 56.4%)	Allergy	95 (12.7%)
		Previous health/ medication history of patient	80 (10.7%)
		Palliative care patient	61 (8.2%)
		Patient age	53 (7.1%)
		Patient frailty	31 (4.1%)
	Patient decision making and knowledge (n = 191/748, 25.5%)	Patient or parent has poor understanding	130 (17.4%)
		Patient non-compliant with instructions	37 (4.9%)
Staff-related factors (N = 3,366, 50.3%)	Staff decision making (n = 968/3366, 28.8%)	Failure to follow protocol	451 (13.4%)
		Inadequate skill set or knowledge	279 (8.3%)
		Dispensing medication from Patient Medication Record (PMR)	55 (1.6%)
		Dispensing medication from label	44 (1.3%)
		Wrong professional carries out task	23 (0.7%)
	Mistakes, slips and lapses (n = 2,118/3366, 62.9%)	Similar medication names or appearances	864 (25.7%)
		Distraction/oversight	453 (13.5%)
		Mistakes involving multi-compartment compliance aids (MCCAs)	237 (7.0%)
		Not specified otherwise	231 (6.9%)
		Medication delivery	105 (3.1%)
		Misread/ did not read	97 (2.9%)
		Haste/poor time management	62 (1.8%)
	Other staff-related factors (n = 280, 8.3%)	Not double checked by a 2nd person	184 (5.5%)
		Handwriting	47 (1.4%)
		No or poor supervision or assistance	23 (0.7%)
Equipment-related factors (N = 655, 9.8%)	Design and usability of equipment (n = 604/655, 92.2%)	Issues with medication storage	470 (71.8%)
		Medication packaging	100 (15.3%)
		Poor equipment design	34 (5.2%)

Table 3.9 Principal contributory factors identified (Continued)

Contributory factor theme (number and percentage of total contributory factors, n=6,688)	Contributory factor subtheme (number and percentage of contributory factor theme)	Most common examples of contributory factors	Frequency (number and percentage of N: contributory factor theme)
Service-related factors (N = 1791, 26.8%)	Issues related with protocols (n = 490/1791, 27.4%)	Other non-specified protocols being inadequate, inefficient or absent	377 (21.0%)
		Medication related protocols such as repeat prescribing	93 (5.2%)
	Continuity of care (n = 358/1791, 20.0%)	Continuity of care within primary care	113 (6.3%)
		Care given by locum or agency staff	113 (6.3%)
		Continuity of care between secondary care and primary care	107 (6.0%)
	Working conditions (n = 696/1791, 38.9%)	Busy/overloaded by work	524 (29.3%)
		Inadequate provision of healthcare staff	151 (8.4%)
	Education and training (n = 69/1791, 3.9%)	Deficiencies in knowledge and others' roles	69 (3.9%)
	Service availability and delivery (n = 136/1791, 7.6%)	Lack of stock	53 (3.0%)
		Medication order	37 (2.1%)
		Owed medication	31 (1.7%)
		Long wait for service such as in emergency	14 (0.8%)
Other factors (N = 128, 1.9%)	Others (n = 128)	Patient requiring syringe driver	64 (50.0%)
		Confusion due to generic drug name rather than proprietary name	36 (28.1%)

Continuity of care (delivery of seamless care to patients across care settings or healthcare professionals) such as from secondary care to primary care or within primary care was amongst the most common service-related factors reported. Table 3.9 provides a summary of other service-related factors.

Patient-related factors mostly included the physiological and physical characteristics of the patient. These included allergy, which may explain

some of the adverse drug reaction incidents mentioned earlier on in this chapter. Others included previous health or medication history and potentially vulnerable patients such as children and the frail elderly.

The most frequently reported equipment-related factor was issues relating to the storage of medication; for example, a medication stored in the wrong area of the dispensary. This was followed by medication packaging issues such as when repackaging a medication into a white box before dispensing in a community pharmacy.

Contributory factors relating to more specific incident categories will be expounded upon in the next chapter (Chapter 4). See Appendix 6 for a detailed list of reported contributory factors from the sample.

3.6 Medicines involved in incidents

Although, 92.6% (n = 4647) of the sample reports described at least one medicine that was involved in the incidents, a small number of reports did not (n = 370, 7.4%). In total, 7240 medicines were identified in the included reports. A total of 1041 (14.3%) medicines were involved with no harm incidents, 1829 (25.3%) with mild harm incidents, 862 (11.9%) with moderate harm incidents, 72 (1.0%) with severe harm incidents and 36 (0.5%) with death incidents. The rest of which were involved with incidents where harm severity could not be determined (n = 3400, 47.0%). Table 3.10 shows the most frequently identified classes of medicines (frequency of more than 100) at level 3 (pharmacological) of the ATC classification system and the harm severity associated with them.

Opioid analgesics and antithrombotic agents (mostly warfarin) were involved in more incidents that caused severe harm or death (n = 19/108, 17.6%), where severity of harm could be established. Although penicillin antibiotics were not in the top thirteen of medicine classes involved, they were the third medicine class involved with patient deaths. Antiepileptics were associated with the highest number of incidents to have caused moderate harm, followed by opioids and antithrombotic agents.

The relationship between medicine classes and incident categories, and harm severity will be discussed further in Chapter 4. See Appendix 7 and Appendix 8 for a detailed list of all medicines described, classified at levels 1, 2 and 3 of the ATC classification system.

Table 3.10 Principal medicines and harm severity (ATC 3) (n = 4502, 62.2%)

Drug class	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Antidepressants	46 (9.6)	149 (31.2)	43 (9.0)	2 (0.4)	1 (0.2)	236 (49.5)	477 (10.6)
Opioids	68 (15.9)	111 (25.9)	68 (15.9)	4 (0.9)	4 (0.9)	174 (40.6)	429 (9.5)
Antiepileptics	50 (12.6)	117 (29.4)	71 (17.8)	2 (0.5)	0 (0.0)	158 (39.7)	398 (8.8)
Insulins and analogues	54 (14.5)	118 (31.6)	33 (8.8)	0 (0.0)	0 (0.0)	168 (45.0)	373 (8.3)
Antithrombotic agents	50 (15.2)	71 (21.6)	68 (20.7)	4 (1.2)	7 (2.1)	129 (39.2)	329 (7.3)
Antipsychotics	16 (5.8)	85 (30.6)	43 (15.5)	1 (0.4)	0 (0.0)	133 (47.8)	278 (6.2)
Beta blocking agents	30 (12.4)	58 (24.0)	27 (11.2)	3 (1.2)	0 (0.0)	124 (51.2)	242 (5.4)
Drugs used in addictive disorders	60 (29.0)	40 (19.3)	11 (5.3)	0 (0.0)	1 (0.5)	95 (45.9)	207 (4.6)

Table 3.10 Principal medicines and harm severity (ATC 3) (n = 4502, 62.2%) (Continued)

Drug class	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Lipid modifying agents	48 (23.5)	37 (18.1)	16 (7.8)	4 (2.0)	0 (0.0)	99 (48.5)	204 (4.5)
Selective calcium channel blockers with mainly vascular effects	14 (7.2)	44 (22.6)	19 (9.7)	3 (1.5)	1 (0.5)	114 (58.5)	195 (4.3)
Blood glucose lowering drugs, excluding insulins	20 (10.6)	57 (30.3)	18 (9.6)	3 (1.6)	1 (0.5)	89 (47.3)	188 (4.2)
Angiotensin Converting Enzyme (ACE) inhibitors	21 (12.5)	41 (24.4)	16 (9.5)	3 (1.8)	0 (0.0)	87 (51.8)	168 (3.7)
Drugs for treatment of peptic ulcer	20 (12.7)	36 (22.8)	16 (10.1)	3 (1.9)	0 (0.0)	83 (52.5)	158 (3.5)
Beta-lactam antibacterials, penicillins	21 (14.6)	43 (29.9)	18 (12.5)	1 (0.7)	3 (2.1)	58 (40.3)	144 (3.2)
Anti-inflammatory and antirheumatic products, non-steroids	7 (5.5)	24 (18.9)	24 (18.9)	2 (1.6)	2 (1.6)	68 (53.5)	127 (2.8)
Other drugs for obstructive airway diseases, inhalants	38 (30.2)	22 (17.5)	4 (3.2)	0 (0.0)	0 (0.0)	62 (49.2)	126 (2.8)
Other analgesics and antipyretics	25 (20.8)	19 (15.8)	11 (9.2)	2 (1.7)	1 (0.8)	62 (51.7)	120 (2.7)
Thyroid preparations	21 (17.9)	28 (23.9)	8 (6.8)	1 (0.9)	0 (0.0)	59 (50.4)	117 (2.6)
Antiglaucoma preparations and miotics	13 (11.5)	20 (17.7)	3 (2.7)	3 (2.7)	0 (0.0)	74 (65.5)	113 (2.5)
Hypnotics and sedatives	28 (25.7)	34 (31.2)	3 (2.8)	1 (0.9)	1 (0.9)	42 (38.5)	109 (2.4)
Total	**650 (14.4)**	**1154 (25.6)**	**520 (11.6)**	**42 (0.9)**	**22 (0.5)**	**2114 (47.0)**	**4502 (100.0)**

3.7 Summary of findings

This chapter has demonstrated the main characteristics of medication safety incidents in primary care reported to the National Reporting and Learning System (NRLS) in England and Wales. These included the number of incidents reported, quality of reports, origin of incidents, healthcare staff involved, age and gender of patients, medicines involved, main incident categories and the most common contributory factors reported. The following findings were identified:

- Near miss incidents were uncommonly reported to the NRLS or were not captured accurately in the database.
- Some incident reports were submitted from a different care setting to the one where the incidents occurred.
- General practice incidents were more likely to result in a higher level of harm than those occurring in other primary care settings.
- Medication incident reports from primary care that describe a higher level of harm (severe harm or death) are likely to involve doctors.
- Although female patients were more commonly involved with medication safety incidents, male patients were more likely to be involved with severe harm or death incidents.
- Dispensing incidents were the most commonly reported medication safety incidents in primary care (n = 3380, 67%).
- Adverse drug reactions (not errors) accounted for 4% (n = 220) of incident reports.

- Antidepressants (n = 477) were the most frequently reported medicines, followed by opioid analgesics (n = 429), antiepileptics (n = 398), insulins (n = 373) and antithrombotic agents (n = 329).

Although the quality of incident reports could be better, this national database provides a unique opportunity for improvement studies of patient safety incidents. In the following chapter, I will explore in detail the various incident categories identified, including their characteristics, contributory incidents and reported contributory factors in order to generate recommendations for improvement informed by existing literature and identify areas or gaps for further research.

Chapter 4 Results: Medication incident categories

4.1 Overview of chapter

In this chapter, I will build on Chapter 3 (which focused on Objectives 1 – 3) and address Objectives 4 and 5. I will do so whilst focusing on the medication incident categories identified in Chapter 3 referring to the different stages of the medication use process: prescribing and monitoring, Dispensing and administration stages. The objectives are stated below:

1. Describe the characteristics of medication incident reports in primary care such as location or care setting of occurrence, patients' age and gender, healthcare professional involved, types and frequency of incidents and contributory factors.
2. Determine the medicines or medicinal classes that are most frequently involved and associated with what degrees of patient harm.
3. Determine which characteristics are associated with what degree of patient harm.
4. Identify potential priority areas for intervention by mapping relationships between themes e.g. incident types vs contributory factors and understanding the contextual factors.
5. Make recommendations and identify areas for quality improvement projects and future research.

Prescribing and monitoring responsibilities are usually held by the same care setting in primary care, consequently the prescribing and monitoring incident categories described in Chapter 3 were merged and analysed in this chapter (n = 467 of 5017 reports, 9.3%). The categories comprise mostly of errors made during medication use process. Through a combination of descriptive and thematic analyses of reports, I will describe in detail the types of incidents identified and the contributory factors that emerged from the different categories. I will demonstrate how the characteristics of these incident reports alongside the contributory factors can be used to identify areas of weakness and priority areas needing intervention to improve medication patient safety. A synthesis of intervention ideas from existing literature to identify potential interventions that could address these areas will also be provided. I will then describe my recommendations in the form of a driver diagram; mapping priority areas to suggested intervention(s) informed by the literature, for improved safety of medication use in primary care.

4.2 Characteristics of medication incidents

4.2.1 Care setting of occurrence

Given most prescriptions in primary care originate from general practice, it is not surprising that, following the verification of care setting of occurrence, the majority of prescribing and monitoring incidents originated from general practices (n = 402 of 467, 86.1%). Some of the reports described the specific part of the general practice where the

incidents occurred; this included out of hours (OOH) general practice, specific health clinics and walk in centres. Prescribing and monitoring incidents also originated from other areas of community nursing, medical and therapy services including care homes. It was not clear where most of the other incidents originated from, however a small number of incidents were attributed to areas such as dental service, mental health service, prison service and police stations. Table 4.1 shows the care settings where prescribing and monitoring incidents originated and the harm severities associated with them.

In the previous chapter (3), I described how some incidents are not reported from the actual care setting of occurrence and this was evident for prescribing and monitoring incidents. For example, of the 402 incidents originating from the general practice, 37 (9.2%) were reported by a community pharmacy and six (1.5%) were reported by a hospital. These were mostly due to the error being identified in the community pharmacy before dispensing, or in the hospital following admission. These incidents were then reported to the local incident management system in each healthcare organisation and then sent in batched returns to the NRLS.

Table 4.1 Reported care setting of occurrence for prescribing and monitoring incidents broken down by harm severity (n = 467)

Reported care setting of occurrence	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
General practice	62 (16.4)	104 (27.6)	70 (18.6)	9 (2.4)	8 (2.1)	124 (32.9)	377 (80.7)
OOH GP	2 (16.7)	1 (8.3)	3 (25.0)	0 (0.0)	0 (0.0)	6 (50.0)	12 (2.6)
Health clinic	1 (9.1)	5 (45.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (45.5)	11 (2.4)
Walk in centre	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	2 (0.4)
Sub-total	**65** (16.2)	**111** (27.6)	**73** (18.2)	**9** (2.2)	**8** (2.0)	**136** (33.8)	**402 (86.1)**
Community nursing, medical and therapy service including care homes	10 (22.2)	18 (40.0)	3 (6.7)	0 (0.0)	1 (2.2)	13 (28.9)	**45 (9.6)**
Dental service	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	**2 (0.4)**
Prison service	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.2)**
Police station	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.2)**
Mental health service	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	**1 (0.2)**
Not known	7 (46.7)	2 (13.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (40.0)	**15 (3.2)**
Total	**84** (18.0)	**131** (28.1)	**78** (16.7)	**9** (1.9)	**9** (1.9)	**156** (33.4)	**467 (100.0)**

For dispensing incidents, where the setting of occurrence could be clearly corroborated, the majority occurred in community pharmacy, as might be expected given that most patients in primary care receive their medication from community pharmacy. However, a small number of dispensing incidents occurred in other areas of primary care including

general practices that dispense medication to patients as part of the services provided. See Table 4.2 for the breakdown of primary care settings that reported these incidents and the harm severities attributed to them.

Table 4.2 Reported care setting of occurrence for dispensing incidents broken down by harm severity (n = 3380)

Reported care setting of occurrence	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Community pharmacy	532 (16.2)	726 (22.1)	307 (9.3)	21 (0.6)	6 (0.2)	1694 (51.6)	**3286 (97.2)**
General practice	8 (12.9)	17 (27.4)	16 (25.8)	0 (0.0)	1 (1.6)	20 (32.3)	**62 (1.8)**
Community nursing, medical and therapy service	5 (38.5)	4 (30.8)	1 (7.7)	0 (0.0)	0 (0.0)	3 (23.1)	**13 (0.4)**
Community and general dental service	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	**1 (0.0)**
Not known	2 (11.1)	4 (22.2)	1 (5.6)	0 (0.0)	0 (0.0)	11 (61.1)	**18 (0.5)**
Total	**547** (16.2)	**751** (22.2)	**325** (9.6)	**21** (0.6)	**7** (0.2)	**1729** (51.2)	**3380 (100.0)**

Of the dispensing incidents with clear harm severity, a higher proportion from general practice (n = 17/42, 40.5%) resulted in a serious harm compared to those from community pharmacy (n = 334/1592, 21.0%). Some dispensing incidents occurred in community pharmacy but the reports originated from other settings including community nursing (n = 119/3286, 3.6%) and general practice (n = 72/3286, 2.2%).

Where the setting of occurrence could be clearly verified, the majority of administration incidents originated from community nursing in primary

care (n = 617 of 760, 81.2%). Community nursing is nursing care provided outside of hospital and included patients' homes, nursing or care homes and schools. Some reports described the specific community nurse settings where the incident occurred, however, a substantial number of reports did not, and only mentioned community nursing (see Table 4.3). Administration incidents also occurred in general practices, mostly during administration of vaccines. Few incidents were reported to originate from other care settings such as community pharmacies and dental services (where incidents occurred as a result of administering anaesthesia during dental treatment). Table 4.3 shows the reported care settings where administration incidents occurred and associated harm severity. As with the other medication incident categories, administration incidents were not always reported from the actual care setting of occurrence.

Table 4.3 Reported care setting of occurrence for administration incidents broken down by harm severity (n = 760)

Reported care setting of occurrence	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Community nursing	41 (14.2)	71 (24.7)	6 (2.1)	0 (0.0)	1 (0.3)	169 (58.7)	288 (37.9)
Private accommodation	19 (7.5)	103 (40.6)	41 (16.1)	1 (0.4)	3 (1.2)	87 (34.3)	254 (33.4)
Care home	5 (11.1)	13 (28.9)	8 (17.8)	1 (2.2)	1 (2.2)	17 (37.8)	45 (5.9)
Nursing home	3 (15.0)	3 (15.0)	2 (10.0)	0 (0.0)	0 (0.0)	12 (60.0)	20 (2.6)
School	3 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (70.0)	10 (1.3)
Sub-total	**71** (11.5)	**190** (30.8)	**57** (9.2)	**2** (0.3)	**5** (0.8)	**292** (47.3)	**617 (81.2)**
General practice	14 (12.6)	12 (10.8)	5 (4.5)	1 (0.9)	1 (0.9)	78 (70.3)	111 (14.6)
Health clinic	1 (7.1)	4 (28.6)	1 (7.1)	0 (0.0)	0 (0.0)	8 (57.1)	14 (1.8)
Sexual Assault Referral Centre (SARC)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (0.1)
Sub-total	**15** (11.9)	**16** (12.7)	**6** (4.8)	**1** (0.8)	**1** (0.8)	**87** (69.0)	**126 (16.5)**
Community pharmacy	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (60.0)	5 (0.7)
Dental service	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	1 (50.0)	2 (0.3)
Prison service	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (0.1)
Not known	0 (0.0)	1 (11.1)	1 (11.1)	0 (0.0)	0 (0.0)	7 (77.8)	9 (1.2)
Total	**86** (11.3)	**209** (27.5)	**65** (8.6)	**3** (0.4)	**6** (0.8)	**391** (51.4)	**760 (100.0)**

4.2.2 Reported staff members involved

Unsurprisingly, the majority of prescribing and monitoring incidents involved doctors. However, a considerable number of these merely

described the incident without mention of the person(s) involved. For example, "*Ritalin prescribed incorrectly. Dose changed by hospital and repeat medication list not updated correctly so mother was picking up extra Ritalin in error.*" The most frequent group of staff members identified from prescribing and monitoring incident reports were general practice staff; which may also include doctors, and nurses who were mostly independent and supplementary prescribers. In a small number of reports, other specific staff members were noted to be involved with these incidents. Table 4.4 lists the reported staff members involved in prescribing and monitoring incidents.

Table 4.4 Reported staff members involved with prescribing and monitoring incidents (n = 467)

Reported staff member	Frequency (%)
Doctor	**242 (51.8)**
General practice (GP) staff	**158 (33.8)**
Nurse	**17 (3.6)**
Out of hours (OOH) staff	**3 (0.6)**
Receptionist	**3 (0.6)**
Prescription clerk	**3 (0.6)**
Healthcare assistant	**2 (0.4)**
Dentist	**2 (0.4)**
OOH Doctor	**1 (0.2)**
Drug service staff	**1 (0.2)**
Carers	**1 (0.2)**
Health clinic staff	**1 (0.2)**
Unknown	**33 (7.1)**

The majority of dispensing incident reports did not specifically mention the staff member involved in the incident as was described in Chapter 3 (n = 3100/3380, 91.7%). However, of those that did, the pharmacist was the most frequently reported staff member to be solely involved in dispensing incidents (n = 215, 6.4%). This was mostly when only the pharmacist undertook all the processes of dispensing before handing the medication to the patient. This was followed by delivery driver (n = 26, 0.8%), mostly involving the delivery of medication to the wrong patient; and doctor (n = 19, 0.6%). Others included nurses (n = 10, 0.3%), dispensers (n = 3, 0.1%) and pre-registration pharmacists (n = 2, 0.1%).

Staff members most commonly involved with incidents whilst administering medications to patients were nurses (n = 488/760, 64.2%) and carers (n = 50/760, 6.6%). GP practice staff not specifically mentioned by role were involved in 57 administration incidents (7.5%). Other healthcare professionals reported to be involved in administration incidents included doctors (n = 14, 1.8%), pharmacy staff (n = 12, 1.6%), dentists (n = 2, 0.3%) and healthcare assistants (n = 2, 0.3%) albeit in a few reports. Family members were sometimes reported to be involved in administration incidents, these were when parents or family members were responsible for administering patient's medications. A number of incidents did not involve any healthcare professional due to the nature of the incident. Most of these were as a result of patients' self-administration of overdose (n = 64, 8.4%).

4.2.3 Reported age of patients

The reported age of patients in the different categories followed a similar pattern to the whole sample analysed in Section 3.3.6, with few differences. The patients' age was described in 216 of 467 (46.3%) prescribing and monitoring incident reports; 1725 0f 3380 (51.0%) dispensing incident reports; and 464 of 760 (61.1%) administration incident reports. Of those, the number of incidents reported mostly increased across the patient age group up to 85 years, after which there is a drop in the number of incidents in each of the categories (see Figure 4.1). However, for administration incidents, the number of incidents were mostly reported in younger and older patients between the ages of one month to 11 years (n = 68/464, 14.7%) and 46 years and over (n = 344/464, 74.1%). Patients between the ages of 12 and 45 years were least involved with administration incidents (n = 48/464, 10.3%). Patients aged between 66 and 85 years were involved with the most number of incidents in all categories; 43.1% (n = 93/216) for prescribing and monitoring incidents, 37.6% (n = 649/1725) for dispensing incidents, and 40.5% (n = 188/464) for administration incidents where age was recorded.

Both age and level of harm were described in 148 (31.7%) prescribing and monitoring incident reports, 736 (21.8%) dispensing incident reports and 222 (29.2%) administration incident reports. Of these, for prescribing and monitoring incidents, 65% (96 of 148 reports) resulted in no or mild harm, 28% (n = 41/148) resulted in moderate harm while 7% (n = 11/148) reports resulted in severe harm or death. Higher levels

of harm severity were experienced mostly in patients aged between 56 and 85 years of age as shown in Figure 4.2. This was mostly due to multiple co-morbidities (described in reports) in these patients contributing to the outcome of incidents. Figure 4.2 is a stacked bar chart demonstrating the frequency of harm severity per age group for the three categories displayed side by side.

For dispensing incidents, the majority of incidents resulted in no or mild harm (n = 571/736, 77.6%), with some resulting in moderate harm (n = 153/736, 20.8%) and severe harm or death (n = 12/736, 1.6%). However, in the age group of one month to one year, 50% (n = 7) of incidents describing harm severity reported moderate harm whilst the other 50% reported no or mild harm. Although the over 85 years age group did not have the highest frequency of incidents reported, they had the largest proportion of incidents describing severe harm or death (n = 5/12, 41.7%).

For administration incidents, more than 81% (n = 180/222) of these resulted in no or mild harm. Of the remaining reports, 33 incidents (14.9%) resulted in moderate harm and 6 (2.7%) resulted in severe harm or death. In total, 50% of incidents (n = 3) that resulted in severe harm or death were experienced by patients in the 46 to 55 years age group (see Figure 4.2). While the incident that resulted in death was a case of overdose of an opioid administered to the patient, the two incidents that resulted in severe harm involved patients with mental illnesses and on multiple medications (polypharmacy), which may have contributed to the occurrence of the incidents. The 46 – 55 years group

was also the only age group with more than one reported incident to have no ‘no harm’ incidents. Most of the incidents in this age group involved syringe drivers which may suggest palliative care patients.

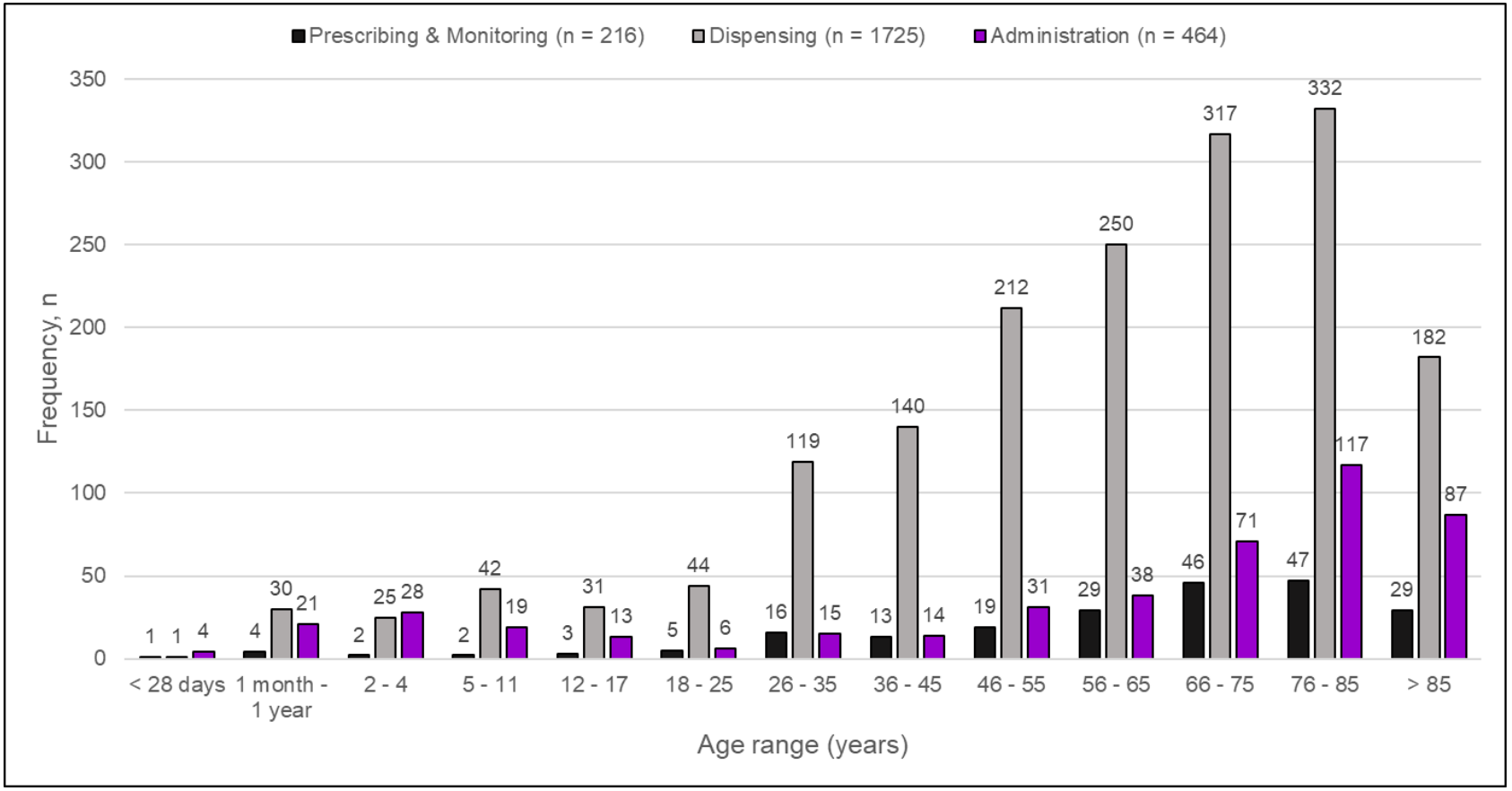


Figure 4. 1 Reported frequency of incident reports by age group

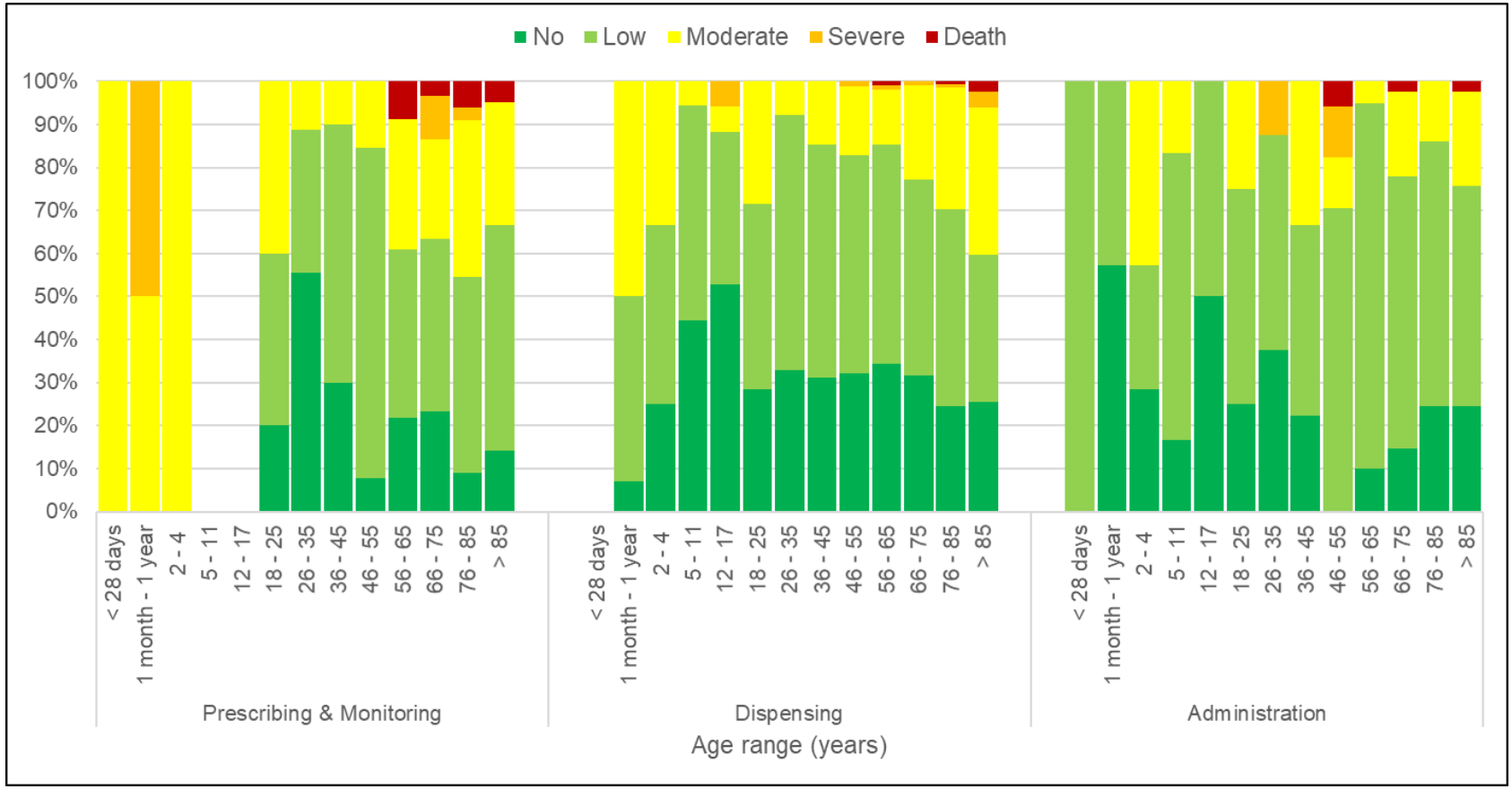


Figure 4. 2 Proportions of level of harm severity per age group for prescribing & monitoring (n = 148), dispensing (n = 736) and administration (n = 222) incidents

4.2.4 Gender of patients

The gender of patients involved in each incident category was consistent with the findings of the overall sample described in Chapter 3.3.5. Gender was recorded for 168 of 467 (36.0%) prescribing and monitoring incidents, 1180 of 3380 (34.9%) dispensing incidents and 326 of 760 (42.9%) administration incidents. Of these, female gender was consistently reported to be involved in higher proportions of reports; showing a similar trend as the overall sample. Table 4.5 shows the frequency of harm severity by gender of the three incident categories.

Table 4.5 Reported gender of patients involved in incident categories and associated harm severity proportions (n = 1674)

Gender	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Prescribing and monitoring incidents							
Female	14 (14)	39 (39)	18 (18)	4 (4)	1 (1)	25 (25)	**101 (60.1)**
Male	8 (12)	24 (36)	14 (21)	3 (4)	5 (7)	13 (19)	**67 (39.9)**
Total	**22 (13)**	**63 (38)**	**32 (19)**	**7 (4)**	**6 (4)**	**38 (23)**	**168 (100.0)**
Dispensing incidents							
Female	147 (20)	328 (44)	113 (15)	1 (0)	2 (0)	157 (21)	**748 (63.4)**
Male	90 (21)	177 (41)	54 (13)	8 (2)	1 (0)	102 (24)	**432 (36.6)**
Total	**237 (20)**	**505 (43)**	**167 (14)**	**9 (1)**	**3 (0)**	**259 (22)**	**1180 (100.0)**
Administration incidents							
Female	19 (10)	70 (36)	26 (13)	2 (1)	1 (1)	78 (40)	**196 (60.1)**
Male	17 (13)	39 (30)	12 (9)	1 (1)	2 (2)	59 (45)	**130 (39.9)**
Total	**36 (11)**	**109 (33)**	**38 (12)**	**3 (1)**	**3 (1)**	**137 (42)**	**326 (100.0)**

4.3 Types of incidents

4.3.1 Primary incident types

4.3.1.1 Prescribing and monitoring incidents

Prescribing and monitoring incidents made up 9.3% (n = 467) of the total medication incidents reported in primary care (n = 5017). Of these, multiple incident types were described but the most common incident described was prescribing the wrong dose of medication, most of which were overdoses (see Table 4.6). The majority of these resulted in no, mild or moderate harm with only one incident resulting in severe harm and one resulting in death. The following incident report (Example 1) resulted in the only death associated with this type of incident and identifies communication error as contributing to the incident. Warfarin was the most frequent medication associated with wrong dose prescriptions.

> **Example 1:** *Patient discharged from hospital on [date] - no updated warfarin dose or International Normalised Ratio (INR) results sent to GP. INR checked and information added to INRstar (or did not enter correct dose as was changed in hospital). Patient prescribed 2mg daily (subsequently found dose in hospital was 0.5mg). Patient suffered GI bleed and died [date].*

The second most frequent type of incident was prescribing the wrong medication (see Example 2). These incidents resulted in no, mild or moderate harm, where harm severity could be established in the reports. Insulin was the most common type medication associated with prescribing the wrong item.

> **Example 2:** *Dr prescribed wrong medication for patient. Prescribed Eprex (epoetin alfa) 1000 units 0.5ml pre filled syringes instead of low molecular weight heparin like alphaparin 3000 units 0.3ml pre filled syringes. Patient admitted to hospital for operation but due to the error, the patient could not be operated on.*

Prescribing unsafe medication to patients was also common. These incidents included prescribing either a known contraindicated medication or a medication otherwise deemed unsafe due to the patient's health or medication history. Non-steroidal anti-inflammatory drugs (NSAIDs) and warfarin were the most common medications involved with unsafe prescribing. For example, one report described NSAIDs being repeatedly prescribed to a patient with a past medical history of bleeding ulcers without gastric protection; this eventually led to the patient being admitted into intensive care unit with a possible perforated duodenal ulcer. The report described the clinician not looking at patients' past medical history as contributing to the incident. In another Example (3), the prescriber did not take the patient's ongoing medical status into account before prescribing the medication. The majority of incidents, however, resulted in no, mild or moderate harm with three incidents resulting in severe harm.

> **Example 3:** *A type 2 diabetic patient with impaired renal function was presented with possible ureteric colic and prescribed diclofenac - renal status not taken into account. Patient admitted to hospital some days later with acute renal failure - possibly triggered by NSAID.*

Prescribing a medication that a patient is known to be allergic to was also a common incident identified. Although only 30 reports described this type of incident, it resulted in the highest proportion of death with

three cases identified (see Example 4). Other identified cases resulted in no, mild or moderate harm to patients. The majority of the reports described insufficiencies in documentation, including ease of access and use of information as contributing to the incident. Antibiotics such as amoxicillin and trimethoprim were the most commonly involved medications with 21 of 30 incident involvement (70%).

> **Example 4:** *Patient was prescribed amoxicillin. The clinical notes showed a record of penicillin allergy but amoxicillin had been prescribed in the past. It was therefore taken from past acutes on the computer and prescribed. Patient died later that day.*

Other less frequent types of prescribing incidents included wrong strength prescribed, wrong number of doses prescribed and previously stopped medication being prescribed in error (see Table 4.6 below).

Monitoring incidents were described in 36 (7.7%) of the 467 incident reports. These mostly included the lack of monitoring during medication treatment or when a dose of medication was not adjusted as a result of monitoring. For example, one report described a GP to have failed in checking a patient's digoxin levels following a dosage increase, which led to patient being admitted into hospital with digoxin toxicity. Two incidents resulted in patient death whilst most of the other monitoring incidents resulted in mild or moderate harm. Patients' co-morbidities or polypharmacy and transfer of patient care from secondary to primary care were reported to contribute to these incidents. Warfarin was the most common medication involved with monitoring incidents (21 of 36 reports, 58%). Example 5 describes a monitoring incident where the

initiating doctor failed to monitor kidney function before prescribing the medication.

> **Example 5:** *Patient in chronic renal failure prescribed lisinopril by Dr A on [date] without having had a blood test to check kidney function. Dosage subsequently increased to 5mg on [date]. Dr B continued with medication simultaneously initiating a blood test on [date]. Results returned on [date] showed kidney function grossly abnormal. Dr C requested further blood test on [date] when the lisinopril was stopped. Results showed deterioration from earlier test. Patient admitted to [name] on [date] with acute renal failure.*

Errors made at the clinical treatment decision phase was also described in 26 (5.6%) of 467 reports, mostly resulting in mild or moderate harm to patients (see Example 6). One clinical treatment decision incident resulted in severe harm and one resulted in death to patient. Incidents included wrongly deciding to not give a treatment or giving a treatment which is in some way wrong. Inadequate knowledge of the prescriber or insufficient assessment or investigations were described as contributing to these incidents.

> **Example 6:** *Patient with familial hypercholesterolaemia (FH) under consultant care prescribed Atorvastatin. Cholesterol value at 4.3mmol/l. Medication changed by GP to simvastatin 40mg, cholesterol rose to 6.1mmol/l. Consultant had previously written to GP with details of diagnosis and medication required. This has been done to ensure patient receives required medication. Consultant had informed [name] because of the potential clinical risk.*

Table 4.6 shows the types of incidents identified broken down by harm severity. Harm severity was identified in 311 incident reports (66.6%). Of these, 96 incidents (31%) resulted in moderate, severe harm or death (serious harm). Although prescribing and monitoring incidents

during medication related processes were not the most frequent incident category identified, they resulted in the most patient deaths in primary care (n = 9/24, 37.5%).

Table 4.6 Prescribing and monitoring incident types and harm severity allocation (n = 467)

Medication incident types	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Prescribing / Prescription incidents							
Wrong dose	1 (8.3)	1 (8.3)	0 (0.0)	1 (8.3)	0 (0.0)	9 (75.0)	12
Overdose	15 (25.9)	14 (24.1)	14 (24.1)	0 (0.0)	1 (1.7)	14 (24.1)	58
Under-dose	4 (33.3)	4 (33.3)	1 (8.3)	0 (0.0)	0 (0.0)	3 (25.0)	12
Sub-total	20 (24.4)	19 (23.2)	15 (18.3)	1 (1.2)	1 (1.2)	26 (31.7)	**82 (17.6)**
Wrong medication	18 (26.9)	21 (31.3)	7 (10.4)	0 (0.0)	0 (0.0)	21 (31.3)	**67 (14.3)**
Unsafe medication	7 (16.3)	15 (34.9)	9 (20.9)	3 (7.0)	0 (0.0)	9 (20.9)	43
Contraindicated	2 (12.5)	5 (31.3)	5 (31.3)	0 (0.0)	0 (0.0)	4 (25.0)	16
Teratogenic prescribed to a pregnant woman	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (66.7)	3
Sub-total	9 (14.5)	21 (33.9)	14 (22.6)	3 (4.8)	0 (0.0)	15 (24.2)	**62 (13.3)**
Medication prescribed for patient who is known to be allergic	3 (10.0)	10 (33.3)	7 (23.3)	0 (0.0)	3 (10.0)	7 (23.3)	**30 (6.4)**
Wrong strength	4 (19.0)	5 (23.8)	6 (28.6)	0 (0.0)	0 (0.0)	6 (28.6)	**21 (4.5)**
Wrong number of doses prescribed	5 (27.8)	4 (22.2)	2 (11.1)	0 (0.0)	1 (5.6)	6 (33.3)	**18 (3.9)**
Stopped medication being prescribed	3 (25.0)	2 (16.7)	0 (0.0)	1 (8.3)	0 (0.0)	6 (50.0)	**12 (2.6)**
Wrong or no advice given when prescribing	1 (11.1)	4 (44.4)	1 (11.1)	1 (11.1)	1 (11.1)	1 (11.1)	**9 (1.9)**

Table 4.6 Prescribing and monitoring incident types and harm severity allocation (n = 467) (Continued)

Medication incident types	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Prescribing / Prescription incidents							
Prescription incomplete or inaccurate	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (57.1)	**7 (1.5)**
Wrong patient	4 (57.1)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28.6)	**7 (1.5)**
Wrong formulation	0 (0.0)	2 (40.0)	1 (20.0)	0 (0.0)	0 (0.0)	2 (40.0)	**5 (1.1)**
Duplicate prescription	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (75.0)	**4 (0.9)**
Illegible/ unclear prescription	1 (33.3)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	**3 (0.6)**
Incorrect timing of medication	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**2 (0.4)**
Incorrect route prescribed for medication	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.2)**
Prescribing/prescription incidents otherwise not known	11 (14.7)	17 (22.7)	7 (9.3)	2 (2.7)	0 (0.0)	38 (50.7)	**75 (16.1)**
Monitoring incidents							
Lack of monitoring - not commenced	0 (0.0)	2 (14.3)	5 (35.7)	0 (0.0)	2 (14.3)	5 (35.7)	**14 (3.0)**
Medication dose not adjusted as a result	0 (0.0)	6 (54.5)	4 (36.4)	0 (0.0)	0 (0.0)	1 (9.1)	**11 (2.4)**
Other monitoring incidents	0 (0.0)	3 (27.3)	3 (27.3)	0 (0.0)	0 (0.0)	5 (45.5)	**11 (2.4)**
Clinical treatment decision							
Wrong treatment with medication given	1 (14.3)	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42.9)	**7 (1.5)**
Insufficient treatment given	0 (0.0)	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	**5 (1.1)**
No treatment given when appropriate	0 (0.0)	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	**4 (0.9)**
Other clinical treatment decision errors	1 (10.0)	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	3 (30.0)	**10 (2.1)**
Total	**84** (18.0)	**131** (28.1)	**78** (16.7)	**9** (1.9)	**9** (1.9)	**156** (33.4)	**467 (100.0)**

4.3.1.2 Dispensing incidents

Wrong medication being dispensed was the most common type of dispensing incident reported (Example 7). At least 82 (7%) of the 1180 reports described the wrong type of insulin being dispensed, making insulin the most common medication involved in this type of incident.

> **Example 7:** *Prescription presented for chlordiazepoxide 5mg tablets at a dose of one four times a day for alcohol withdrawal. This was labelled and dispensed as chlorpromazine 50mg tablets, again with a dose of one four times a day. Patient took incorrect medication for two to three days, during this period and he had a seizure.*

Dispensing the wrong strength of medication was the second most common incident type (see Example 8), morphine (n = 36) and levothyroxine (n = 31) were the most frequent medications involved here.

> **Example 8:** *Patient was prescribed digoxin 62.5mcg on [date], by mistake digoxin 250mcg was dispensed instead. Patient felt unwell for few days. Error was noticed by the family member on [date]. Patient's family contacted the pharmacy, record checked and possible overdose identified. Doctor was called in and patient was examined. Family was told to withhold the dose just in case if the problem is related to medication. Patient collapsed and later died in hospital.*

The third most common type of incident identified was wrong formulation dispensed (see Example 9). Carbamazepine (n = 20) and chloramphenicol (n = 15, where the ear formulation was mistaken for the eye formulation) were the most frequent medications involved with selecting the wrong formulation.

> **Example 9:** *Tegretol 400mg was given instead of Tegretol Retard 400mg. The patient took the medicine away with them and noticed it*

> *wasn't right so came back into store and asked someone if this was correct and they informed him that the packaging had changed and that it was the correct medication. The patient then took the medication and became very ill with really bad headache, dizziness and fell out of bed.*

Wrong dose dispensed was also commonly described (see Example 10). Most reported overdose as the error that occurred (see Table 4.7). Warfarin (n = 14) and methadone (n = 13) were the most frequent medications involved with wrong doses being dispensed.

> **Example 10:** *GP rang to ask for a change to be made to a community dosage box. Two tablets to be added and one taken out each day. GP called into the pharmacy on [date] to ask about the tablets in the box as the patient had been unwell over the weekend. It became clear that the tablet had not been removed as requested by the doctor leading to an increased (instead of reduced) dose of the drug. The patient had taken the increased dose of medication for several days. The box was re-made and sent to the patient. The patient had a fall overnight following this and was admitted to hospital with a head injury*.

Dispensing medication to the wrong patient was also common (see Example 11). Methadone (n = 31) for drug addiction was the most recurring medication involved in these reports.

> **Example 11:** *Prescription for the patient was labelled under a patient of the same name but with a different address. The medication was then delivered to this address and the son of this patient called to say they had received medication that their mother does not take. We swiftly collected the medication from the patient's address and re-dispensed it to the correct patient.*

Other types of incidents described included wrong quantity of medication dispensed, wrong label on medication and medication wrongly being not dispensed. Table 4.7 shows the different types of

dispensing incidents identified and related patient harm severity. Of the reports where harm severity could be established (n = 1651, 48.9% of all dispensing incidents), the majority of reports resulted in no or mild harm (n = 1298/1651, 78.6%). Two types of errors: dispensing of wrong medication and wrong strength were responsible for the majority of incidents that resulted in a serious harm (n = 238/353, 67.4%). A considerable proportion of wrong dose errors also resulted in serious harms (n = 32/353, 9.1%) with the majority being overdose dispensed. It was not possible to determine the harm severity of 51% of dispensing incident reports (n = 1729).

Table 4.7 Dispensing incidents and harm severity allocation (n = 3380)

Dispensing incident types	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Wrong medication	101 (8.6)	298 (25.3)	134 (11.4)	11 (0.9)	2 (0.2)	634 (53.7)	**1180 (34.9)**
Wrong strength	129 (13.5)	222 (23.1)	86 (9.0)	3 (0.3)	2 (0.2)	517 (53.9)	**959 (28.4)**
Wrong formulation	67 (27.6)	48 (19.8)	9 (3.7)	0 (0.0)	0 (0.0)	119 (49.0)	**243 (7.2)**
Wrong dose	5 (9.4)	7 (13.2)	5 (9.4)	0 (0.0)	0 (0.0)	36 (67.9)	53
Overdose	18 (13.0)	38 (27.5)	20 (14.5)	0 (0.0)	2 (1.4)	60 (43.5)	138
Under-dose	6 (11.8)	18 (35.3)	4 (7.8)	1 (2.0)	0 (0.0)	22 (43.1)	51
Sub-total	29 (12.0)	63 (26.0)	29 (12.0)	1 (0.4)	2 (0.8)	118 (48.8)	**242 (7.2)**
Wrong patient	49 (25.4)	35 (18.1)	15 (7.8)	2 (1.0)	0 (0.0)	92 (47.7)	**193 (5.7)**
Wrong quantity	76 (62.8)	4 (3.3)	2 (1.7)	0 (0.0)	0 (0.0)	39 (32.2)	**121 (3.6)**

Table 4.7 Dispensing incidents and harm severity allocation (n = 3380) (continued)

Dispensing incident types	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Wrong label	37 (43.0)	7 (8.1)	7 (8.1)	0 (0.0)	0 (0.0)	35 (40.7)	86
No label	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3
Sub-total	39 (43.8)	8 (9.0)	7 (7.9)	0 (0.0)	0 (0.0)	35 (39.3)	**89 (2.6)**
Not dispensed	14 (16.7)	23 (27.4)	16 (19.0)	1 (1.2)	0 (0.0)	30 (35.7)	**84 (2.5)**
Out of date medication	11 (16.4)	14 (20.9)	3 (4.5)	0 (0.0)	0 (0.0)	39 (58.2)	**67 (2.0)**
Stopped medication being dispensed to patient	2 (7.7)	5 (19.2)	6 (23.1)	1 (3.8)	0 (0.0)	12 (46.2)	**26 (0.8)**
Wrong advice at dispensing stage	1 (6.7)	3 (20.0)	5 (33.3)	1 (6.7)	0 (0.0)	5 (33.3)	**15 (0.4)**
Wrong time	3 (23.1)	2 (15.4)	2 (15.4)	0 (0.0)	0 (0.0)	6 (46.2)	**13 (0.4)**
Inappropriate medication	0 (0.0)	3 (37.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (62.5)	**8 (0.2)**
Medication dispensed to a patient who is known to be allergic	1 (20.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)	**5 (0.1)**
Wrong route	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**2 (0.1)**
Dispensing incidents otherwise not known	24 (18.0)	20 (15.0)	11 (8.3)	1 (0.8)	1 (0.8)	76 (57.1)	**133 (3.9)**
Total	**547** (16.2)	**751** (22.2)	**325** (9.6)	**21** (0.6)	**7** (0.2)	**1729** (51.2)	**3380 (100.0)**

4.3.1.3 Administration incidents

Administration incidents made up 15.2% (n = 760) of the 5017 medication incidents reported in primary care. They included administration of vaccines (n = 163/760, 21.4%) and other medications

(n = 597/760, 78.6%). The most frequent incident type identified was medication not administered at all, most of which resulted in no or mild harm to patients. Table 4.8 shows all the types of administration incidents described, broken down by harm severity. Insulins and antithrombotic agents such as enoxaparin and dalteparin that required injecting were the most common medications being missed out (n = 72/166, 43.4%). The following Example (12) resulted in moderate harm where the patient ended up in hospital following her insulin not being administered over the weekend due to scheduling errors.

> **Example 12:** *Message received from [name] informing me they had received a phone call from [name]'s A&E about [patient name]. She had presented to the department very confused saying she hadn't had any insulin for 2 days. I was told to ask for staff nurse [staff name] or [staff name 2] when I ring back. I checked the weekend list and realised her name was not on the list. I contacted [staff name 3] who works with Mrs [patient name] GPs. She stated she was on the list last week and not sure why she wasn't on it this week. At the time of calling, the doctors were with Mrs [patient name]. Presently, she is still in hospital.*

Administration of the wrong dose by a third party was the second most frequent type of incident described (n = 147/760, 19.3%). These were mostly related to an overdose of medication being administered (n = 87/147, 59.2%). Patients' self-administration of an overdose was also a frequent incident. All incidents that were verified to have caused death, involved an overdose of medication (n = 6). Most other verified wrong dose incidents resulted in no or mild harm (n = 84). However, 38 incidents resulted in moderate harm, which was the highest proportion of incidents to have resulted in moderate harm compared to other types

of incidents (see Table 4.8). This may suggest that harm severity may be more severe in incidents involving overdose than other types of incidents. Insulins (n = 42), opioid analgesics such as morphine and diamorphine (n = 24), and antithrombotic agents such as enoxaparin and warfarin (n = 13) were the most frequent types of drugs involved with wrong dose incidents. Examples 13 and 14 show examples of incidents involving the wrong dose of medication being administered by a third party and by self-administration respectively.

> **Example 13:** *Routine visit to administer lunch time dose of insulin. Patient's blood sugar was 28.4mmols. I noticed at this point that morning dose of insulin had been administered incorrectly. 7 International units of Humalog mix 30 had been administered (lunch time dose) instead of the 22 International units (morning dose). I spoke to the nurse who explained it was an oversight and she didn't read the prescription card correctly.*
>
> **Example 14:** *Patient took 4 co-dydramol tablets on Monday at 12pm, 5pm, 9pm, Tuesday at 6am and then vomited at 1230pm. He then took another 2 tablets at one pm. He was admitted to hospital with overdose at 6pm and put on a drip for 24 hours. The reason he took 4 tablets is his tablets were in 2 containers (one original pack and one split white pack). He assumed they were 2 different painkillers as in different packs and didn't read the names properly.*

Wrong number of doses (n = 115/760, 15.1%) was also frequently described, mostly involving vaccines (n = 63/115, 54.8%). This involved erroneously administering the intended dose of medication more than once. Harm severity could not be corroborated in most of these incidents (n = 72/115, 62.6%). However, where it could be, 39 of the remaining 43 incidents resulted in no or mild harm to the patient (90.7%) with the remaining four resulting in moderate harm. Again,

insulin (n = 28) and various types of vaccines (n = 63) were the most commonly involved medications in this type of incident. Examples 15 and 16 shows wrong dose incidents involving insulin and a vaccine respectively.

> **Example 15:** *Patient was given two doses of his evening insulin by two separate nurses, one at 1645, then again at 17:30. Discussed with nurse who administered second dose. Nurse states that she visited the patient by mistake as she had been allocated another patient. Nurse stayed with patient until ambulance arrived. Nurse contacted hospital this morning and patient is due for discharge today.*
>
> **Example 16:** *Child brought to immunisation clinic by father. Personal Child Health Record (PCHR) book was not available and stated child needed pre - school booster and MMR II. Immunisation schedule checked and I did not see that child had been called for Hib + MMR. Child health called me the following week to point out that according to the records, this child had already had a pre-school booster. Informed mother by phone - child well.*

In another incident similar to Example 15, but with some contributory factors described, the nurse responsible for administering the insulin to the patient described running late and being unable to find the patient notes. In her haste to catch up and due to her familiarity with the patient, she administered the medication before checking the patient's notes. She later found the notes and discovered another nurse (who visited in error) had already been to administer the medication. The patient was eventually sent to hospital and admitted for observation.

Table 4.8 Administration incidents and harm severity allocation (n = 760)

Medication incident types	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Medication not administered	14 (8.5)	56 (34.1)	8 (4.9)	2 (1.2)	0 (0.0)	84 (51.2)	**164 (21.6)**
Wrong dose	3 (9.1)	9 (27.3)	3 (9.1)	0 (0.0)	1 (3.0)	17 (51.5)	33
Overdose	8 (9.2)	27 (31.0)	12 (13.8)	0 (0.0)	3 (3.4)	37 (42.5)	87
Under-dose	3 (15.0)	10 (50.0)	1 (5.0)	0 (0.0)	0 (0.0)	6 (30.0)	20
Sub-total	14 (10.0)	46 (32.9)	16 (11.4)	0 (0.0)	4 (2.9)	60 (42.9)	**140 (18.4)**
Patient self-administered overdose unintentionally	1 (1.5)	21 (31.3)	22 (32.8)	1 (1.5)	2 (3.0)	20 (29.9)	**67 (8.8)**
Wrong number of doses	3 (5.8)	25 (48.1)	4 (7.7)	0 (0.0)	0 (0.0)	20 (38.5)	**52 (6.8)**
Medication administered at incorrect time	7 (21.2)	8 (24.2)	0 (0.0)	0 (0.0)	0 (0.0)	18 (54.5)	**33 (4.3)**
Wrong medication	7 (24.1)	7 (24.1)	5 (17.2)	0 (0.0)	0 (0.0)	10 (34.5)	**29 (3.8)**
Wrong patient	1 (9.1)	3 (27.3)	3 (27.3)	0 (0.0)	0 (0.0)	4 (36.4)	**11 (1.4)**
Medication out of date	3 (30.0)	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (50.0)	**10 (1.3)**
Wrong formulation	1 (20.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)	**5 (<1)**
Medication administered to a patient with a known allergy	0 (0.0)	2 (50.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)	**4 (<1)**
Stopped medication being administered to patient	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (75.0)	**4 (<1)**
Medication administered via incorrect route	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)	**3 (<1)**
Syringe driver faulty	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**2 (<1)**
Contraindicated medicine administered	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (<1)**

Table 4.8 Administration incidents and harm severity allocation (n = 760) (Continued)

Medication incident types	Re-coded harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Administration incidents otherwise not known	13 (18.1)	21 (29.2)	5 (6.9)	0 (0.0)	0 (0.0)	33 (45.8)	**72 (9.5)**
Vaccine specific administration							
Wrong number of doses	5 (7.9)	6 (9.5)	0 (0.0)	0 (0.0)	0 (0.0)	52 (82.5)	**63 (8.3)**
Wrong vaccine	7 (16.3)	3 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	33 (76.7)	**43 (5.7)**
Wrong time	5 (31.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (68.8)	**16 (2.1)**
Vaccine out of date	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)	**8 (1.1)**
Wrong dose	1 (14.3)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (71.4)	**7 (0.9)**
Wrong vaccine formulation	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (80.0)	**5 (<1)**
Contraindicated vaccine	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	2 (66.7)	**3 (<1)**
Reconstitution error	1 (33.3)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	**3 (<1)**
Wrong patient	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	**2 (<1)**
Not administered	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	**2 (<1)**
Wrong site	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	**2 (<1)**
Other vaccine administration incidents otherwise not known	1 (11.1)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	7 (77.8)	**9 (1)**
Total	**86** (11.3)	**209** (27.5)	**65** (8.6)	**3** (0.4)	**6** (0.8)	**391** (51.4)	**760 (100)**

Other less frequent types of administration incidents included wrong medication administered (n = 72/760, 9.5%) - mostly vaccines, and medication administered at incorrect time (n = 49/760, 6.4%). In total, harm severity was verified in 369 of the reports (48.6%). Of these, 74

incidents (20%) resulted in serious harms (moderate, severe harm and death) with the remaining incidents resulting in no or mild harm.

4.3.2 Contributory incident types

4.3.2.1 Prescribing and monitoring incidents

In total, 162 (34.7%) prescribing and monitoring incident reports described at least one incident in the preceding chain of events leading up to the primary incident. These are referred to as contributory incidents. There were 35 reports that described two contributory incidents and five reports that described three contributory incidents. A total of 202 contributory incidents were described in these reports.

The most frequent contributory incident was the error in the transfer of patient information from secondary care to primary care. This was mostly when a patient was moved back into primary care from a hospital stay and there were issues relating to the transfer of their updated medication record (such as not being transferred in a timely manner or not transferred at all). The second most frequent contributory incident was incorrect documentation or lack of availability of medical records, followed by prescribing errors. Issues with documentation mostly involved patients' medical records being inaccurate or unclear, or records not being available when needed; this applies to information such as allergy status of patients. Other common contributory incidents described in the reports are listed in Table 4.9 below.

Table 4.9 The most frequent contributory incidents involved in prescribing and monitoring incidents (n = 202)

Types of incidents	Frequency (%)
Errors in transfer of patient information from secondary to primary care setting at systems level	**48 (23.8)**
Incorrect documentation or availability of medical records. This includes lack of access, not up to date records or missing information, and inaccurate or unclear records	**31 (15.3)**
Prescribing errors	**21 (10.4)**
Errors in communication between healthcare professionals and patients	**16 (7.9)**
Errors in communication amongst healthcare professionals	**13 (6.4)**
IT errors including use errors and technical factors	**12 (5.9)**
Errors in transfer of patient information within primary care settings at system level	**10 (5.0)**
Error in the process of assessing patients, including taking medical history and identifying at risk patients	**8 (4.0)**
Errors in the process of laboratory investigations	**6 (3.0)**
Errors in the clinical treatment decision making	**5 (2.5)**
Errors in managing appointments in primary care	**3 (1.5)**
Lack of patient access to healthcare professional	**3 (1.5)**
Inefficient or lack of follow up of patient	**3 (1.5)**
Other	**23 (11.4)**
Total	**202 (100.0)**

4.3.2.2 Dispensing incidents

A total of 290 (8.6%) incident reports described at least one contributory incident leading up to the primary dispensing incident. In total, 38 reports described two contributory incidents and two reports described three contributory incidents, giving a total of 330 contributory incidents. Table 4.10 shows the most common contributory incidents with a frequency of at least 10 described in the dispensing incident reports.

Table 4.10 The most frequent contributory incidents involved in dispensing incidents (n = 330)

Types of incidents	Frequency (%)
Wrong label at dispensing stage	**89 (27.0)**
Errors in transfer of patient information within primary care setting at systems level	**30 (9.1)**
Wrong dose of medication prescribed	**23 (7.0)**
Errors in communication amongst healthcare professionals – human failures	**16 (4.9)**
Wrong strength of medication prescribed	**14 (4.2)**
Wrong formulation of medication dispensed	**13 (3.9)**
Errors in transfer of patient information from secondary to primary care setting at systems level	**11 (3.3)**
Other prescribing incidents such as medication not prescribed when appropriate	**11 (3.3)**
Incorrect documentation or availability of medical records	**10 (3.0)**
Errors in communication between healthcare professionals and patients – human failures	**10 (3.0)**
Other	**103 (31.2)**
Total	**330 (100.0)**

4.3.2.3 Administration incidents

In total 346 (45.5%) of 760 administration incident reports described at least one contributory incident. This was the category with the highest proportion of reports that had contributory incidents described in the reports. This demonstrated how incidents in the early stages of the medication process can filter through the system and contribute to the occurrence of administration incidents, even when being overseen by healthcare professionals. In total, 97 (12.8%) reports described two contributory incidents, 17 (2.2%) reports described three contributory

incidents and four reports described four contributory incidents. A total of 463 contributory incidents were included (see Table 4.11).

Table 4.11 The most frequent contributory incidents involved in Administration incidents (n = 463)

Types of incidents	Frequency (%)
Incorrect documentation or availability of medical records	**99 (21.4)**
Dispensing incidents	**57 (12.3)**
Errors in managing patient appointments	**52 (11.2)**
Errors in communication amongst healthcare professionals – human failures	**40 (8.6)**
Errors in transfer of patient information within primary care setting at systems level	**29 (6.3)**
Errors in transfer of patient information from secondary to primary care setting at systems level	**28 (6.1)**
Errors during referral processes	**21 (4.5)**
Errors with syringe driver	**20 (4.3)**
Prescribing incidents	**19 (4.1)**
Errors in communication between healthcare professionals and patients – human failures	**16 (3.5)**
Other	**82 (17.7)**
Total	**463 (100.0)**

The most frequent contributory incidents related to the incorrect documentation or availability of patients' medical records. Most of these were patients' records not being updated or an important piece of information such as allergy status of patient missing from updated records. These could be related to medical information following hospital discharge or following care given in primary care. Others included healthcare professionals' inability to access patients' records when needed (for example, when doctors make home visits) and

inaccurate or unclear medical information being recorded. The second most frequent type of contributory incident was dispensing incidents. They included wrong medication, strength and dose being dispensed prior to administration. Table 4.11 shows the common contributory incidents described in administration incident reports.

4.4 Reported contributory factors

4.4.1 Prescribing and monitoring incidents

A total of 662 contributory factors were coded from the 467 incident reports. At least one contributory factor was identified in 358 (76.7%) of the 467 reports. More than one contributory factor was coded in 58.5% (n = 273) of reports. Contributory factors were categorised into staff-related factors, patient-related factors, service-related factors, equipment-related factors, and other factors. Table 4.12 shows the breakdown of all coded contributory factors identified in these reports.

Staff-related factors were the most commonly described factors, mostly involving errors during decision making due to inefficiencies in skill set or knowledge and the failure to follow standard operating procedures or protocols. Other common staff factors included mistakes, slips or lapses due to distractions or oversights, similarities of medications and misreading patient information. Other staff factors include those less frequently reported; these are further described in Table 4.12.

Patient factors were the second most common group of contributory factors reported, most of which were patients' physiological and physical characteristics. Patients' polypharmacy and drug interactions

associated with them were the most frequent patient factors to have contributed to errors in prescribing and monitoring. Patients' previous health or medication history was also frequently described. These patient factors were mostly not considered during prescribing or monitoring of medications, hence contributed to incidents. Other patient characteristics described included allergy, palliative care patient, patient's age and frailty. Patient or parent's lack of understanding of instructions was also described in some cases to have contributed to incidents.

The most commonly described service-related factor was the continuity of patient care between care settings. Deficiencies were described during the transfer of patient care mostly from secondary to primary care but also within primary care settings. Issues relating to protocols or procedures being inadequate, inefficient or absent, especially repeat medication related protocols were described as a common factor to contribute to incidents. Other less frequent service-related factors were also described (see Table 4.12). Deficiencies with equipment, such as IT, was described as contributing to some incidents.

Table 4.12 Reported contributory factors associated with prescribing and monitoring incidents (n = 662)

Contributory factor theme (% of n)	Contributory factor subtheme (percentage of N)	Most common examples of contributory factors	Frequency (number and % of N)
Patient-related factors (N = 188, 28.4%)	Patient characteristics (n = 160/188, 85.1%)	Concomitant use of other medication and drug interaction	46 (24.5)
		Previous health/ medication history of patient	32 (17.0)
		Allergy	17 (9.0)
		Palliative care patient	17 (9.0)
		Patient age	11 (5.9)
		Patient frailty	11 (5.9)
		Pregnancy	7 (3.7)
		Other pathophysiological factors	19 (10.1)
	Patient decision making and knowledge (n = 19/188, 10.1%)	Patient or parent has poor understanding	14 (7.4)
		Patient non-compliant with instructions	5 (2.7)
	Other patient-related factors (n = 9/188, 4.8%)	Area where patient lives and its characteristics	7 (3.7)
		Other patient factors	2 (1.1)
Staff-related factors (N = 243, 36.7%)	Staff decision making (n = 112/243, 46.1%)	Inadequate skill set or knowledge	62 (25.5)
		Failure to follow protocol	44 (18.1)
		Wrong professional carries out task or not carried out at all	6 (2.5)
	Mistakes, slips and lapses (n = 98/243, 40.3%)	Distraction/oversight	29 (11.9)
		Similar medication names or appearances	13 (5.3)
		Misread/ did not read	13 (5.3)
		Mistakes involving multi-compartment compliance aids (MCCAs)	9 (3.7)
		Other types of mistakes or not specified otherwise	34 (14.0)
	Other staff-related factors (n = 33/243, 13.6%)	Hand writing	7 (2.9)
		Other staff factors	26 (10.7)
Equipment-related factors (N = 24, 3.6%)	Design and usability of equipment (n = 24/24, 100.0%)	Poor equipment design	13 (54.2)
		Other factors	11 (45.8)

Table 4.12 Reported contributory factors associated with prescribing and monitoring incidents (continued)

Contributory factor theme (number and % of total contributory factors, n=662)	Contributory factor subtheme (number and % of contributory factor theme)	Most common examples of contributory factors	Frequency (number and % of N: contributory factor theme)
Service-related factors (N = 183, 27.6%)	Issues related with protocols (n = 78/183, 42.6%)	Other protocols being inadequate, inefficient or absent	40 (21.9)
		Medication related protocols mostly repeat prescribing	38 (20.8)
	Continuity of care (n = 87/183, 47.5%)	Continuity of care between secondary care and primary care	50 (27.3)
		Continuity of care within primary care	25 (13.7)
		Care given by locum or agency staff	10 (5.5)
		Continuity of care not otherwise specified	2 (1.1)
	Working conditions (n = 12/183, 6.6%)	Busy/overloaded by work	5 (2.7)
		Inadequate provision of healthcare staff	5 (2.7)
		Other working conditions such as team factors	2 (1.1)
	Education and training (n = 6/183, 3.3%)	Deficiencies in knowledge and others' roles	6 (3.3)
Other factors (N = 24, 3.6%)	Others (n = 24/24, 100%)	Patient requiring syringe driver	10 (41.7)
		Other organisational factors	7 (29.2)
		Off license use of medication	4 (16.7)
		Confusion due to generic drug name rather than proprietary name	2 (8.3)
		Morphine conversion calculation error	1 (4.2)

4.4.2 Dispensing incidents

A total of 4,623 contributory factors were identified from the 3380 dispensing incident reports. At least one contributory factor was described in 2,290 (67.8%) reports with the remaining 1,090 (32.2%) reports not describing any contributory factor. Some reports described

more than one factor to have contributed to the error (n = 1363, 40.3%). These factors were also categorised into staff-related factors, service-related factors, equipment-related factors, patient-related factors and other factors. Table 4.13 shows the breakdown of all coded contributory factors described in these reports.

Staff-related factors were the most commonly described factors involved in dispensing errors, the majority of which involved mistakes, slips and lapses. Whilst most of the reports describing these gave additional information to establish their causes, some only mentioned mistake as a contributory factor. The most frequently described staff-related factors were mistakes due to the similarity of medication names or appearances, followed by failure to follow protocol, i.e. procedures or regulations and mistakes, slips or lapses from distractions or oversight. Other common factors included errors involving Multi-Compartment Compliance Aids (MCCAs) or dosette boxes, work not being double checked by a second person, inadequate skill set or knowledge and delivery of medication.

The most commonly described service-related factor was the working conditions being busy or overloaded with work. Protocols or procedures for dispensing being inadequate, inefficient or absent was the second most common factor described. Inadequate provision of healthcare staff such as lack of holiday or sickness cover and overall insufficient number of staff was also frequently described in reports. Care given by locum staff was the most common factor involving the continuity of care

that was described in dispensing incident reports. See the summary of other service-related factors in Table 4.13.

Table 4.13 Reported contributory factors associated with dispensing incidents

Contributory factor theme (number and % of total contributory factors, n=4,623)	Contributory factor subtheme (number and % of contributory factor theme)	Most common examples of contributory factors	Frequency (number and % of N: contributory factor theme)
Patient-related factors (N = 153, 3.3%)	Patient characteristics (n = 118/153, 77.1%)	Patient age	21 (13.7)
		Previous health/ medication history of patient	17 (11.1)
		Concomitant use of other medication and drug interaction	15 (9.8)
		Allergy	13 (8.5)
		Substance misuse patient	11 (7.2)
		Patient's behaviour such as fraudulent behaviour	10 (6.5)
		Care home patient including nursing home	7 (4.6)
		Patient frailty	6 (3.9)
		Palliative care patient	5 (3.3)
		Physical or mental disability of patient	5 (3.3)
		Pregnancy	3 (2.0)
		Other pathophysiological factors	3 (2.0)
		Language barrier	2 (1.3)
	Patient decision making and knowledge (n = 27/153, 17.6%)	Patient or parent has poor understanding	22 (14.4)
		Patient non-compliant with instructions	5 (3.3)
	Other patient-related factors (n = 8/153, 5.2%)	Area where patient lives and its characteristics	5 (3.3)
		Other patient factors	3 (2.0)

Table 4.13 Reported contributory factors associated with dispensing incidents (continued)

Contributory factor theme (number and % of total contributory factors, n=4,623)	Contributory factor subtheme (number and % of contributory factor theme)	Most common examples of contributory factors	Frequency (number and % of N: contributory factor theme)
Staff-related factors (N = 2629, 56.9%)	Staff decision making (n = 603/2629, 22.9%)	Failure to follow protocol	350 (13.3)
		Inadequate skill set or knowledge	133 (5.1)
		Dispensing medication from Patient Medication Record (PMR)	55 (2.1)
		Dispensing medication from label	44 (1.7)
		Wrong professional carries out task or not carried out at all	21 (0.8)
	Mistakes, slips and lapses (n = 1782/2629, 67.8%)	Similar medication names or appearances	829 (31.5)
		Distraction/oversight	345 (13.1)
		Mistakes involving multi-compartment compliance aids (MCCAs)	201 (7.6)
		Not specified otherwise	148 (5.6)
		Medication delivery	91 (3.5)
		Misread/ did not read	56 (2.1)
		Haste/poor time management	49 (1.9)
		Similar patient names	37 (1.4)
		Transposed labels	26 (1.0)
	Other staff-related factors (n = 244/2629, 9.3%)	Not double checked by a 2nd person	176 (6.7)
		Hand writing	38 (1.4)
		No or poor supervision or assistance	17 (0.6)
		Physical and mental wellbeing including fatigue and stress	10 (0.4)
		Other staff factors such as language barrier	3 (0.1)
Equipment-related factors (N = 562, 12.2%)	Design and usability of equipment (n = 562/562, 100.0%)	Issues with medication storage	458 (81.5)
		Medication packaging	92 (16.4)
		Poor equipment design	5 (0.9)
		Other factors	7 (1.2)

Table 4.13 Reported contributory factors associated with dispensing incidents (continued)

Contributory factor theme (number and % of total contributory factors, n=4,623)	Contributory factor subtheme (number and % of contributory factor theme)	Most common examples of contributory factors	Frequency (number and % of N: contributory factor theme)
Service-related factors (N = 1212, 26.2%)	Issues related with protocols (n = 304/1212, 25.1%)	Other non-specified protocols being inadequate, inefficient or absent	271 (22.4)
		Medication related protocols such as repeat prescribing	33 (2.7)
	Continuity of care (n = 128/1212, 10.6%)	Care given by locum or agency staff	88 (7.3)
		Continuity of care within primary care	28 (2.3)
		Continuity of care between secondary care and primary care	8 (0.7)
		Continuity of care not otherwise specified	4 (0.3)
	Working conditions (n = 649/1212, 53.5%)	Busy/overloaded by work	500 (41.3)
		Inadequate provision of healthcare staff	137 (11.3)
		Other working conditions such as team factors	12 (1.0)
	Education and training (n = 28/1212, 2.3%)	Deficiencies in knowledge and others' roles	28 (2.3)
	Service availability and delivery (n = 103/1212, 8.5%)	Owed medication	29 (2.4)
		Manufacturing and supply issues such as specials	23 (1.9)
		Medication order	19 (1.6)
		Lack of stock	19 (1.6)
		Long wait for service such as in emergency	13 (1.1)
Other factors (N = 67, 1.4%)	Others (n = 67/67, 100.0%)	Confusion due to generic drug name rather than proprietary name	29 (43.3)
		Other organisational factors	25 (37.3)
		Old duplicate prescription	4 (6.0)
		Patient requiring syringe driver	3 (4.5)
		Morphine conversion calculation error	3 (4.5)
		Off license use of medication	2 (3.0)
		Rare use of medicine/strength	1 (1.5)

Equipment-related factors mostly involved the design and usability of equipment used during dispensing. The most frequent factor relating to this was issues with medication storage, such as the proximity of similar medications or medication being stored in the wrong place. Medication packaging was also commonly described as a contributory factor, mostly involving factory packaging or re-packaging of medication before dispensing.

Patient-related factors mostly involved the physiological and physical characteristics of the patient, such as the patient's age, previous health or medication history, use of other medication, and allergy status (see Table 4.13). Others included patient's lack of understanding and non-compliance of instructions.

4.4.3 Administration incidents

In total, 959 contributory factors were coded from the 760 administration incident reports. At least one contributory factor was described in 74.7% (n = 568) of the reports and more than one contributory factor was described in 33.9% (n = 258) of reports. As in the other categories, these were divided into staff-related factors, service-related factors, patient-related factors, equipment-related factors and other factors. Table 4.14 shows the breakdown of contributory factors coded from administration incident reports.

Staff-related factors were the most common contributory factors identified in reports. They mostly involved mistakes, slips or lapses of staff. Some reports described more information about the reasons for

these, which included distractions or oversights, misreading of information and similarities of medication names. Errors during the staff decision making processes contributed to incidents which could be due to failure to follow procedures or inefficiencies in skill set or knowledge. Further examples of staff-related factors with less frequency are described in Table 4.14.

Service-related factors made up the second most common factor type. Continuity of care deficiencies, mostly within primary care, but also between secondary and primary care were the most commonly listed service-related factors in the reports. Issues related to inadequate, inefficient or absent protocols and deficiencies in the provision of education and training were also described. Working conditions such as being busy or overloaded with work and inadequate provision of healthcare staff also contributed to incident occurrence. See Table 4.14 for other service-related factors less frequently described.

Patient-related factors were also commonly described. Patients' lack of knowledge or understanding of instructions was the most common factor affecting patients' decision making. Lack of compliance was another issue identified in reports. Patients' physiological and physical characteristics, such as previous health or medication history and age were described as contributing to incidents. Further examples of these are described in Table 4.14.

Table 4.14 Reported contributory factors associated with Administration incidents (n = 959)

Contributory factor theme (% of n)	Contributory factor subtheme (% of N)	Most common examples of contributory factors	Frequency (number and % of N)
Patient-related factors (N = 225, 23.5%)	Patient characteristics (n = 105/225, 46.7%)	Palliative care patient	21 (9.3)
		Previous health/ medication history of patient and drug interactions	19 (8.4)
		Patient age	10 (4.4)
		Care home patient including nursing home	9 (4.0)
		Physical or mental disability of patient	9 (4.0)
		Patient's behaviour such as fraudulent behaviour	7 (3.1)
		Patient frailty	7 (3.1)
		Language barrier	6 (2.7)
		Other pathophysiological factors	17 (7.6)
	Patient decision making and knowledge (n = 108/225, 48.0%)	Patient or parent has poor understanding	88 (39.1)
		Patient non-compliant with instructions	20 (8.9)
	Other patient-related factors (n = 12/225, 5.3%)	Area where patient lives and its characteristics	7 (3.1)
		Other patient factors	5 (2.2)
Staff-related factors (N = 399, 41.6%)	Staff decision making (n = 181/399, 45.4%)	Failure to follow protocol	84 (21.1)
		Inadequate skill set or knowledge	67 (16.8)
		Wrong professional carries out task or not carried out at all	30 (7.5)
	Mistakes, slips and lapses (n = 205/399, 51.4%)	Distraction/oversight	73 (18.3)
		Other mistakes, slips and lapses not specified otherwise	52 (13.0)
		Misread/ did not read	26 (6.5)
		Mistakes involving multi-compartment compliance aids (MCCAs)	20 (5.0)
		Similar medication names or appearances	17 (4.3)
		Medication delivery	9 (2.3)
		Haste/poor time management	8 (2.0)
	Other staff-related factors (n = 13/399, 3.3%)	Physical and mental wellbeing including fatigue and stress	3 (0.8)
		No or poor supervision or assistance	2 (0.5)
		Other staff factors	8 (2.0)

Table 4.14 Reported contributory factors associated with Administration incidents (n = 959) (continued)

Contributory factor theme (number and % of total contributory factors, n=959)	Contributory factor subtheme (number and % of contributory factor theme)	Most common examples of contributory factors	Frequency (number and % of N: contributory factor theme)
Equipment-related factors (N = 37, 3.9%)	Design and usability of equipment (n = 37/37, 100.0%)	Poor equipment design	12 (32.4)
		Issues with medication storage	9 (24.3)
		Medication packaging	7 (18.9)
		Other factors	9 (24.3)
Service-related factors (N = 249, 26.0%)	Issues related with protocols (n = 68/249, 27.3%)	Other non-specified protocols being inadequate, inefficient or absent	54 (21.7)
		Medication related protocols such as repeat prescribing	14 (5.6)
	Continuity of care (n = 113/249, 45.4%)	Continuity of care within primary care	53 (21.3)
		Continuity of care between secondary care and primary care	38 (15.3)
		Care given by locum or agency staff	13 (5.2)
		Lack of support	4 (1.6)
		Continuity of care not otherwise specified	5 (2.0)
	Working conditions (n = 22/249, 8.8%)	Busy/overloaded by work	10 (4.0)
		Inadequate provision of healthcare staff	8 (3.2)
		Other working conditions such as team factors	4 (1.6)
	Education and training (n = 31/249, 12.4%)	Deficiencies in knowledge and others' roles	31 (12.4)
	Service availability and delivery (n = 15/249, 6.0%)	Manufacturing and supply issues and lack of stock, e.g. medication order	15 (6.0)
Other factors (N = 49, 5.1%)	Others (n = 49/49, 100.0%)	Patient requiring syringe driver	34 (69.4)
		Other organisational factors	15 (30.6)

Deficiencies with equipment such as syringe drivers or where medications were stored were also described as contributing to some of

the incidents. Other factors such as organisational factors, staff factors and equipment factors were less frequently identified in reports.

4.5 Medicines involved in incidents

4.5.1 Prescribing and monitoring incidents

A total of 407 (87%) of 467 incident reports described the medication(s) involved in the incident. Within these, 572 medicines or medicinal classes were mentioned, which were classed using the ATC classification system. Table 4.15 shows the most frequent ATC level 3 medicinal classes identified broken down by the harm severities associated with them.

Antithrombotic agents, mostly warfarin, were the most frequent medications involved in incidents. They were also involved with the most harm to patients compared to other classes. Opioids, such as morphine and oxycodone, were also highly recurrent medications involved with these incidents. Incidents involving medicines used in addictive disorders such as methadone and buprenorphine only resulted in no or mild harm. However, incidents involving NSAIDs and diuretics, such as furosemide and bumetanide, had higher proportions resulting in a harm severity of moderate harm, severe harm and death (see Table 4.15). As previously reported, harm severity could not be established for all incident reports. See Appendix 9 and 10 for a detailed list of ATC level 1, 2 and 3 classification of all medications involved in these incidents.

Table 4.15 Most commonly reported classes of medicines involved in prescribing and monitoring incidents and harm severity associated with them (ATC level 3) (n = 369, 64.5%)

Drug class	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Antithrombotic agents	3 (4.8)	23 (36.5)	19 (30.2)	4 (6.3)	2 (3.2)	12 (19.0)	**63 (17.1)**
Opioids	7 (11.7)	17 (28.3)	21 (35.0)	0 (0.0)	1 (1.7)	14 (23.3)	**60 (16.3)**
Antipsychotics	5 (18.5)	7 (25.9)	7 (25.9)	0 (0.0)	0 (0.0)	8 (29.6)	**27 (7.3)**
Insulins and analogues	9 (34.6)	7 (26.9)	4 (15.4)	0 (0.0)	0 (0.0)	6 (23.1)	**26 (7.0)**
Drugs used in addictive disorders	5 (23.8)	7 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	9 (42.9)	**21 (5.7)**
High-ceiling diuretics	0 (0.0)	4 (21.1)	7 (36.8)	1 (5.3)	2 (10.5)	5 (26.3)	**19 (5.1)**
Beta-lactam antibacterials, penicillins	6 (31.6)	6 (31.6)	3 (15.8)	0 (0.0)	1 (5.3)	3 (15.8)	**19 (5.1)**
Antiinflammatory and antirheumatic products, non-steroids	0 (0.0)	3 (15.8)	7 (36.8)	2 (10.5)	1 (5.3)	6 (31.6)	**19 (5.1)**
Sulfonamides and trimethoprim	0 (0.0)	4 (25.0)	7 (43.8)	0 (0.0)	0 (0.0)	5 (31.3)	**16 (4.3)**
Antidepressants	2 (12.5)	8 (50.0)	2 (12.5)	0 (0.0)	1 (6.3)	3 (18.8)	**16 (4.3)**
Antiepileptics	0 (0.0)	7 (50.0)	3 (21.4)	0 (0.0)	0 (0.0)	4 (28.6)	**14 (3.8)**
Immunosuppressive agents	1 (7.7)	2 (15.4)	1 (7.7)	0 (0.0)	0 (0.0)	9 (69.2)	**13 (3.5)**
Anxiolytics	4 (33.3)	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	6 (50.0)	**12 (3.3)**
Hypnotics and sedatives	3 (25.0)	4 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (41.7)	**12 (3.3)**

Table 4.15 Most commonly reported classes of medicines involved in prescribing and monitoring incidents and harm severity associated with them (ATC level 3) (n = 369, 64.5%) (Continued)

Drug class	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
ACE inhibitors, plain	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0 (0.0)	5 (45.5)	**11 (3.0)**
Other analgesics and antipyretics	3 (27.3)	2 (18.2)	2 (18.2)	2 (18.2)	0 (0.0)	2 (18.2)	**11 (3.0)**
Beta blocking agents, plain	4 (40.0)	2 (20.0)	1 (10.0)	1 (10.0)	0 (0.0)	2 (20.0)	**10 (2.7)**
Total	**55 (14.9)**	**105 (28.5)**	**86 (23.3)**	**11 (3.0)**	**8 (2.2)**	**104 (28.2)**	**369 (100.0)**

4.5.2 Dispensing incidents

In total, 3244 (96%) dispensing incident reports described at least one medicine involved. In total, 5460 medicines were identified from the reports and classified. Table 4.16 shows the most frequently identified classes of medicines at level 3 of the ATC classification system and the harm severity associated with them. Where severity of harm could be established, medicinal classes with larger proportions of serious harm incidents included antithrombotic agents (n = 36/91, 39.6%), antipsychotics (n = 35/108, 32.4%), selective calcium channel blockers (n = 23/72, 31.9%), angiotensin II antagonists (n = 16/57, 28.1%), antiepileptics (n = 57/204, 27.9%) and opioid analgesics (n = 34/130, 26.2%). Antithrombotic agents, mostly warfarin, were involved with the most incidents resulting in death. Meanwhile, angiotensin II antagonists, such as valsartan and candesartan, were involved in the most incidents with a severe harm outcome. See Appendix 11 and 12

for a detailed list of ATC level 1, 2 and 3 classification of all medications involved in the incidents.

Table 4.16 Most commonly reported classes of medicines involved in dispensing incidents and harm severity associated with them (ATC level 3) (n = 3543, 64.9%)

Drug class	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Antidepressants	44 (10.0)	133 (30.3)	37 (8.4)	1 (0.2)	0 (0.0)	224 (51.0)	**439** (12.4)
Antiepileptics	47 (13.4)	100 (28.5)	56 (16.0)	1 (0.3)	0 (0.0)	147 (41.9)	**351** (9.9)
Opioids	47 (18.4)	49 (19.1)	31 (12.1)	2 (0.8)	1 (0.4)	126 (49.2)	**256** (7.2)
Antipsychotics	7 (3.1)	66 (29.6)	34 (15.2)	1 (0.4)	0 (0.0)	115 (51.6)	**223** (6.3)
Beta blocking agents	23 (10.4)	53 (23.9)	24 (10.8)	2 (0.9)	0 (0.0)	120 (54.1)	**222** (6.3)
Lipid modifying agents	44 (23.8)	35 (18.9)	12 (6.5)	0 (0.0)	0 (0.0)	94 (50.8)	**185** (5.2)
Selective calcium channel blockers with mainly vascular effects	12 (6.6)	37 (20.2)	19 (10.4)	3 (1.6)	1 (0.5)	111 (60.7)	**183** (5.2)
Insulins and analogues	31 (17.1)	43 (23.8)	14 (7.7)	0 (0.0)	0 (0.0)	93 (51.4)	**181** (5.1)
Blood glucose lowering drugs, excluding insulins	19 (11.1)	52 (30.4)	14 (8.2)	3 (1.8)	1 (0.6)	82 (48.0)	**171** (4.8)
Drugs used in addictive disorders	48 (30.6)	27 (17.2)	11 (7.0)	0 (0.0)	0 (0.0)	71 (45.2)	**157** (4.4)
Antithrombotic agents	30 (19.6)	25 (16.3)	34 (22.2)	0 (0.0)	2 (1.3)	62 (40.5)	**153** (4.3)
Drugs for treatment of peptic ulcer	20 (13.6)	32 (21.8)	12 (8.2)	2 (1.4)	0 (0.0)	81 (55.1)	**147** (4.1)
ACE inhibitors, plain	18 (12.2)	37 (25.2)	9 (6.1)	2 (1.4)	0 (0.0)	81 (55.1)	**147** (4.1)
Other drugs for obstructive airway diseases, inhalants	37 (30.8)	19 (15.8)	2 (1.7)	0 (0.0)	0 (0.0)	62 (51.7)	**120** (3.4)

Table 4.16 Most commonly reported classes of medicines involved in dispensing incidents and harm severity associated with them (ATC level 3) (n = 3543, 64.9%) (Continued)

Drug class	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Antiglaucoma preparations and miotics	12 (11.0)	20 (18.3)	1 (0.9)	3 (2.8)	0 (0.0)	73 (67.0)	**109** (3.1)
Angiotensin II antagonists	15 (14.3)	26 (24.8)	7 (6.7)	8 (7.6)	1 (1.0)	48 (45.7)	**105** (3.0)
Thyroid preparations	20 (19.0)	24 (22.9)	5 (4.8)	1 (1.0)	0 (0.0)	55 (52.4)	**105** (3.0)
Beta-lactam antibacterials, penicillins	15 (14.4)	28 (26.9)	8 (7.7)	0 (0.0)	0 (0.0)	53 (51.0)	**104** (2.9)
Antiinflammatory and antirheumatic products, non-steroids	7 (7.4)	19 (20.0)	7 (7.4)	0 (0.0)	1 (1.1)	61 (64.2)	**95** (2.7)
Other analgesics and antipyretics	21 (23.3)	15 (16.7)	2 (2.2)	0 (0.0)	1 (1.1)	51 (56.7)	**90** (2.5)
Total	**517 (14.6)**	**840 (23.7)**	**339 (9.6)**	**29 (0.8)**	**8** (0.2)	**1810 (51.1)**	**3543 (100.0)**

4.5.3 Administration incidents

In total, 662 (87%) reports described the medication(s) involved in the incident. A total of 809 medicines or medicinal classes were described in the reports. Table 4.17 shows the most frequent ATC level 3 medicinal classes described in administration incidents broken down by harm severity.

Insulins were the most frequent medication involved in administration incidents followed by antithrombotic agents such as warfarin and enoxaparin. Opioids, such as morphine, oxycodone and fentanyl were the third most frequent medications involved.

Table 4.17 Most commonly reported classes of medicines involved in administration incidents and harm severity associated with them (ATC level 3) (n = 638, 78.9%)

Drug class	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Insulins and analogues	11 (7.1)	63 (40.4)	13 (8.3)	0 (0.0)	0 (0.0)	69 (44.2)	156 (24.5)
Antithrombotic agents	12 (14.1)	13 (15.3)	10 (11.8)	0 (0.0)	0 (0.0)	50 (58.8)	85 (13.3)
Opioids	8 (10.3)	36 (46.2)	11 (14.1)	1 (1.3)	2 (2.6)	20 (25.6)	78 (12.2)
Viral vaccines	9 (12.9)	10 (14.3)	1 (1.4)	0 (0.0)	0 (0.0)	50 (71.4)	70 (11.0)
Bacterial vaccines	11 (16.7)	3 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	52 (78.8)	66 (10.3)
Bacterial and viral vaccines, combined	3 (8.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	31 (91.2)	34 (5.3)
Antipsychotics	3 (13.6)	10 (45.5)	0 (0.0)	0 (0.0)	0 (0.0)	9 (40.9)	22 (3.4)
Hypnotics and sedatives	1 (5.6)	7 (38.9)	2 (11.1)	0 (0.0)	1 (5.6)	7 (38.9)	18 (2.8)
Immunostimulating agents	1 (6.3)	4 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (68.8)	16 (2.5)
Antiepileptics	1 (6.3)	7 (43.8)	2 (12.5)	0 (0.0)	0 (0.0)	6 (37.5)	16 (2.5)
Antidepressants	0 (0.0)	3 (18.8)	3 (18.8)	1 (6.3)	0 (0.0)	9 (56.3)	16 (2.5)
Other antianaemic preparations	3 (23.1)	4 (30.8)	0 (0.0)	0 (0.0)	0 (0.0)	6 (46.2)	13 (2.0)
Vitamin B12 and folic acid	4 (30.8)	3 (23.1)	0 (0.0)	0 (0.0)	0 (0.0)	6 (46.2)	13 (2.0)
Other analgesics and antipyretics	1 (7.7)	1 (7.7)	3 (23.1)	0 (0.0)	0 (0.0)	8 (61.5)	13 (2.0)
Corticosteroids for systemic use, plain	1 (8.3)	6 (50.0)	2 (16.7)	0 (0.0)	1 (8.3)	2 (16.7)	12 (1.9)
Dopaminergic agents	1 (10.0)	3 (30.0)	1 (10.0)	0 (0.0)	0 (0.0)	5 (50.0)	10 (1.6)
Total	**70 (11.0)**	**173 (27.1)**	**48 (7.5)**	**2 (0.3)**	**4 (0.6)**	**341 (53.4)**	**638 (100.0)**

Opioids (n = 3/9, 33%) were the most frequent class of medication involved in incidents with a confirmed harm severity of severe harm or

death. Incidents during administration of vaccines were also frequently described and involved viral vaccines, bacterial vaccines and a combination of both. Other frequent medicinal classes identified in administration incidents are listed in Table 4.17. As previously discussed, harm severity could not be corroborated for all reports and were classified as unclear where this was the case. See Appendix 13 and 14 for a full list of ATC levels 1, 2 and 3 classifications of all medications involved in these incidents.

4.6 Identifying priority areas for improvement

In this section, I aim to highlight priority areas of weakness relating to each of the incident categories. These could be targeted for improvement in order to decrease the occurrences of medications incidents in primary care.

4.6.1 Prescribing and monitoring incidents

In total, 381 (81.6%) of 467 reports contained at least one contributory factor or contributory incident. These were re-examined and thematically analysed as described in section 2.7.3. Insights from the thematic analysis combined with findings from stage two (EDA) of the data analysis, including cross tabulations with contributory factors (Table 4.12), were used to identify key issues in the form of themes that could be targeted for improvement strategies. There was some overlap of reports across the generated themes due to some reports describing multiple reasons as to the occurrence of the incident.

The themes that emerged from the analysis of these incidents were:

- **Active failures due to insufficient protocols, workforce and equipment** – this included incidents where unsafe acts such as mistakes, slips, lapses and procedural violations were committed by staff;
- **Inadequate procedures for implementing medication changes at transfer of care between settings** – this included incidents where vital information about patient healthcare had not been communicated in a timely manner, or acted upon within and between primary and secondary care providers;
- **Need for improved staff education and training** – this included incidents in which the knowledge (facts, information and skills) of staff was poor.

I will now describe and interpret each theme, including the frequency of occurrence whilst considering the role of the associated contributory factors. Where relevant, the contributory incidents leading up to the prescribing or monitoring incidents (using recursive model of incident analysis) alongside other contextual issues identified by the thematic analysis will be discussed.

4.6.1.1 Active failures due to insufficient protocols, workforce and equipment

As previously noted, staff-related contributory factors were the most frequently described in reports which also correlated with the most frequently reported prescribing and monitoring incidents. These were mostly active failures such as mistakes, slips, lapses and procedural violations. Factors relating to working conditions, including equipment

issues and protocol or guideline inadequacies, were also frequently reported. More than 54% (n = 207) of the reports described at least one of these factors, mostly relating to prescribing the wrong medication or dose and prescribing a medication to a patient who is known to be allergic. Reports described some of these factors happening concurrently leading up to an incident (n = 78/381, 21%).

Failure to adhere to procedures, guidelines or working protocols were seen to have compounded the effect of other contributory factors in multiple reports, eventually causing an incident to occur. This is demonstrated in Example 17, where the doctor did not pay attention (contributory factor) to the information being displayed (allergy – contributory factor) on the screen before prescribing the medication. This was compounded by the doctor not following procedure (contributory factor) of reading through the warnings displayed, which they blamed on the impracticalities of the equipment (contributory factor). Example 18 describes another incident where the procedure was not adhered to, which led to the patient's record not updated (contributory incident), thereby missing the drug interactions warning (contributory factor) and causing a medication incident.

> **Example 17:** *Patient with a known allergy to trimethoprim was prescribed trimethoprim. Patient suffered allergic reaction and was hospitalised. Error thought to be due to GP being able to override warnings on the system and proceed to prescribe. GP involved said many irrelevant warnings come up so they tend to become blasé.*
>
> **Example 18:** *Miconazole given to patient on warfarin - INR rose from 1.9 to 6.1. Warfarin had not been listed on repeat medication list as it was being dispensed from the pharmacy. Automated interaction*

> *warning did not flag up problem. Need to check compliance with protocol which was not followed and states warfarin should be on repeat list.*

Due to the procedures, protocols or guidelines sometimes being inadequate or inefficient (contributory factor) (n = 67), they additionally promoted active failures by staff. These mostly involved procedures relating to repeat prescribing of patients' medications. Reports described situations where better procedures or guidelines could have prevented incidents. Most of these involved mistakes made by staff (see Example 19) and lapses in system, such as the lack of review or monitoring of medications on repeat list which eventually led to an incident and potential harm to patients (see Example 20).

> **Example 19:** *Prescribing error occurred when GP incorrectly converted oral morphine to diamorphine for a syringe driver. Three times the recommended dose was prescribed. Dose was queried but thought ok as GP had calculated it. The patient was administered the syringe driver and became drowsy and unwell. The medicine has been adjusted. The cause is uncommon procedure. Medicines management team after discussion with GP suggested actions to improve procedure such as second GP check on calculations.*

> **Example 20:** *Prescription clerk noticed that the patient was on methotrexate but had not had recent blood test (last one [date]). On speaking to patient it was discovered that he hadn't been under a rheumatologist for 5 years and so had not had bloods checked by them. Methotrexate was on repeat. Although the directions stated 'monthly blood tests', the patient had not had them. No checks were made to ensure patient was being monitored before scripts were signed. (Lack of monitoring)*

Reports also described insufficient staff and increased workload or busy times as contributory factors which sometimes promoted mistakes, slips

or lapses. Increased workload was sometimes the result of a lack of staff. The following Example (21) describes lack of staff due to sickness, which added to the workload or pressure on the nurse involved. This promoted the mistake and led to the patient's overdose.

> **Example 21:** *Accidental transposition of warfarin dose leading to a higher reading for the INR range between 2.5 and 3.5. I had written 7mg Monday to Friday and 6mg Saturday and Sunday. This resulted in an increased INR of 4.3 at the next clinic visit by the patient. This was highlighted by another senior nurse. I was under pressure due to staff sickness within the team at the time and both clinics at [Name] were new to me as were the patients which all needed imputing onto the software.*

In another incident involving warfarin dosage, the INR was tested and found to be too high. The results were communicated to the doctor via urgent email and a personal reminder by the receptionist to action the email and adjust the patient's dose accordingly. However, the doctor failed to do so due to oversight (contributory factor) because the surgery was very busy (contributory factor) and the doctor did not see the email until much later. The patient therefore carried on taking their previous dose and had to be administered vitamin K when they got admitted to hospital the following day (for an entirely different reason) and the hospital identified that the patient was over anti-coagulated. Example 22 describes another prescribing incident where a prescription was issued in a haste during a busy time, which resulted in a mistake being made.

> **Example 22:** *When client attended his appointment, I noticed when checking his next prescription due that the daily dose was incorrect. It showed 32mgs Subutex instead of 8mgs. As this prescription was*

printed as a follow on, I then checked back on the system and noted that the previous prescription has also been issued at the incorrect dose. It transpired that the error originally occurred at the start of treatment on [date] when another key worker started the client on treatment with the doctor and I issued the follow on script (dose was still within therapeutic range). Incorrect prescription was given out during a very busy time. Need to ensure that adequate time is allowed to check prescriptions thoroughly during busy times.

Other operational issues were reported to have promoted mistakes; these included handwritten (contributory factor) summary discharge letters from the hospital which were misread (contributory factor) and led to prescribing incidents in primary care (see Examples 23 and 24). Issues relating to transfer of patient information are discussed further as part of the next theme.

Example 23: *Prescribing error, handwritten discharge note from hospital stated spironolactone 12.5mg. It was misread as 125mg and incorrect dose was prescribed in primary care. Urea and electrolytes checked correctly 7 days later and showed deteriorating renal function. Error realised, patient informed, dose corrected and follow up arranged.*

Example 24: *[X] year old male paediatric patient with renal impairment and under the care of children's hospital. Patient was admitted to hospital on [date] following a UTI infection. Patient was discharged on [date – 2 days later] and a handwritten inpatient discharge letter was sent to GP surgery with details of medication on discharge. One of the medications recorded on the discharge letter was spelt incorrectly as RENEGEL with dose: one (800mg) PRN (with meals). When added to the prescribing screen of the patient's notes by GP, this was recorded as sevelamer 800mg tablets (Renagel). When the prescription was printed and given to the mother of the patient, she explained to the GP that her child was not being prescribed Renagel i.e. sevelamer HCL 800mg tablets but had in fact been prescribed and dispensed REMEGEL tablets containing calcium carbonate 800mg as an*

unlicensed calcium supplement by children's hospital. Therefore the GP at the practice had issued a script for incorrect medication.

4.6.1.2 Inadequate procedures for implementing medication changes at transfer of care between settings

Whilst prescribing or monitoring medication, prescribers did not always have or use the most up to date patient information available to deliver seamless care to patients (continuity of care). In total, 87 (23%) of the 381 incidents reported continuity of care as a contributory factor. This was mostly as a result of communication errors in the transfer of information - mostly from secondary care to primary care, but sometimes within primary care settings (contributory incidents) (n = 58/381, 15%). These errors mostly resulted in prescribing incidents involving a wrong medication or dose, or a stopped medication being prescribed to patients. Five of the 58 incident reports resulted in monitoring incidents where monitoring was not commenced or treatment not adjusted as a result of monitoring performed elsewhere. When patients are admitted to the hospital due to changes in their conditions, their medication regimen commonly gets changed or altered. This is then disseminated to the primary care settings for consideration in future prescribing. Errors or inefficiencies during this process of dissemination contributed to incident occurrences. Reports described changes being communicated to the primary care setting but not being actioned (n = 25/58, 43%) before issuing a new prescription. For example, in one report, a patient's warfarin dose was changed by the INR clinic following blood test, however, this change was not implemented by the surgery and a higher dose was still prescribed to

the patient. This led to patient being admitted due to the increase in INR levels. Patients on multi-compartment compliance aids, MCCAs (contributory factor) were also affected by this, as new repeat prescriptions were generated sometimes automatically without applying changes communicated from the hospital. See dispensing incident reports (Section 4.6.2) for MCCA related incidents. Some reports suggested that the procedures for receiving and inputting changes on discharge letters were not rigorous enough (see Example 25).

> **Example 25:** *Patient's daughter rang and asked to speak to the practice nurse because her mother had had a hypoglycaemic attack the night before. On enquiry about diabetic medication, daughter reported that glimepiride was 3mg and in a nomad system (MDS). It was suggested that this needed reducing. However, the discharge letter from [name] hospital already reduced it to 2mg. 3mg had been issued by the practice twice since this discharge letter. Patient has suffered as a consequence of the error.*

Incorrect or incomplete information transfer (n = 9/58, 16%) was also described in reports which led to incidents and harm to patients. Patients changing practices in primary care experienced such errors (see Example 26) but most of the incidents involving incorrect or incomplete information originated from secondary care following hospital discharge. Example 27 describes one such case, which contributed to a severe outcome to the patient as a result of omissions in the discharge letter. General practice procedures were mostly reviewed as a result of these incidents.

> **Example 26:** *Prescription was dispensed correctly but the doctor had prescribed the wrong strength. Apparently, the patient had changed from one practice to another and it seems there was an error in*

information passed between surgeries which led to wrong strength being prescribed. There was poor communication between the practices.

Example 27: *Patient was recently admitted and new medications added. Medication list on discharge letter did not include some of the patient's previous regular medications, so GP assumed they had been discontinued by the hospital. One month later, patient had cerebrovascular accident (CVA). Patient was very hypertensive on admission. It was subsequently discovered that the hospital had intended her to continue antihypertensive medications even though they were omitted from discharge medication list.*

Although not as frequent, other reasons that contributed to incident occurrence included delayed transfer of patient information or no information transfer at all.

4.6.1.3 Need for improved staff education and training

Reports described inadequate knowledge or training as a fairly common recurring factor contributing to prescribing incidents, including during clinical treatment decisions (n = 70/381, 18%). Inadequate knowledge or skill set was the single most common contributory factor identified in these reports (n = 62). These mostly resulted in prescribing the wrong dose and unsafe or contraindicated medication. Prescribers were reported to have prescribed, or advised patients to take, medications that they should not have, or taken with caution, without adequate consideration of the implications of their pathophysiological factors (contributory factors), such as previous medications or conditions. This was sometimes reportedly due to staff's lack of knowledge of such implications at the time of prescribing. The following Examples (28 and 29) described incidents of inappropriate advice or prescription from

possible lack of knowledge. Example 28 eventually led to patient's death, whilst the outcome of Example 29 was not clearly described.

> **Example 28:** *Complaint came in from patient's wife. Patient rang up with a sore mouth following chemotherapy for GI cancer. GP advised he purchased OTC ibuprofen 400mg. He did this, had a GI bleed and died.*

> **Example 29:** *Spoke to patient on [date] re: suprapubic pain. Offered acupuncture by midwife which patient declined. Advised to see GP for physio referral or for analgesia. GP was seen and prescribed ibuprofen. Patient took 5 tablets in total before looking on the internet and read that drug is unsafe in 3rd trimester. Patient rang me today, [date] at [time]. I checked with [name] pharmacy and they confirmed ibuprofen is not to be prescribed in 3rd trimester.*

Some reports described a lack of education and training of prescribers within some specialist areas, which contributed to the occurrence of incidents. The following Example (30) describes an incident where the GP believed that they made the right decision in managing a patient's diabetes medication. However, the reporter (a specialist nurse) thought the doctor would benefit from further education and training. Example 31 is another incident that caused the deterioration of patient's condition, in which it was also identified that further training in that area would be beneficial to GPs.

> **Example 30:** *Patient rung me to let me know that she had seen her GP Dr [name] yesterday seeking advice for recurrent hypos. Patient has type 2 diabetes. The advice given by the Dr was to stop both doses of her long acting insulin Lantus, 48 units taken in the morning and 32 units taken in the evening giving a grand total of 80 units of insulin. The Dr had made no adjustment to patient's usual Novorapid (rapid acting insulin) doses that she has immediately before her meals. Doses usually taken are 44 units before breakfast, 48 units before*

lunch and 52 units before evening meal. Dr [name] had written down these instructions and requested that she was reviewed in 3 weeks. I suggested that patient monitors her blood glucose level at least 4 times a day immediately before her meals and before bed and at any other time over the weekend if she feels unwell. If blood glucose levels increase above 20 mmols, to reintroduce 10 units of Lantus in the evening and to ring me next [day]. I discussed issue with GP involved but to no particular outcome. GP involved continued to still believe her rationale with her decision to stop insulin was correct and would still review in 3 weeks. Diabetes team alerted to this error as they deal with education of healthcare professionals. Consultant responsible for this patient to be alerted on his return from annual leave.

Example 31: *I rang this patient's GP surgery to double check the dose of dopamine agonist therapy (pramipexole) prescribed. The patient had been prescribed almost 6 times less than what he had been on the previous month. The patient was reporting to be less mobile and in low mood stating that he sees 'no point in living'. GP prescribed antidepressants to the patient. The correct prescription was supplied using dosage guide supplied by specialist nurse. This area of prescribing is complex and GPs felt they need some additional training and are going to try to organise having a specialist nurse go to the practice to talk at an in house target.*

Other prescribing errors due to lack of knowledge of contraindications, accurate dosing and drug interactions, amongst others, were reported (see Examples 32, 33 and 34).

Example 32: *Asthmatic patient came to see the doctor about a problem he was having. It was noted during the consultation that the patient was very short of breath. Upon doing a medication review, it was noted the patient was prescribed and taking atenolol and this was making him short of breath. All clinicians were then made aware of contraindication of drug in asthmatic patient.*

Example 33: *Digoxin toxicity due to too high a dose of digoxin for age and renal function was identified. Patient had become confused over the preceding weeks and the digoxin level was 3.2 mcg/litre. There*

was a lack of awareness of digoxin dosages, toxicity effects and monitoring especially in elderly patients.

Example 34: *Patient seen by GP OOH. Urinary tract infection diagnosed and prescribed trimethoprim. Patient was on methotrexate – serious interaction. Patient came into A&E and was admitted. The prescription was carried on by A&E staff. Pharmacist stopped the medication in the medical assessment unit (MAU). The GP was contacted and confirmed he was unaware of the interaction between the two drugs.*

4.6.2 Dispensing incidents

A total of 2346 (69.4%) of 3380 dispensing incidents had at least one contributory factor or contributory incident which were re-examined as described in Section 2.7.3.

After exploring the results quantitatively using frequency tables and cross tabulations, clusters of incident reports of like phenomena deemed important and/or highly recurrent were extracted and thematically analysed as a group. This additional process of grouping was done partly to break down the large number of reports into smaller, meaningful groups for thematic analysis. Insights from the thematic analysis, combined with the findings from stage two (EDA) of the data analysis, were used to identify the priority areas in the form of themes relating to each cluster of reports which could be targeted for improvement strategies. The clusters of reports identified for grouping which will be described further were:

- Picking errors during dispensing
- Serious harm incidents

- Incidents involving Multi-Compartment Compliance Aids (MCCAs)

4.6.2.1 Picking errors during dispensing

A total of 1,571 (67%) of the 2346 incident reports were as a result of a picking error during the dispensing process. This may indicate underlying problems or issues specific to the picking stage of the process. Outcomes were described in 762 (49%) of the 1,571 reports, mostly resulting in patients' clinical harm and other non-clinical inconveniences. The most common outcomes included medication overdose, repeated visits to and from healthcare providers and hospital admissions. The severity of patient harm was identified in 720 (46%) of the reports. Whilst 556 incidents resulted in no or mild harm, 153 incidents resulted in moderate harm, seven incidents in severe harm and four incidents resulted in death. The remaining reports had insufficient detail to assess harm severity (n = 851, 54%). The picking errors identified from the dispensing incidents were:

- Wrong item dispensed (n = 797, 51%)
- Wrong strength dispensed (n = 614, 39%)
- Wrong formulation dispensed (n = 160, 10%)

Just over half of these reports described the age of the patient (n = 803, 51%). A trend in patient's age similar to that found in Section 3.3.6 was also seen here, with increasing number of reports with age.

The themes that emerged from the analysis of these incidents in conjunction with contributory factors identified (Table 4.13) were:

- **Medication similarity oversights** – this included incidents resulting from similar medication names or packaging and where medications are stored;
- **Lack of adequate or implemented protocols** – this included incidents arising from inadequate procedures or guidelines and lack of adherence to them by staff;
- **Suboptimal working environment** – this included incidents promoted by distractions, work flow (busy) and insufficient staffing levels;
- **Need for improved staff education and training** – this included incidents in which the knowledge (facts, information and skills) of staff was poor.

There was also some overlap of reports across the generated themes in this group. From the thematic analysis, it was apparent that one contributory factor could predispose another factor, leading up to an incident occurrence. This is evident from some of the examples given later on. I will now describe and interpret each theme that emerged, reporting the frequency of occurrence whilst considering the role of the associated contributory factors and, where relevant, the contributory incidents leading up to the dispensing incidents (recursive model of incident analysis) alongside other contextual issues identified.

4.6.2.1.1 Medication similarity oversights

Incident reports described the similarity of medication in some way as the most common contributory factor to picking errors (n = 787, 50%). This mistake or slip usually happens by picking the wrong medicine with

a similar name or similar manufactured packaging (especially when it comes to picking the wrong strength) (see Examples 35 and 36). Examples of similar medication names described in reports included atenolol, amlodipine, amitriptyline and allopurinol, trimethoprim and trimeprazine, chlorphenamine and chlorpromazine, carbamazepine and oxcarbazepine.

> **Example 35:** *The patient was prescribed amongst other things hydralazine 25mg tablets which was dispensed on [date]. On the [date], [name] hospital phoned to say the patient had been admitted to hospital for a fall. On checking her medication it was discovered that she had been given hydroxyzine 25mg tablets instead of hydralazine tablets.*
>
> **Example 36:** *Amitriptyline 25mg tablets dispensed against a prescription for atenolol 25mg tablets. Taken 4 tablets. Admitted to hospital after collapse at evening meal. Remained in hospital for 5 days. Item was dispensed as a walk-in prescription. Additional risk may be similar packaging design of the medication.*

The similarity of names or packaging sometimes led to the medicine being stored in the wrong place while putting away stock, then being picked wrongly from the right place during dispensing (see Example 37). Medication storage was described 438 times as a contributory factor. This included situations arising due to the proximity of similar medications, or when a medication is stored in the wrong place. A wrong label (contributory incident) was sometimes generated where a similar medication was selected from the drop down list. This label was then printed and used to pick the wrong medicine (see Example 38). Incidents involving similarity of medications led to harm severity varying from no harm to death depending on type of medication and other

factors. Insulins (n = 33) were the most common type of medication involved in picking errors as a result of similarities of names and/or packaging.

> **Example 37:** *Pilocarpine 4% eye drops were dispensed instead of hypromellose 0.3 % on the [date]. The patient picked up the prescription on [date] and used the eye drops shortly afterwards. He then experienced pain / soreness / stinging and went to [name] surgery. He was then seen by Dr [name] who examined the eye and gave the patient a supply of hypromellose eye drops. The packaging for hypromellose and pilocarpine is very similar and although they are not stored near to each other, it is possible the pilocarpine may have been put away incorrectly with the hypromellose.*

> **Example 38:** *Eye drops were labelled as travoprost 40mcg / ml since [date] although prescription said travoprost 40mcg / ml / timolol 5mg / ml. The right medication has been dispensed to patient on previous occasions (Duotrav). On [date], patient was given the wrong item Travatan, mistake spotted by the pharmacist the day after when surgery contacted to check prescription.*

4.6.2.1.2 Lack of adequate or implemented protocols

Many reports described issues relating to procedures or protocols as a contributory factor to picking errors (n = 511, 33%). Inadequate standard operating procedures (SOPs), or lack thereof, were described in reports as a contributory factor (n = 190). This included absence of SOPs for certain tasks in the dispensary or instances where SOPs were insufficient or inadequate. For example, when a pharmacist is left on their own in the dispensary and there is a lack of personnel to double check their work. Poorly designed SOPs relating to dispensing process were also reported as contributory factors (see Example 39).

> **Example 39:** *9 x Morphine ampoules 10mg/ml were supplied against a prescription for 9 x methadone 10mg/ml ampoules. The patient was also correctly supplied with 3 x methadone 50mg/5ml and methadone oral solution 1mg/ml sf. The patient injected 7 x morphine 10mg/ml ampoules and 2 x morphine 10mg/ml ampoules were returned to the pharmacy. Only two ampoules of Physeptone 10mg/ml were in stock at the time of dispensing. The Pharmacy computer system has been ordering the methadone ampoules generically and may have been putting the item on an order pad that did not supply the item.* ***Cluttered front bench*** *where main walk in/ substance misuse prescriptions are checked. No proper structure to where prescriptions are located, for example a repeat prescription will be on the bench with walk in prescriptions while other benches are not being used.*

Where established SOPs were present, a lack of adherence to them (contributory factor) was commonly reported (n = 273). This sometimes involved a locum (n = 60) covering for a regular staff, this is mostly a pharmacist who is not familiar with the SOPs of the pharmacy (see Example 40). Permanent staff members were also reported not to adhere to SOPs, for example, when a patient's previous record is used to dispense a new prescription despite this not being compliant with the SOP. This usually resulted in the wrong label (contributory incident) being produced, which eventually led to picking the wrong item from the shelves.

> **Example 40:** *Detrusitol 4mg should have been supplied. Detrusitol 1mg & 4mg XL dispensed. Script need to be taken over to product (when picking) - not trying to remember items on prescriptions. Remind locum of SOP, locum not to dispense and check all by themselves. Another member of staff to also check labels and drugs.*

Medication overdose was one of the most common outcomes involved with procedural issues which led to some clinical harm to patients.

Repeated visits to or from healthcare providers was also a common outcome. The majority of incidents resulted in mild or no harm, where harm severity was identified. Morphine (n = 22) and insulin (n = 22) were the most common medicines described in these reports.

4.6.2.1.3 Suboptimal working environment

A total of 497 (32%) reports described suboptimal working conditions as contributing to picking errors. Being very busy (n = 356) in the dispensary was one of the most frequently reported factor. This was usually compounded by insufficient number of staff (n = 103) (contributory factor) which overloaded work on the staff members. This sometimes led to haste (n = 26) (contributory factor) during the dispensing process which increased the likelihood of errors. Distractions from staff and other tasks (n = 208) during picking and checking of prescriptions were described to be compounded by poor working conditions in reports. Contributory factors resulting in suboptimal working conditions were frequently reported alongside other factors, suggesting they may predispose other contributory factors to dispensing incidents. These included similarity of medication names and packaging as discussed earlier (see Examples 41, 42, 43).

> **Example 41:** *Prescription was labelled on [date], due to busy time period and pharmacy being under staffed the prescription wasn't dispensed before the patient representative arrived to collect it on the morning of [date]. It was dispensed on the morning of the [date] whilst the patient representative was waiting. The pharmacy was busy at the time. The regular pharmacist wasn't in on the day and the pharmacy was down a member of staff. Prescription was dispensed and it stated "propranolol 10mg tablets (56)" What was thought to be the correct*

item was selected and dispensed by the technician before being checked by the pharmacist who supplied to the patient (representative). When the patient representative brought the medication back to the pharmacy the morning after it was found that one packet of propranolol 10mg tablets was supplied and one packet of metoclopramide 10mg tablets had been supplied (both drugs have almost identical packaging). The patient had taken 1 tablet, no harm came to the patient and his GP was notified as soon as the pharmacy was made aware of the incident.

Example 42: *Prescription received for amitriptyline 25mg tablets, TWO to be taken at NIGHT. Label and PMR correct, however atenolol 25mg was dispensed and checked and administered for approximately 18 days until patient's husband went to [name] out of hours due to the ill health of his wife where the duty doctor spotted the error. Apparent causes – Interruptions by phone / Staff.*

Example 43: *Repeat prescription for atenolol 25mg tablets was received but amitriptyline 25mg tablets were dispensed. There was an issue with staff shortages due to illness which led to the pharmacist dispensing without assistance and therefore no double checking was carried out. This was a case of similar drug names, strengths and location in dispensary leading to a picking error.*

4.6.2.1.4 Need for improved staff education and training

Inadequate knowledge or training (n = 110, 7%) was also reported frequently in reports, albeit the least commonly recurring theme. Staff members were reported to dispense a different formulation due to not being aware of other formulations (see Example 44). Other sources of confusion due to lack of knowledge included generic name use on prescriptions (n = 25) instead of proprietary brand names (see Example 45). Staff members not fully trained led to the occurrence of picking errors in some instances (see Example 46).

Example 44: *The script called for paracetamol and metoclopramide tablets 500mg + 5mg, I supplied paracetamol and metoclopramide effervescent powder 500mg + 5mg. I must be more aware of the various formulations of this product in the future.*

Example 45: *Patient given Sevikar 10/40 tablets instead of Inegy 10/40 new product and patient took tablets. Patient came to no harm but cholesterol level went up on last GP check. Spoke to GP and patient and both parties have no further actions required. Briefed team as prescription written generically, reviewed both drugs' location on shelf and be aware of generic drug names.*

Example 46: *Mother of a child was given prescription and went to the pharmacy. Prescription was not available so the mother returned to [name] OOH and erythromycin granules not diluted given from the cupboard. Mother gave 1 teaspoon of granules 4 times a day. Mother took the child to the GP next day and child was admitted as a precaution. Child in hospital less than 24 hours and then discharged. OOH GP asked for training to be provided to OOH staff and protocol reviewed.*

Wrong information being passed on to patients following queries was also identified as an issue (see Example 47 below). Some patients queried the dispensing error after occurrence but were reassured wrongly by the staff, which ended up compounding the incidents and increasing the chance of a more harmful outcome.

Example 47: *Tegretol 400mg was given instead of Tegretol Retard 400mg.The patient took the medicine away with them and noticed it wasn't right so came back into store and asked someone if this was correct and they informed him that the packaging had changed and that it was the correct medication. The patient then took the medication and became very ill with really bad headache and dizziness, fell out of bed. His wife came into store and wasn't very happy that her husband had become very ill as a result of this. Apparent causes: pressure - very busy, similar package and lack of knowledge.*

4.6.2.2 Serious harm incidents

Of the 2,346 incident reports, 257 (11%) resulted in a patient outcome of moderate harm, severe harm or death. Using the WHO ICPS definitions described in Chapter 1, moderate harm was a major reduction in bodily function or hospital admission, whilst severe harm was major permanent loss of function or disability. Incidents resulting in moderate, severe harm and death were referred to as serious harm incidents in this thesis, derived from a previous NIHR study [83]. Some of these incidents led to serious preventable adverse effects as a result of errors by healthcare professionals, therefore making it vital to understand the reasons behind their occurrence and how they can be prevented in the future.

Table 4.18 (adopted from Table 4.7) shows the types of dispensing incidents that caused serious harm to patients. Almost two thirds of the incidents were picking errors of wrong medication or wrong strength (n = 155, 60%). Some of the outcomes included medication overdose, deterioration of medical condition, loss of consciousness and changes in physiological parameters; the majority of which resulted in hospital admission or increased length of stay.

Table 4.18 Dispensing incidents causing serious harm (n = 257)

Dispensing incident types	Harm severity (row %)			Total (column %)
	Moderate	Severe	Death	
Wrong medication	85 (92.4)	5 (5.4)	2 (2.2)	**92 (35.8)**
Wrong strength	59 (93.7)	2 (3.2)	2 (3.2)	**63 (24.5)**
Wrong dose	3 (100.0)	0 (0.0)	0 (0.0)	3
Overdose	19 (95.0)	0 (0.0)	1 (5.0)	20
Under-dose	3 (75.0)	1 (25.0)	0 (0.0)	4
Sub-total	25 (92.6)	1 (3.7)	1 (3.7)	**27 (10.5)**
Not dispensed	16 (94.1)	1 (5.9)	0 (0.0)	**17 (6.6)**
Wrong patient	13 (86.7)	2 (13.3)	0 (0.0)	**15 (5.8)**
Wrong formulation	9 (100.0)	0 (0.0)	0 (0.0)	**9 (3.5)**
Stopped medication being dispensed to patient	6 (85.7)	1 (14.3)	0 (0.0)	**7 (2.7)**
Wrong advice at dispensing stage	5 (83.3)	1 (16.7)	0 (0.0)	**6 (2.3)**
Wrong label	5 (100.0)	0 (0.0)	0 (0.0)	**5 (1.9)**
Wrong quantity	2 (100.0)	0 (0.0)	0 (0.0)	**2 (0.8)**
Wrong time	2 (100.0)	0 (0.0)	0 (0.0)	**2 (0.8)**
Out of date medication	1 (100.0)	0 (0.0)	0 (0.0)	**1 (0.4)**
Dispensing incidents otherwise not known	9 (81.8)	1 (9.1)	1 (9.1)	**11 (4.3)**
Total	**237** (92.2)	**14** (5.4)	**6** (5.4)	**257 (100.0)**

Less than half of the reports described the age of the patient (n = 122, 48%). However, the majority of these were aged 66 years or over (n = 71/122, 58%) which may indicate age as a contributory factor to serious harm incidents. Contributory incidents such as prescribing errors, communication errors and wrong label being prepared during

dispensing preceded some of the incidents. Warfarin (n = 32) and morphine (n = 27) were the two most common medicines involved in these incidents. Following thematic analysis of this group of reports, the same themes emerged as with the picking error incidents (discussed earlier), these were:

- **Medication similarity oversights** – this included incidents resulting from similar medication names or packaging and where medications are stored;
- **Lack of adequate or implemented protocols** – this included incidents arising from inadequate procedures or guidelines and lack of adherence to them by staff;
- **Suboptimal working environment** – this included incidents promoted by distractions, work flow (busy) and insufficient staffing levels;
- **Need for improved staff education and training** – this included incidents in which the knowledge (facts, information and skills) of staff was poor.

4.6.2.2.1 Medication similarity oversights

Issues relating to similarity of names and appearances were mentioned in 70 serious harm reports (27%). For example, in one of the reports, a patient was prescribed allopurinol for gout but was dispensed atenolol in error. This resulted in the patient experiencing a massive drop in pulse rate and later being admitted to hospital to have a pacemaker installed. Atenolol and allopurinol were placed near each other on the shelf and had a similar name which contributed to the error. The

following example reports (Examples 48 and 49) demonstrate how similarities in names or appearances could contribute to a serious harm error, either directly or indirectly (through putting away stock in the wrong place, for example).

> **Example 48:** *Dispensing error: Angitil (diltiazem) XL 300mg capsules was dispensed against a prescription requesting Adipine (nifedipine) XL 30mg Tablets. Quantity dispensed was 56 capsules. Patient already taking atenolol 100mg tablets. On [date], patient had a fall at home and was admitted to hospital. Dispensing error was noticed by hospital staff and phoned us to inform us of the error. Patient at this stage was in bradycardia and hospital was trying to stabilise her condition, unfortunately next day she passed away. Medication location changed for Angitil even though it was already in another draw but directly underneath the Adipine pack.*

> **Example 49:** *A prescription was received for prednisolone 5mg tablets take 6 each day. Correct labels were produced and split to 1 x 28 and 1 x 14, the treatment was for an emergency for COPD patient so was not taken until October. The patient was admitted to hospital around [date] and the incident was reported to the pharmacy on [date]. It appears that gliclazide 80mg box was given with the label for 14 prednisolone 5mg tablets. The patient was admitted to hospital in a hypoglycaemic coma and is seriously ill. It appears to be due to human error on the part of the pharmacist, possibly aggravated by similar packaging between ACTAVIS gliclazide and ACTAVIS prednisolone tablet packaging both being purple and white in colour. It is possible that the two drugs arrived in the same order and an error in putting the goods away may have compounded the error.*

4.6.2.2.2 Lack of adequate or implemented protocols

Again, issues relating to procedures or protocols were frequently described in serious harm incident reports (n = 95, 37%) as contributory factors. Example 48 above describes the lack of adherence to protocol and the inadequacies to the SOPs already in place which could

contribute to the occurrence of an incident. Example 8 (described earlier and stated again below) is another report of an incident involving a narrow therapeutic index drug which resulted in the patient's death. Loopholes in the SOP were eluded to (but not described), although this was not the only factor to have contributed to the death of the patient with age and co-morbidities being additional factors.

> **Example 8:** *Patient was prescribed digoxin 62.5mcg on [date], by mistake, digoxin 250mcg was dispensed instead. Patient felt unwell for few days, error was noticed by the family member on [date]. Family contacted the pharmacy, record was checked and possible overdose identified. Doctor was called in and patient was examined. Family was told to withhold the dose just in case if the problem is related to medication. Patient collapsed and later died in hospital.*

4.6.2.2.3 Suboptimal working environment

There were 78 mentions of suboptimal working conditions from 59 (23%) serious harm reports described as contributing to the occurrence of the dispensing incident. This included being busy, distractions and insufficient staffing levels. See section 4.6.2.1.3 for more details of this theme.

4.6.2.2.4 Need for improved staff education and training

Incident reports where staff members were reported to have deficiencies in their knowledge or training contributing to the incident were also reported (n = 19, 7%). Again, this was the least occurring theme, with only 22 mentions. This included confusion with generically written prescriptions and the provision of false information to patients due to lack of knowledge; see section 4.6.2.1.4 for more information about this theme.

4.6.2.3 Incidents involving Multi-Compartment Compliance Aids (MCCAs)

Whilst coding dispensing incident reports, those involving MCCAs or dosette boxes were linked to different types of incidents than the overall sample, where picking errors were the predominant incident type. These reports could highlight areas of improvement specific to MCCA dispensing safety.

Incidents involving MCCAs were reported in 201 (9%) reports. Table 4.19 shows the incident types involved with MCCAs. Wrong dose, wrong patient and not dispensed incidents were responsible for 62% (n = 124/201) of the reports. Some incidents did not describe the outcome or had insufficient information to ascertain the outcome (n = 69, 34%). Other incidents described outcomes such as missed doses, overdose, deterioration of condition, other patient clinical harm, hospital admissions and other non-clinical outcomes such as repeated visits to and from healthcare providers. Severity of harm to patient was identified in 113 (56%) incidents. The remaining incidents had insufficient detail to assess harm severity (n = 88, 44%).

The majority of patients were aged 66 years or over where patients' age was reported (n = 74/92, 80%). A number of the incidents (n = 44, 22%) had contributory incidents. Communication errors involving the transfer of patient information either between primary care providers or secondary to primary care were the most common types of contributory incidents identified. Examples include a patient's discharge summary not being sent to the pharmacy promptly or actioned before their

medication being dispensed, resulting in a dispensing incident occurring.

Antidiabetic medication (e.g. metformin and gliclazide) and antithrombotic drugs (e.g. warfarin) were the most commonly involved drugs in this group of incidents. Other common ones included furosemide and digoxin.

Following thematic analysis of MCCA reports, themes already identified in other clusters of reports (although in different contexts) and an additional theme were identified. This suggests that similar factors contribute to the occurrence of different types of dispensing incidents. The themes identified with MCCA dispensing incidents were:

- **Lack of adequate or implemented protocols** – this included incidents arising from inadequate procedures or guidelines and lack of adherence to them by staff;
- **Suboptimal working environment** – this included incidents promoted by distractions, work flow (busy) and insufficient staffing levels;
- **Inadequate procedures for implementing medication changes at transfer of care between settings** – this included incidents in which vital information about patient healthcare had not been communicated in a timely manner or acted upon within and between primary and secondary care providers; this was the new theme identified from this cluster of dispensing incidents.

Table 4.19 Dispensing incidents involving MCCAs (n = 201)

Dispensing incident types	Harm severity (row %)						Total (column %)
	No	Mild	Moderate	Severe	Death	Unclear	
Wrong dose	2 (40.0)	2 (40.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5
Overdose	6 (26.1)	7 (30.4)	2 (8.7)	0 (0.0)	0 (0.0)	8 (34.8)	23
Under-dose	2 (11.1)	4 (22.2)	1 (5.6)	1 (5.6)	0 (0.0)	10 (55.6)	18
Sub-total	10 (21.7)	13 (28.3)	4 (8.7)	1 (2.2)	0 (0.0)	18 (39.1)	**46 (22.9)**
Wrong patient	7 (17.1)	9 (22.0)	7 (17.1)	0 (0.0)	0 (0.0)	18 (43.9)	**41 (20.4)**
Not dispensed	5 (13.5)	7 (18.9)	11 (29.7)	0 (0.0)	0 (0.0)	14 (37.8)	**37 (18.4)**
Stopped medication being dispensed to patient	1 (6.3)	4 (25.0)	5 (31.3)	0 (0.0)	0 (0.0)	6 (37.5)	**16 (8.0)**
Wrong strength	2 (16.7)	3 (25.0)	1 (8.3)	0 (0.0)	0 (0.0)	6 (50.0)	**12 (6.0)**
Wrong medication	2 (16.7)	3 (25.0)	2 (16.7)	0 (0.0)	0 (0.0)	5 (41.7)	**12 (6.0)**
Wrong time	2 (25.0)	0 (0.0)	2 (25.0)	0 (0.0)	0 (0.0)	4 (50.0)	**8 (4.0)**
Wrong quantity	2 (28.6)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	4 (57.1)	**7 (3.5)**
Wrong label	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (50.0)	**4 (2.0)**
Wrong formulation	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	**1 (0.5)**
Out of date medication	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	**1 (0.5)**
Dispensing incidents otherwise not known	2 (12.5)	1 (6.3)	3 (18.8)	0 (0.0)	0 (0.0)	10 (62.5)	**16 (8.0)**
Total	**35** (17.4)	**40** (19.9)	**37** (18.4)	**1** (0.5)	**0** (0.0)	**88** (43.8)	**201 (100.0)**

4.6.2.3.1 Lack of adequate or implemented protocols

Issues relating to protocols featured prominently in MCCAs involved incidents (n = 68, 34%). This included inadequate protocols (contributory factor) such as repeat prescription procedures (see Example 5.24) and the preparation procedures of MCCA packs, including double checking being inadequate or inefficient (n = 45). Where these procedures were sound, staff not adhering to them (contributory factor) (n = 26) was an issue that contributed to incident occurrence. Dispensing or delivery to the wrong patient was one of the most common types of incident involving MCCAs. An example of this is a delivery driver delivering medication to the wrong patient whilst they may not be fully adhering to procedures during delivery. Example 50 is an example of such, where the driver was reminded about following company procedure - although the reporter did not explain how the driver broke company procedures.

> **Example 50:** *Patient received wrong medication dosette tray (MCCA). Patient didn't realise and carried on taking medication assuming that the Dr had changed some of the items. She took the medication for a few days, on feeling unwell she called an ambulance, she was admitted and has since been allowed to go home and is well. This error was made by the delivery driver and although they had been busy on that day they have been made aware of the error and have been asked to be extra vigilant and follow company procedures when delivering.*

4.6.2.3.2 Suboptimal working environment

Multiple dispensing errors involving MCCA packs were also reported to occur due to inadequate working environment in some way, as reported in other clusters of reports. This included busy times, distractions, lack

of staff and MCCA packs being prepared in haste. These factors were described at least 68 times in 45 (22%) reports. Suboptimal working environment also compounds other factors from other themes in the process of making an error, such as not adhering to procedure and inefficient repeat prescription request procedures (See Examples 51 and 52).

> **Example 51:** *Monthly blistered MCCA pack, patient prescribed two tabs three times a day. Most blisters correct with two tablets inside them, on three occasions however, there were three tablets in one of the packs. Other packs were assumed to be correct as was not brought to our attention. The MCCA home was checked in the dispensary and not in the MCCA room as due to lack of time and space in the MCCA room. We were short of staff, pharmacist was interrupted as there was no dispenser and healthcare assistant.*

> **Example 52:** *Both 62.5mcg digoxin and 125mcg on prescription was requested and prescription was given by doctor. Patient was previously changed from 125mcg to 62.5mcg. Dispenser made MCCA pack under pressure on Friday, pharmacist checked MCCA pack as per prescription. Need better system for MCCA, will get help from apm. Pressure - very busy.*

4.6.2.3.3 Inadequate procedures for implementing medication changes at transfer of care between settings

During preparation and dispensing of MCCA packs, the dispensing team did not always have up to date information regarding the patient to avoid the occurrence of MCCA incidents. This was usually a result of errors in the transfer of up to date patient information or communication between healthcare professionals (as previously discussed for prescribing and monitoring incidents). A total of 29 reports described this theme (14%). Patients on MCCA packs are usually on multiple

medications and have other co-morbidities, hence likely to have regular changes in their medications. Reports described information not being transferred to the pharmacy from the GP or hospital, either at all, or in good time following discharge; this was a contributory incident leading to MCCA related incidents (see Example 53). Updated information was sometimes received but not actioned due to inadequate procedures. Insufficient communication between patient or patient's carers and the healthcare professionals dispensing their MCCA packs also contributed to the occurrence of incidents.

> **Example 53:** *The patient was admitted into [name] hospital ward and released on [date]. Gliclazide and simvastatin tablets had been stopped at the hospital and Humulin M3 insulin had been started. These changes were included in the discharge notice sent to the GP surgery. The GP surgery contacted us 2 weeks later about these changes. The reason given for the delay in notifying us is that the regular prescription clerk that normally handles this paperwork had gone on holiday and their work was not done by someone else. The hospital had given her seven days of medication. As we had no knowledge of the changes, we supplied her regular medication on [date] without the changes being implemented. We were informed later that the patient has been admitted to hospital.*

4.6.3 Administration incidents

In total, 640 (84.2%) of 760 reports with at least one contributory factor or contributory incident were re-examined and thematically analysed as described in section 2.7.3. As with the other two categories previously discussed, insights from the thematic analysis were combined with stage two (EDA) of the data analysis to identify key issues which could be targeted for improvement strategies. Similar themes to those

previously identified are also reported in this section. Two additional themes - specific to administration incidents only - were also identified. Again, there was also some overlap of reports across the generated themes, due to the description of multiple reasons for incident occurrence in reports.

The themes that emerged from the analysis of these incidents were:

- **Active failures due to insufficient protocols, workforce and equipment** – this included incidents in which unsafe acts such as mistakes, slips, lapses and procedural violations were committed by staff;
- **Inadequate administrative practices –** this included incidents resulting from deficiencies or inadequacies of the administrative practices such as scheduling of appointments or recording care given to patients (new theme);
- **Inadequate procedures for implementing medication changes at transfer of care between settings** – this included incidents in which vital information about patient healthcare had not been communicated in a timely manner or acted upon within and between primary and secondary care providers;
- **Insufficient communication of medicines information to patients** – this included incidents in which patients had poor knowledge about their medicines mostly due to poor communication from the healthcare professionals (new theme);

- **Need for improved staff education and training** – this included incidents in which the knowledge (facts, information and skills) of staff was poor.

I will now describe and interpret each theme; reporting on frequency of occurrence whilst considering the role of the associated contributory factors. Where relevant, the contributory incidents leading up to the administration incidents (recursive model of incident analysis), alongside other contextual issues, will also be identified.

4.6.3.1 Active failures due to insufficient protocols, workforce and equipment

Active failures by members of staff, such as not adhering to protocols, mistakes, slips and lapses were the most frequent contributory factors described in administration incident reports (see Table 4.14). These were described in reports to be promoted by other factors such as working conditions (e.g. being busy or overloaded with work), inadequate procedures or guidelines and syringe driver faults or issues. A total of 312 (49%) of the 640 reports described at least one of these contributory factors and they contributed to the majority of the administration incidents previously described. They were described repeatedly in reports compounding each other (n = 178/640, 28%). This theme was also identified for prescribing and monitoring incidents (described in more detail in Section 4.6.1.1). The following example reports illustrate such cases relating to administration incidents.

Example 54 describes an incident where failure to use the discharge summary document (failure to follow procedure – contributory factor)

influenced the mistake of recording the wrong information on the Medicines Administration Record (MAR) sheet, which contributed to the occurrence of the incident alongside the error made from the hospital. Issues relating to information transfer from hospitals to primary care affecting medication administration will be discussed in section 4.6.3.3. Some reports described a lack of availability of a MAR sheet, which contributed to staff not following procedure of administration, in turn causing an incident (see Example 55).

> **Example 54:** *Patient A was discharged from the hospital on [date] and needs carers to administer her medication. The district nurse wrote the MAR chart as baclofen 10mg three times per day. However, the lady was supposed to be having baclofen 25mg three times a day. The carer noticed it today as the patient was complaining of increased muscle spasms since being home from hospital. The drug chart sent from the hospital stated 25mg three times per day and so did her medication boxes. However, there was another lady's baclofen in the same bag (Patient B) and her medication had been prescribed as 10mg three times per day. I have taken this lady's medication out of the house and have contacted the hospital to notify them and have informed the patient's GP that she has not had enough baclofen for the past 3 days. District nursing team reminded of the importance of using the discharge summary to check any medication and not just the medication box.*

> **Example 55:** *[Nurse] visited a palliative care patient with student nurse to provide personal care and pressure relief. During visit, patient displayed symptoms of pain. Nurse asked husband if she had been given any Oxynorm today, to which the reply was no. The nurse stated she would give some and gave what was written on the bottle. Oxynorm syrup 10mg/1ml (4ml). Patient had recently been reduced to between 1 and 2ml and the husband was giving this as needed. The nurse did not know this and there was no MAR sheet in the house or directive to give medication. [Nurse] informed me on her return to the*

office that she had given the Oxynorm and how much she gave her. I was due to visit the patient later that day. During visit, patient was totally non responsive and pupils were fixed, pulse was 70. Patient was repositioned. Relative commented to me that 40mg of Oxynorm had been given as the staff nurse stated this during visit at which point they realised she had been given more than was currently prescribed. He also stated that the patient was less responsive since having it.

Inadequate protocols or procedures compounded active failures. A number of reports have described patients receiving the same dose twice from two different visiting nurses. Most of these reports described the second visiting nurse administering the medication before checking and signing the necessary documents which contributed to the incident, sometimes alongside other factors (see Examples 56 and 57). These mistakes could possibly be prevented by amending the procedure to check the documents first and confirm whether or not the patient had the medication before administration.

Example 56: *Received a phone call at 16:30 hours from a patient to say that he had not had a district nurse visit to administer his Clexane injection that was due at 15:00. Visited at 16:45 and gave injection as per prescription sheet. When completing signature form, I noticed that a staff nurse had actually visited at 15:30 and administered the Clexane injection. Patient had no recollection of the visit.*

Example 57: *I visited a patient and administered night time medication as per joint medication chart (ferrous sulphate, temazepam and trazodone). When I went to sign chart after patient had had medication, I found it had already been signed for by the carer who had visited at approximately 17:00 hours - medication charted for 22:00 hours. I phoned and checked with senior carer on duty who phoned carer and confirmed she had also given medication.*

The conditions in which the staff were working also contributed to them committing active failures leading up to administration incidents. These included distractions from family members and excessive workload, which could cause staff members to perform their duties in haste (see Examples 58 and 59).

> **Example 58:** *Called to review patient's symptoms of nausea as she had been vomiting the previous day and overnight. I checked the syringe driver was working. On doing this I realised that none of the medication had been administered. I opened the box and the plunger end of the syringe was not connected to the plunger of the driver and the syringe was only loosely attached to the driver. It would appear that the syringe driver had been set up properly but the plunger may well have slipped when putting it into the safety case which means the plunger was not positioned properly. The dynamics in this family environment were very tense and the staff member may well have been distracted during the procedure. There is also evidence to show that the nurse asked another team for help during the day as she was working alone and inundated with work but they responded that they did not have the capacity to help.*

> **Example 59:** *While visiting afternoon patients, I arrived at an insulin patient's house, I looked at insulin chart and administered a dose of 30iu of Levemir and 2iu of Novorapid as BM was 196mmols as I thought was stated in chart. Once administered I realised that it was the morning dose that I had given. I contacted district nurse and urgent care to explain what I had done. The doctor on call phoned me back and said he would liaise with [name] who decided that patient should be admitted to the hospital for monitoring overnight. I then explained this to patient who agreed to be admitted. The patient's wife does tend to talk to the nurses during the insulin procedure and this could have been a contributing factor.*

4.6.3.2 Inadequate administrative practices

Incidents were frequently reported to have manifested from some form of breakdown in administrative processes (n = 147/640, 23%). Although there were issues with administrative practices that contributed to prescribing, monitoring and dispensing incidents, they were considerably more of an issue during the administration of medications. Medication not administered and administration of wrong number of doses of medication (mostly vaccines), were the most frequently resulting incident outcome. Errors or inefficiencies in managing appointments for patient visits in primary care was described in reports as one of the most frequent administrative errors contributing to incidents (n = 61/640, 10%). Patients' medication were described to have been omitted mostly as a result of the patient being left out of the visiting schedule in error. Patients were also administered double the dose they were meant to have at different times within a short period of time as a result of multiple visits from healthcare professionals (mostly nurses). This was due to scheduling errors by staff; such as allocating a single patient to multiple nurses, or a nurse mistakenly visiting a patient not on their schedule (see Examples 60 and 61).

> **Example 60:** *Missed visit to administer glargine insulin. Not allocated on early visits by band X staff nurse. The checking system also failed because of miscommunication between band X and Y as they each thought the other one would continue to check off the visits. The patient and GP was informed that the medication had been missed and monitoring took place. The patient did not suffer any ill effects from the omission of the insulin being administered.*

> **Example 61:** *Patient's name on two nurses' weekend list as completed by myself. Patient seen by one nurse and medications given but MAR sheet not signed, although nursing notes completed. 2nd nurse visited and checked MAR sheet and gave another dose of her morning medications. On writing in the notes, she realised the patient had already had a visit earlier and had been given morning medications. Due to change of staff working the weekend, the list had to be changed. Some staff had already printed off the old list. I had also left the old list for another staff member.*

Other administrative issues that were frequently described involved the documentation processes of patients' information (n = 99/640, 15%). Some reports described multiple forms of administrative incidents contributing to one administration incident. The most frequently described documentation issue was patients' records not being updated (n = 41/99, 41%) with the most up to date information when they should have been. This resulted in important information not being considered which could result in missed or delayed administration, wrong dose administered or administration of medication that a patient was previously allergic to (see Examples 62 and 63). The unavailability of patient information or records when they should have been available, also contributed to the occurrence of administration incidents (n = 26/99, 26% - Example 64). Nurses or carers were required to record their visits and details of the administration carried out. However, inefficiencies and errors in doing so contributed to multiple administration incidents. These included records that were not clear or inaccurate (n = 13/99, 13% - Example 65) and omitted documentation on the care given which could result in important information not being

updated on patients' records as previously described (n = 10/99, 10% - Example 66).

Example 62: *Client was transferred to staff member's case load with a number of other clients. Unfortunately, staff member omitted to document his next depot due date in diary resulting in this being missed until [date] (should have been administered 4 days earlier). Staff member attended client's home on [date – 4 days later] but he was not available. Risperdal Consta 25mg given at next/earliest convenience of [date – the following day]. Doctor informed and advised to give the next dose on [date – after 2 weeks].*

Example 63: *Patient had an adverse reaction to first dose of IV flucloxacillin 1g when administered by [name] staff. At midnight, out of hours nurses visited the patient's home and administered the second dose of IV antibiotic and he experienced a reaction to the IV therapy. The nurses monitored him and adverse reaction eventually subsided. Then, OOH returned to [name] and they discussed the patient with staff in the department who stated he had had a reaction to his first dose that was administered in [name]. They looked through his assessment/ notes and nothing had been documented about a reaction to the IV infusion nor had it been mentioned verbally earlier in the evening when they spoke to the nurse who had administered the antibiotic.*

Example 64: *The client is normally given a BuTrans patch on a Tuesday. However she had removed her patch on the previous Friday and the nurse has scribed that, therefore the patch should have been renewed on the Friday. However, on the Friday a Healthcare Professional (HCA) moved the chart and it could not be located. It was noticed on the weekly CD drug check on the Sunday that the client had not had her patch renewed. The on call GP alerted and informed that the client was not expressing any pain. The patch was renewed.*

Example 65: *When a patient's records were summarised the dose of thyroxine was recorded as 25mcg instead of 125mcg. She became confused and her Thyroid Stimulating Hormone (TSH) went up to 150*

(picked up 2 weeks ago). Patient now getting better on correct dose of thyroxine.

Example 66: *Daughter of patient called evening service to say her mother had not received her evening insulin. On arrival, I checked the care plan and there was no entry recorded on the drug administration record and no documentation noted in the evaluation sheet. Blood glucose was then checked which indicated 22.0mmol and 16units of Humulin M3 was administered. I then documented on the yellow drug administration record and in the evaluation. As I then went to sign the visiting record sheet, I noticed that the patient appears to have had a visit at 16:00 as there was a signature present. I then contacted the day nurse who had signed the visiting sheet, she told me that she had visited and administered the evening insulin but forgot to sign the yellow drug administration record and complete the evaluation. I then contacted evening service team co-ordinator and [name] GP. Observations taken and appeared to be in range. Daughter advised and agreed to stay the night to monitor her mother and to call [name] if she felt her condition deteriorates. Patient Left stable and comfortable.*

4.6.3.3 Inadequate procedures for implementing medication changes at transfer of care between settings

This theme - previously described for prescribing and dispensing incidents - was also identified as an issue during administration of medications (n = 142 of 640 reports, 22%). Errors or inefficiencies during the dissemination of written patient information from secondary care to primary care or within primary care (contributory incidents) were also frequently described to affect seamless care to patients and cause administration incidents. These mostly resulted in the omission of medication, but also repeated administration of the same dose and administration of the wrong dose. Frequent medications in this theme included insulins (n = 40) and anticoagulants such as warfarin (n = 7)

and enoxaparin (n = 15). Outcomes included deterioration of condition, readmission to hospital and occasionally death. Issues described previously, such as information received but not actioned, incorrect or incomplete information transfer, delayed transfer or no information transfer at all, were also described in administration incident reports (see Examples 67, 68 and 69).

> **Example 67:** *Diabetic nurse consultant (DNC) faxed information about [patient] to reduce her insulin dosage to [name] - this was not actioned, therefore patient remained to be given a higher dose of insulin over a bank holiday period. Also, the DNC tasked to the weekend a district nurse (DN) to action the new dose and was informed. However the new dose of insulin was not implemented. Patient has had a few hypoglycaemic attacks throughout the bank holiday period and OOH staff have omitted insulin without discussing with the on-call diabetic specialist nurse.*

> **Example 68:** *A patient was discharged from hospital with what we were informed a Butrans patch and we had authorisation to change this in a week's time which I did on the allocated date. However, the nurse whom came to visit later that day asked to see the patch I took off as she was assessing her pain relief and noted that the patch was actually a Transtec patch and a higher dose and should have in fact been changed every 96 hours (4 days).*

> **Example 69:** *A fax was sent to the surgery from the chemotherapy suite at the hospital instructing the district nurses to administer a Neulasta injection on the [date] for a patient one day post chemotherapy. The fax did not get to the district nurses until [date – 3 days later] and was left for myself to deal with on [date – the following day]. On clarifying with the hospital, I was told it was now too late to administer the Neulasta as it had to be administered within 72 hours of chemotherapy. I contacted the patient and she had not had the injection and tried to contact anyone to administer it.*

Verbal communication about patients' care directly between two healthcare professionals - either via phone call, face to face or otherwise - also led to administration incidents due to misunderstandings or miscommunication between the two healthcare professionals involved (see Example 70).

> **Example 70:** *Patient's own GP contacted the out of hours service (by phone) requesting that a syringe driver be set up with 20mg of diamorphine for this patient (who was on 75mg fentanyl patch). GP spoke to nurse practitioner directly. From reading the notes made by the nurse practitioner, it appears that the nurse practitioner heard this as 120mg diamorphine. However, the nurse practitioner recalculated the dose equivalent to the fentanyl as 90mg and started the syringe driver with this dose. The fentanyl patch was left in situ. The patient died the next morning.*

4.6.3.4 Insufficient communication of medicines information to patients

Communication of medication information to patients or patients' representatives was frequently found to be lacking or inadequate in reports (n = 96/640, 15%). The majority of these reports were incidents relating to unintentional patients' self-administration of overdose, which could have been prevented if the patient had better information about their medicines (contributory factor) communicated to them efficiently. See Example 71 below where opportunity to communicate a medication change to the patient was possibly reduced because the medication was being delivered (contributory factor). This theme was also identified in other administration incident types, although not as often. Examples include administration of wrong number of doses or overdose, and

medication omissions. Example 72 describes an incident where a partially sighted (contributory factor) patient omitted to take her medication due to a lack of communication (contributory incident) about a medication change from her community pharmacy, which resulted in deterioration of her condition.

> **Example 71:** *A frail elderly patient who lived independently was taking 11 x 5mg (i.e. 55mg) of prednisolone for arthritis. GP changed to 2 x 25mg plus 1 x 5mg. Pharmacy dispensed script which was delivered by driver. Change was not communicated to patient and he continued to take 11 tablets (i.e. 250mg) daily for several days. Patient subsequently had a fall and was admitted to hospital where he died.*

> **Example 72:** *Patient was partially sighted so was dispensed her medication in a dosette box (or multi compartment compliance aid, MCCA) by her community pharmacy. This was not discussed with her and she was not shown how to use it. She refused to take her medication because it was not clear to her what was in the box and whether it was the correct medication for her. She was admitted to hospital with fast atrial fibrillation (AF) due to stopping her digoxin.*

A number of reports described insufficient communication of information about warfarin which developed into an incident. These mostly related to change in dosing regimen, tablet strength selection or colour distinction which mostly led to patients taking an overdose. Although patients were sometimes given a printout of instructions, healthcare staff did not ensure patients understood the information provided (see Examples 73, 74 and 75).

> **Example 73:** *Patient started on warfarin and given 5mg tablets only. When INR was taken on [date], the dose was changed by GP, patient was contacted by telephone and informed to take 4mg daily and to have test repeated on [date]. Patient took 4 x 5mg tablets for 3 days as*

instructed. INR was repeated after the three days, this was when the incident was discovered. Patient was then admitted to [name] at this point.

Example 74: *Patient attended INR clinic on [date]. Warfarin was increased from 21mg to 22mg per week. Instructions in patient held record stated 4mg on Monday and 3mg daily. Review in 3 weeks. Patient took 7mg a day till attending 4 weeks later. Patient was admitted with high INR.*

Example 75: *Patient on warfarin, monitored by [name] clinic. Patient took approximately 3mg warfarin daily (i.e. multiples of 1mg tablets). Patient requested repeat prescription and ticked for 5mg tablets. She then took 3 of these (they were a different colour but she did not think this was significant). Patient had to be admitted to the hospital.*

Similar scenarios involving other types of medications (such as methotrexate and opioid analgesics) also existed, which resulted in various levels of harm to the patients (see example 76).

Example 76: *The patient was on 20mg of methotrexate weekly on a Tuesday and always takes 8 x 2.5mg tablets. He was given a prescription for 20mg weekly stating 2 x 10mg tablets which was dispensed correctly by the chemist. However the patient accidentally took 8 x 10mg tablets. It was the first time he had 10mg tablets dispensed and both the 2.5mg and 10mg tablet bottles were identical. He realised what had happened immediately and attended the hospital.*

Patients also reported lack of communication of information following discharge from the hospital which could then lead to deterioration and readmission. The following example (77) describes such an instance where the patient could not administer her medication due to lack of information. This could have prevented readmission, even with the presence of other errors or incidents.

> **Example 77:** *[Patient name] was discharged from the hospital on [date] to temporary accommodation following admission with hyperglycaemia. On the following day at [time] (in the evening), OOH nursing service received a verbal referral from district nurse [name] requesting a visit to patient to check blood glucose levels and to ensure insulin had been taken. On arrival at patient's temporary accommodation, she was found to be cold, wrapped in a blanket and feeling unwell. Blood sugar was checked and found to be very high and showing ketones. Patient commented that she had not had any insulin since discharge from the hospital yesterday. She stated that the district nurses usually give her insulin but she has not seen a nurse since discharge. OOH GP [name] contacted to assess patient's medical condition. OOH GP contacted and [hospital name] medical team who advised readmission to [hospital name]. Ambulance was arranged and it was also noted that she had not had any of her oral medication since discharge as she stated did not know what to take.*

Miscommunications or misunderstandings between healthcare professionals and patients or representatives was a major issue described in reports. This included phone-based and face to face consultations. Patients' or their representatives' lack of knowledge about their vaccines was also frequently described in vaccine incident reports as contributing to the incident occurrence.

4.6.3.5 Need for improved staff education and training

Inadequate skill set or knowledge and lack of education or training of staff (contributory factors) were a common feature in administration incident reports. Of 640 incidents, 89 (14%) featured this theme in reports. Although this was the least frequent theme identified in these reports, it demonstrated similar issues as those identified in the other medication related processes described earlier. Reports described incidents involving the administration of insulin where the nurse or carer

was not fully trained or aware of the procedures for insulin administration and management, resulting in errors manifesting into medication incidents. Examples included an incident in which the healthcare professional did not know to check the blood sugar of the patient before administering the medication, which resulted in a hypoglycaemic attack. Another incident described the blood sugar being checked but the insulin was still administered even though the reading was below the recommended range, again resulting in hypoglycaemic attack which was treated with fast acting glucose. See Example 78 which describes another incident demonstrating lack of knowledge on insulin management in a care home.

> **Example 78:** *Community Diabetes Service (CDS) was contacted by nurse from [name] care home. Nurse had administered insulin when patient blood glucose level was 2.9mmol/l. Hypoglycaemia was not treated prior to insulin being administered because breakfast was due 20 minutes later approximately. Patient was unarousable, blood glucose level was 1.9mmol/l. Nurse administered glucagon injection, blood glucose re-checked and was 3.0mmol/l. Patient confused but talking. Telephone call received again 15 minutes later from staff nurse, patient blood glucose level dropped again to 1.9mmol/l, advised to administer glucagon and dial 999. This incident highlights the lack of basic diabetes education amongst private provider care home staff.*

Reports have also described staff's inadequate skill set or training in relation to the administration of medication for the management of pain in palliative care patients, mostly via syringe drivers. This included dose equivalence calculations and the administration of different opioid medications for breakthrough pain when required (see Examples 79 and 80).

Example 79: *Patient was discharged from [name] hospital on [date]. Overnight carer was visiting who was an untrained member of staff. The patient was in pain and agitated during the whole night despite syringe driver being in situ. [Person name] (main carer) thought that the respite cover was a trained member of staff and able to administer pain relief.*

Example 80: *On arrival at hospice, patient had respiratory rate of 4/minute and was very sedated as a result of 1ml injection (40mg) of diamorphine given at home. This was in effect a dose equivalent to previous total 24 hour morphine dose given as a single stat injection (not the 1/6th approximation as recommended), patient may have died. Prescription and administration of inappropriately large dose of diamorphine as stat for pain leading to acute opioid toxicity with sedation and respiratory depression. Skill and competency issue with staff. After assessment, patient observed, no further opioid administered for approximately 10 hours then appropriate dose recommenced.*

A number of reports described staff's lack of knowledge during the administration of various vaccines which led to incidents such as the administration of the wrong vaccine, inappropriate or contraindicated administration and vaccine formulation errors (see Examples 81 and 82).

Example 81: *Patient attended for pre-school booster and 2nd MMR. Practice nurse administered vaccines. Parents rang on [date] to say they had taken their daughter for a routine check-up at the hospital and the hospital had informed them that because their daughter had a liver transplant in [Month, year], she should not have had any live vaccines i.e. MMR.*

Example 82: *Travel vaccine Ambirix given to protect against hepatitis A or B when it should have been Twinrix. In addition, second dose given at one month instead of six. Practice nurse was not aware until another practice nurse read up on travel vaccines.*

Staff members meant to administer medications to patients were described in multiple reports as not being fully aware of their responsibilities during the administration process of various other medications. This was mostly due to inadequate training of new staff members and lack of regular re-training and information updates for existing staff. Some staff lacked skills to administer medications such as eye drops, which could then lead to incidents relating to the omission of these medications.

4.7 Summary of key issues or priority areas identified

In Section 4.6, priority areas were identified for each of the incident categories analysed. Following the analysis of dispensing incident reports, there were some overlapping themes across all three clusters of reports that were thematically analysed independently. This was also true between the three categories. In summary, the eight themes identified from all medication incident categories were:

- **Active failures due to insufficient protocols, workforce and equipment**
- **Inadequate procedures for implementing medication changes at transfer of care between settings**
- **Need for improved staff education and training**
- **Medication similarity oversights**
- **Lack of adequate or implemented protocols**
- **Suboptimal working environment**
- **Inadequate administrative practices**

- **Insufficient communication of medicines information to patients**

As previously explained, some reports described more than one theme per incident. Example 83 describes such an incident, where a doctor did not consider information about the patient during a clinical treatment decision due to multiple contributory incidents and factors. The outcome of this incident was patient's death. This demonstrate the importance of addressing all of these areas in the medication use process to improve medication safety in primary care.

> **Example 83:** *I saw and assessed a patient with a chest infection. I was aware that he had started chemotherapy for carcinoma of the oesophagus the previous week. I was not aware that this chemotherapy could cause anaemia and that if he had an infection an FBC should be performed. He was admitted to hospital on [date] and died on [date – 6 days later]. His cause of death was cardiorespiratory failure due to septic shock. When I reviewed his care, I found that a letter warning the GP about the possibility of neutropaenic sepsis was issued by the oncologist on Friday [date], received in the practice on [date – 3 days later] but not seen by the GP because it was Christmas eve and the surgery had an early close and because that day, we had over 400 letters in due to delays the previous week. The letter was not seen by a GP (not me) until after I had seen him on [date – 3 days after it was received].*

4.8 Identifying interventions from existing literature

The purpose of this section was to identify concepts that have been used to prevent medication errors and improve safety in primary care, in order to map them to the key issues identified. Studies exist that have sought to improve the safety of prescribing and monitoring of

medications in primary care. However, most of the research proactively addressing the safety of medication is conducted in secondary care. There is potential for intervention ideas based in secondary care to be trialled in primary care with success. Existing studies mostly originated from the United States of America, United Kingdom and other European countries.

Barber, Rawlins and Franklin suggested in their article that interventions to reduce prescribing errors should be based at three levels: 1 - improving training and testing the competence of prescribers; 2 - controlling the environment; and 3 - changing the organisational cultures [176]. My findings on the key areas for improvement identified from the themes generated agree with these suggestions, as some issues discussed were based around similar areas. Interventions such as education, medication reconciliation, changes in work environment, role of information technology and prescribing assessment tools have all been described in the past [177].

A combination of interventions (referred to as complex intervention in some studies) involving more than one type of intervention such as educational, audit and feedback was shown to be more effective in tackling prescribing and monitoring incidents [113, 178-180]. For example, in the cluster randomised controlled trial of interventions by Guthrie et al. which was conducted in Scottish primary care practices, a combination of educational, feedback and a behavioural change component interventions resulted in a more significant reduction of prescribing incidents for a targeted group of medicines compared to just

educational intervention (usual care) [180]. The PINCER trial was also a type of complex intervention which found statistically and clinically significant reduction in high risk prescribing [113].

Interventions could be applied widely or to more specific drug classes with the most potential to be involved in an incident or those that possess the largest threat of harm to patients [181, 182] such as antithrombotic agents and opioid analgesics identified in this chapter.

There was a clear lack of evidence on dispensing error interventions in primary care. Due to this lack of evidence, secondary care literature on medication error interventions were also searched, in order to inform the change ideas for risk reduction strategies to improve the outcome of dispensing. Most of the literature relates to secondary care [84, 183-186]. The majority of the medication error intervention studies in primary and secondary care involved a pharmacist-led type intervention focusing on reducing the rate of prescribing and/or administration errors with less focus on dispensing errors [12, 113, 183, 185, 187-195]. Studies that did focus on dispensing errors, mostly originated from countries such as the United States of America, Australia and United Kingdom.

Again, secondary care based studies dominated the intervention studies associated with administration incidents [125, 196-200]. However, similar ideas from secondary care intervention studies could also be applied to primary care in order to improve medication administration safety.

Just as in prescribing and monitoring incident interventions described earlier, a multifaceted approach interventions involving a combination of education, use of barcode technology and risk management strategies were shown to be a more effective way of reducing administration incidents in various care settings [201-204].

Some priority areas identified were common in each of the three medication incident categories analysed, albeit in different contexts. I will now consider interventions that could more specifically address the priority areas identified.

4.8.1 Active failures due to insufficient protocols, workforce and equipment

Quality assurance approaches such as medication reviews by pharmacists could be triggered and used to ensure the efficiencies and appropriateness of the systems used in the process of medication use. Multiple studies have shown regular medication reviews or interventions involving pharmacists to significantly improve the prescribing and monitoring of patients and reduce inappropriate prescriptions in primary care settings [113, 205-209]. This was also true for patients in secondary care [194, 210, 211]. Most of the intervention studies led by pharmacists involved reviewing patients' electronic health records. This also makes it easier for a patient to be followed up without them being present, as demonstrated in a study about improving the safety of monitoring in primary care [207]. In this study, pharmacists reviewed electronic records of patients that have been referred for psychiatry consultations within one to three months of consultation, with specific

focus on known medications with suboptimal monitoring rates. This was conducted within a primary care behavioural health practice and recommendations were transferred to the primary care providers. Improved safety in the use of psychotropic medications was achieved through a significant increase in monitoring rates and reduced risk of drug interaction. Although this study was based in USA and was restricted to a specific population with no control group, this concept, when extended to wider population at regular intervals could be beneficial in reducing prescribing and monitoring type incidents in the UK [207]. Other studies reviewing electronic patient records to improve medication patient safety not specifically by pharmacists also exist [179, 212, 213].

An assessment criteria was developed to help identify patients at risk of certain medication incidents using their electronic records in a study by Dreischulte and colleagues [214]. They used a 2-round consensus process in which potential criteria were identified from the literature and scored by a panel of experts to generate the final set of criteria for use in UK primary care. Although the criteria were mainly developed with a focus on the prescribing and monitoring stages of the medication use process, the ability to link clinical data (e.g. GP data and dispensing data) in a more advanced clinical information system could mean an even broader set of criteria could be developed. Regular electronic review using assessment criteria could be beneficial in addressing medication safety incidents in a targeted group for example, such as for those patients receiving no or inconsistent monitoring [207]. Other

studies have also included an assessment checklist as part of the interventions to improve prescribing and monitoring of medications [215, 216].

As reported in a systematic review by Madden and colleagues, review of patient records is a new concept that offers the opportunity to improve medication safety. However, further research is needed to ensure validity and reliability of the approach [217]. Examples include studies using the trigger review process; which allowed clinicians in primary care to rapidly search electronic patient records in order to identify risks and errors [218-220].

The PINCER study by Avery et al. (mentioned in Chapter 1) utilised these types of electronic patient record reviews and demonstrated the effectiveness of a pharmacist-led complex intervention which included feedback and educational outreach in reducing prescribing and monitoring errors in GP practices [113].

In a hospital study by Amis and Osicki, a checklist was designed following an audit and handed to day staff on Friday mornings to make sure no unnecessary jobs or prescribing tasks would be left for out of hours' staff since this increased their workload and promoted errors. Reduction of inappropriate prescribing tasks left was achieved and staff felt less pressured, improving their working conditions after three subsequent weekends [221]. The reduction seen was not statistically significant even though it was approaching statistical significance at p value of 0.0615, however, improved job satisfaction and perceived

reduction in workload were described by staff in a post-intervention survey. An increased sample size may have generated a stronger evidence either way. Also, other factors such as selection and observer biases reported in the study may have limited the objective findings. The fact that people were being observed may have led to improved behaviours of staff contributing to the reductions shown. However, the idea of introducing a checklist to reduce or allocate daily prescribing tasks appropriately could be investigated within a primary care practice to see if it could help prevent mistakes slips and lapses by aiming to reduce the workload on staff.

Standardisation of computerised prescribing screens across practices in the country with all doctors familiar with it - as suggested in an article by Barber and colleagues [176] - alongside other IT enhancements such as Clinical Decision Support (CDS) (described in Chapter 1.6) could help promote prescribers to follow the procedure of prescribing, regardless of where they are prescribing from.

Other quality assurance approaches or procedures could be incorporated as part of the improvement efforts to help maintain and also improve the safety of medication use. This could ensure policies and procedures are up to date, clearly written, reflect local circumstances and are being adhered to whilst promoting safety culture. This could be achieved by using a patient safety monitoring mechanism such as the one in the PRIORITIZE study [222]. This was a study that aimed to identify the causes and solutions to medication errors in primary care using novel PRIORITIZE analysis methods.

Primary care clinicians were invited to fill out a questionnaire in order to identify the problems and solutions from their point of views. This approach allows staff to drive the change ideas which could be important in the implementation of important changes. The PRIORITIZE analysis is a systematic method of identifying priorities and possible solutions.

The use of electronic diary, smart phone app and barcode technology for administration of medicines in patient homes could address a number of administration incidents' key issues. This was trialled with success in the administration of coagulation factor concentrate (CFC) for the treatment of haemophilia patients at home. Before infusing the CFC, the patient would launch the phone app and scan the medicine's barcode on the box. This then took them through some safety checks on the screen before the patient self-infused the CFC. The patient and treatment centre would be alerted if any issues were detected. Such intervention has the potential to prevent active failures and errors as a result of inadequate administrative practices whilst saving costs and improving compliance [223]. The effectiveness of barcode technology used for medication administration in hospitals have been described in an article by Cochran and colleagues, ensuring the right medication is given to the right patient at the right time [224]. This system has the potential to be implemented in primary care with positive effects.

Keeping electronic Medication Administration Records (eMAR) in nursing homes was perceived to decrease some of the problems (such as communication problems, inaccuracies with MAR and stress levels)

contributing to the occurrence of administration incidents in a Swedish study [225]. In this study, a prospective case-control survey was conducted in two nursing homes where one had eMAR implemented whilst the other one continued to use regular paper records. Following a questionnaire type data collection, they found statistically significant reductions in the perceived risk of medication administration errors and the overall daily stress levels of staff at 20 weeks post implementation of eMAR. The intervention and control groups were chosen and matched demographically which supports the validity of findings. However, the generalisability of findings could be compromised due to the nature of sample taken. Selection of cases in other parts of the country may have offered different insights. Another hospital based study in Spain also identified eMAR development to be one of the most effective ways of improving medication administration safety following a Failure Mode, Effects and Criticality Analysis (FMECA) involving a multi-disciplinary consensus committee made up of healthcare professionals [200]. Although the results from FMECA are not easily extrapolated to other settings, the ideas and principles could be used and applied to primary care setting to possibly improve the safety of medication administration.

Multiple incidents reported have been described to involve standard syringe drivers. Intelligent infusion pumps with integrated software technology used effectively in hospitals could be used to improve medication administration safety in primary care as well [226, 227].

Use of a standardised protocol or method of assessing the effects of medications such as opioids during administration could help improve the safety of such medicines administration to patients, as demonstrated in a hospital setting [228]. A standardised method of assessing sedation, the Pasero Opioid-Induced Sedation Scale was introduced in the hospital unit as a new patient safety initiative. The nurses reported that the new protocol helps them provide commendable and safe care to patients. This idea could be used for more problematic medicinal classes previously identified. Some of these protocols already exist in primary care for certain medicine classes, like insulins and antithrombotic agents, but may be lacking for other problematic classes such as opioids. Developing and enforcing these protocols could be beneficial to the safety of medication administration to patients.

4.8.2 Inadequate procedures for implementing medication changes at transfer of care between settings

Less than optimal transitions of care from secondary to primary care contribute to medication incidents in primary care. A systematic review looking at interventions during transitions of care for elderly patients mostly during discharge revealed that interventions aimed at improving communication contribute to safe transition of care. Review papers, Randomised Controlled Trials (RCTs) and descriptive studies were included in this systematic review [229]. Effective interventions identified in the review included education and training of healthcare professionals, organisational or cultural interventions (e.g. discharge

protocol or planning, medicines reconciliation, standardized discharge letter, discharge follow-up), and patient- or representative-oriented interventions (e.g. patient awareness and empowerment, discharge support) [229]. However, there was no evidence in the review that one type of intervention was superior to another. Strong evidence was mostly demonstrated where interventions targeted a particular group of patients; therefore, multiple factors may need to be considered based on the healthcare needs of patients before selecting the best approach. This may mean multiple approaches involving multiple stakeholders are used at the same time. This review lacked a thorough assessment of the quality of methods used in the included studies but they took methodological issues into account when making their conclusions. Similarly, Barber and colleagues suggested in their article that a drug history should be taken by the hospital pharmacist and medication changes communicated by that pharmacist to the community pharmacist directly, as well as to the GP in order to improve this transition of care; this ties in with the findings from the review above [176].

Standardisation of discharge summary template from the hospital was also described as an important solution to poor discharge summaries negatively impacting on continuity of care [176, 222, 230].

Studies have demonstrated the effectiveness of a pharmacist-based intervention at discharge from hospital for bridging the gap during continuity of care and helping prevent medication incidents occurring in primary care after discharge [211, 231]. However, this may not be fully

utilised or implemented, therefore contributing to the occurrence of medication incidents. Johansen and colleagues designed a non-blinded RCT based in Norwegian hospitals to improve medication safety in the elderly [211]. In the study protocol of the interdisciplinary collaboration, the intervention involved a structured and standardised discharge summary being given to patients and transferred to the various relevant primary care settings. The intervention also included a follow up phone call to the patient's GP, pharmacy and nursing home, where applicable [211]. This study, when finished, could significantly improve the transfer of information between secondary and primary care and enhance continuity of care. However, the study did not allow for the effect of each arm of the intervention to be measured separately, due to the complex nature of the intervention. Additionally, the lack of blinding may have introduced bias in the study.

Discharge summary documents being transferred via an online system was also found to improve medication safety through improving the timeliness of communication and medication list accuracy [232, 233]. This could help mitigate some of the incidents that have occurred as a result of lack of accurate and timely medication information transfer post-discharge when utilised accurately.

An idea involving the development of "health smart cards" for patients was discussed in one article as a possible solution to inefficiencies during continuity of care [234]. The cards would contain vital patient medical information in the form of a credit card. Although this could be a potential solution, especially in patients with long term conditions, the

costs and technicalities may hamper the implementation of such a system for the moment.

4.8.3 Need for improved staff education and training

Various papers have described a need for improved education for healthcare professionals at undergraduate and postgraduate level [176, 235, 236]. These included better teaching and competency testing on the selection, use and doses of common medicines, as well as factors affecting doses - such as renal and hepatic factors and common interactions. In his article, Schachter suggested informative feedback from regulatory bodies on emerging problematic issues [236]. Literature also recommended specific on the job training in practical prescribing for newly qualified prescribers. For more senior prescribers, the recommendation was that prescribing practice should be included in higher specialist training and in continuing professional development. The PINCER study by Avery et al. utilised an educational outreach as part of the effective complex intervention in reducing prescribing and monitoring errors in GP practices [113]. Another study evaluating the implementation and adoption of the PINCER intervention using a qualitative process evaluation, demonstrated how such intervention developed the relationships between clinicians (mostly GPs and pharmacists) by building respect and improving trust in the care practices [208]. This type of intervention could be important in improving the learning and poor communication amongst healthcare professionals in primary care, thereby improving the continuity of care and the safety of medication use by patients.

As previously described in complex intervention studies, other forms of educational interventions were also described in studies. They included teaching in the form of presentations, workbooks, and practice questions as well as identifying the need to assess competency of prescribing in the form of tests led by a clinical pharmacist-led education programme. A hospital study in the UK identifying educational interventions on paediatric prescribing also came to similar conclusions. The study used a combination of a systematic review, a questionnaire survey, observations and interviews to identify the interventions. Only two papers were identified in the review that involved educational interventions with a significant positive impact. However, both of these were part of a complex intervention, which made it difficult to assess the contribution of the educational interventions. The interventions were: in-service dose calculation tests for medical trainees and a clinical pharmacist-led education programme in a neonatal intensive care unit. Presentations were the most common type of educational intervention described by the respondents of the questionnaire. Although a few respondents provided a competency test, there was a lack of it from the majority of the respondents in this study. There was a lack of evidence as to the evaluation and effectiveness of the interventions identified in this study [235].

Direct personalised feedback of errors to prescribers was also demonstrated to be effective in reducing the frequency of prescribing errors and improving the prescribing standards which was well received by the prescribers [237]. Although this study was based in secondary

care, similar concepts could be used in primary care to improve medication safety.

Gilmartin et al. developed a quality improvement intervention to reduce dispensing errors associated with dose administration aids (DAAs) or MCCAs or dosette boxes in Australia. They developed an educational intervention following a series of focus groups called: ‘Be alert and work together for medicine supply, DAA incident awareness toolkit’. This was delivered by a pharmacist during an education session after which participants completed a qualitative evaluation questionnaire. The intervention was described to have the potential to reduce the occurrence of MCCA dispensing errors ‘very well’ by almost half of the respondents (49.6%) or ‘extremely well’ by a further fifth of respondents (20.5%). The study used a large sample size with a high response rate, which increased the generalizability of findings. However, a more objective approach (quantitative) to evaluation of intervention alongside the subjective findings could provide better evidence of effectiveness [238]. A survey on dispensing errors in community pharmacies in Finland identified the current actions that are taken in the dispensing error managing process and what the pharmacists’ ideal actions would be. They found educational intervention by way of discussion to be considered the most ideal method of managing dispensing errors (76% of respondents) followed by documenting the errors (45% of respondents) [239].

Other studies have demonstrated the effects of educational interventions both to healthcare professionals and patients in improving

medication safety, however, empirical evidence of effectiveness was not always apparent. These included prescribing guidelines, bookmarks, media awareness campaign, patient information cards and posters [229, 240, 241].

Improved training programmes for students (such as simulations) are also beneficial for improving the administration of medications, as shown in one USA study [242]. A well-designed simulation for paediatric medication administrations was evaluated in the study. Student ability to perform important skills necessary for the safe administration of paediatric medications rose following the intensive simulation training. Changes in curriculum with the aim of improving medication patient safety would be the ultimate objective regarding training programmes for students. Various educational interventions were shown in different studies to improve administration safety [198, 243-245], although not always consistent. For example, an educational intervention that involved licensed nurses watching a presentation in two different nursing homes in USA showed a significant improvement in knowledge in one nursing home but not the other, one month post-implementation of intervention (the second however did show an improvement, but this was not statistically significant). The presentation, which was delivered on a DVD, involved a PowerPoint with a voice-over lasting 35 minutes. It contained educational content including performing medication calculations, discriminating between correct and incorrect procedures, recognising indications for commonly used medications and their side effects, and identifying causes of medication

errors along with methods for mitigating them. An increased sample size may have generated more robust statistical evidence, with the small sample limiting generalisability as well [246].

In a systematic review by Harkanen and colleagues evaluating educational interventions for the improvement of medication administration skills and safety of nurses in hospitals [198], 14 studies were reviewed. Educational interventions used in the different studies (including classroom training, e-learning, simulation, slide show presentations, posters, pamphlets and an interactive CD-ROM programme) all appeared to improve medication administration safety in hospitals. Only one study was assessed to be of strong quality, with four classed as moderate quality; these were included in the meta-analysis. Following the meta-analysis, which provided strong evidence, the most effective intervention was a combination of learning programmes: e-learning and a 60-minute PowerPoint presentation. Combining multiple educational intervention ideas or an educational intervention alongside other types of intervention as a single complex intervention is likely to be more effective in educating staff and improve the safety of medication administration. Although this study was conducted in secondary care, similar ideas could also be effective in primary care.

4.8.4 Insufficient communication of medicines information to patients

The PRIORITIZE study by Car and colleagues (discussed earlier) also identified inadequate patient education on medicines use to be one of

the top three problems involved with medication safety incidents, as identified by primary care clinicians. Better communication between healthcare provider and patient, and improved patient education were suggested as improvement strategies to tackle this issue [222]. In one study looking at a pharmacist-led transition of care intervention following hospital discharge in patients identified as having potential barriers to medication adherence following change in regimen, the clinical pharmacist called the patient within two business days of hospital discharge and followed up within seven days. Barriers to adherence and medication errors were assessed qualitatively. Patients' lack of understanding of instructions was the most common theme identified and gave the pharmacist another opportunity to reconcile with the patients, thereby preventing further incidents [206]. This pharmacist-led intervention post discharge was able to prevent further medication safety incidents and possible readmission whilst offering opportunities to improve the discharge process and medication safety. In the RCT protocol by Johansen and colleagues about the interdisciplinary collaboration between secondary and primary care to improve medication safety described earlier, the intervention study involved extensive patient counselling with the pharmacist where they were informed of changes and reasons behind them, along with any other medication-related issues identified. This does not replace the standard discharge meeting between the doctor and the patient. This intervention could significantly improve patient knowledge about their medicines and help reduce administration incidents [211].

Appropriate medication cards containing basic information regarding the medication (including general classification, brand and generic names, indications and side effects) was shown to be another effective way of educating and communicating information regarding new medication to patients - in easy-to-understand language. Healthcare professionals offered guidance and support to patients regarding the content of the medication cards if needed [247].

Scnipper et al. designed a patient portal that is linked to the electronic health record of the patient in the USA. One of the aims of this portal was to improve the communication between the healthcare professional and the patient regarding their medications and allergies by allowing patients to view and modify their information on their records where appropriate, and therefore empowering patients to be active participants in their healthcare. The information was verified by the healthcare professional before updating the electronic health record. This aimed to increase the accuracy of the medication list within patients' medication records, detect and reduce adverse drug events, and improve patients' knowledge of their medication regimen, thereby improving medication safety. Preliminary evaluation of the portal was conducted via an online survey where most patients reported a favourable positive impact [213]. Only a small sample of patients participated in the study which limits generalisability. However, this idea could potentially improve the communication of medicines information to patients, which could have beneficial effect on patient safety.

Patient's access to records could be extended to include secondary care records.

Studies have also demonstrated the positive effects of educational interventions, both to healthcare professionals and patients, as described earlier [229, 241]. Other interventions that incorporate educating patients or representatives regarding medication use within a complex intervention also exist, some of which targeted a specific population, such as antibiotics use in children [248].

4.8.5 Medication similarity oversights

Few studies were identified to have looked at interventions focusing on reducing the rate of dispensing errors in primary care mostly in community pharmacies [238, 239, 249-251]. A study by Cohen et al. [250] ranked the effectiveness of various interventions to improve the safety of dispensing four high alert medications (warfarin, fentanyl patches, oral methotrexate and insulin analogues) in community pharmacies in the United States as part of their study objectives. They found the use of barcoding technology (checking the medication against the prescription) to be the most effective intervention in improving the safety of dispensing medications with a reduction in risk of up to 100%. Other successful intervention strategies included increasing patient counselling, conducting a second data entry verification process during product verification, computer alerts that cannot be bypassed easily and opening the bag at the point of handing out the medication. All these system based interventions showed various degrees of risk reductions for dispensing medications.

A study protocol conducted by Chui et al. [249] about over the counter (OTC) medication dispensing to older adults, identified interventions which could potentially improve their safety. Two system based interventions: 'the redesigning of the physical environment' and 'implementing a clinical decision tool to support pharmacists' were investigated as interventions to improve the safety of OTC dispensing to older adults. The aim was to achieve this by improving the communication between pharmacists and patients. Although this study did not look at dispensing medications from prescriptions, the principles could be applied to mitigate dispensing incidents.

Other studies based in secondary care have also demonstrated the effectiveness of system based interventions and other intervention initiatives in reducing the rate of medication errors including dispensing errors and improve medication safety. These could be refined and adopted for use in primary care and for dispensing errors in primary care. These include technological interventions such as barcoding [251], and systems based, educational and cultural interventions [84, 184, 186, 252, 253].

4.9 Recommendations for safety improvement

I will now make recommendations that could improve the safety of medications use in primary care. I will do so by mapping the key priority issues previously identified for each of the three categories (prescribing and monitoring, dispensing and administration incidents) onto driver diagrams (Figures 4.3, 4.4 and 4.5 respectively) with suggestions of

change ideas and risk reduction strategies. These ideas were informed by synthesis of the literature and from reading the incident reports. Where relevant, evidence of efficacy is also identified, alongside the GRADE rating for assessment of the strength of evidence identified. Figures 4.3, 4.4 and 4.6 illustrates my recommendations for potential interventions or improvement strategies (secondary drivers) on the key issues (primary drivers) identified for each incident category described. However, given that some of the change concepts were tested in different settings, as well as the lack of strength for most of the evidence assessed using GRADE ratings, the effectiveness of these in primary care, especially in community pharmacies, will need to be tested and evaluated. This should include Randomised Controlled Trials and Systematic reviews, in order to provide strong evidence of effectiveness or lack of.

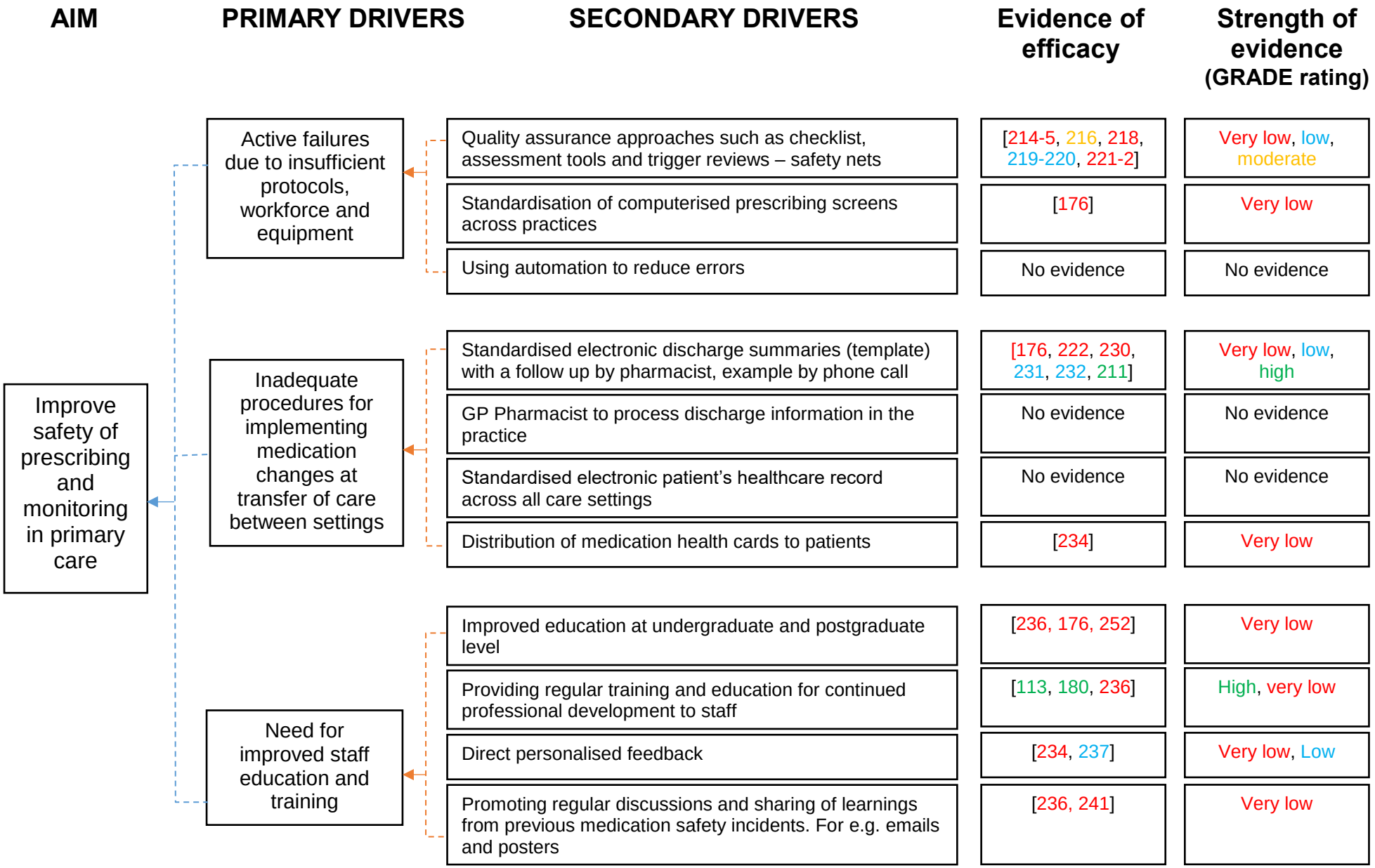


Figure 4. 3 Driver diagram showing potential interventions to improve the safety of prescribing and monitoring in primary care

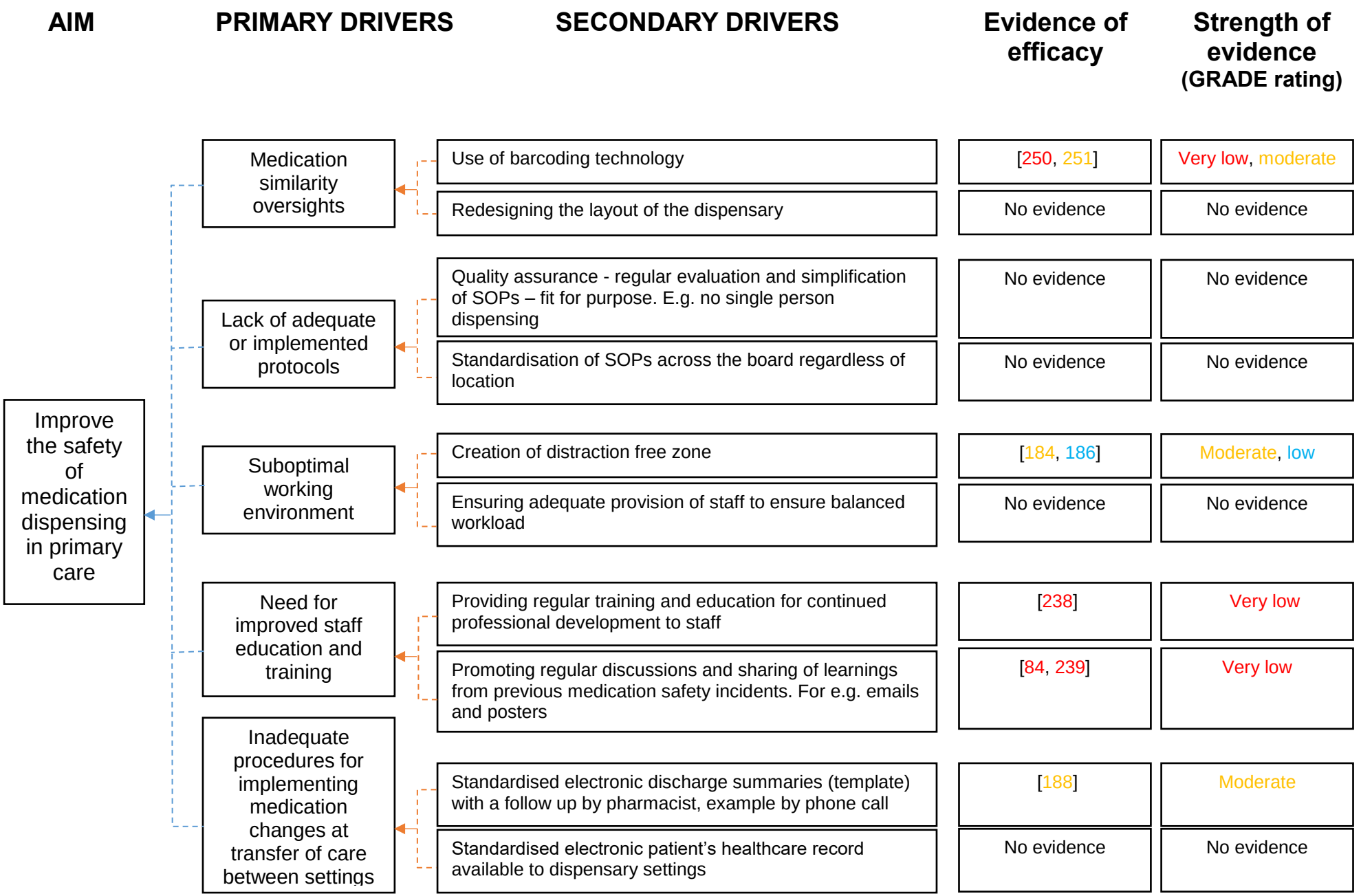


Figure 4. 4 Driver diagram showing potential interventions to improve the safety of medication dispensing in primary care

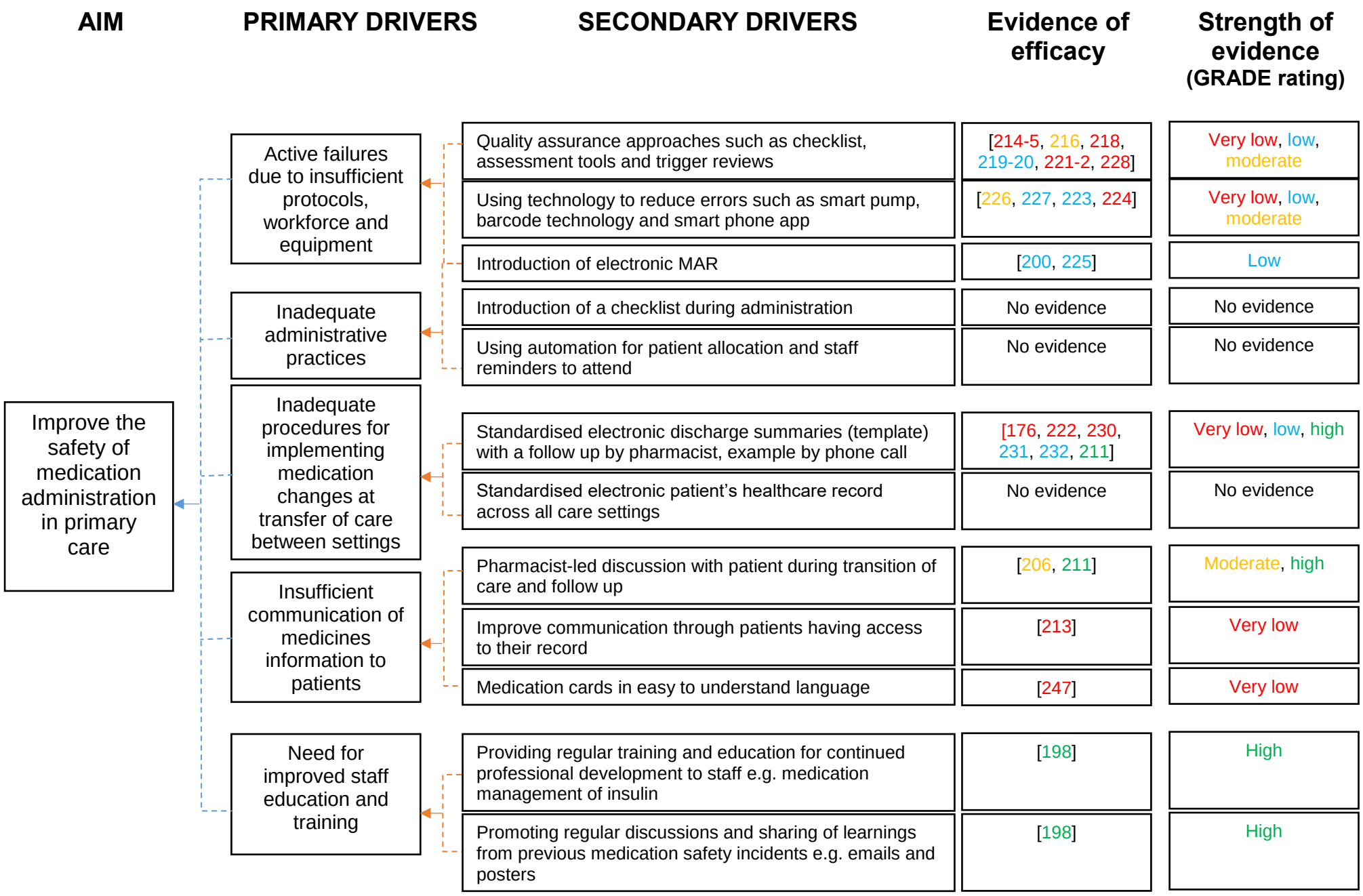


Figure 4. 5 Driver diagram showing potential interventions to improve the safety of medication administration in primary care

4.10 Summary of findings

4.10.1 Prescribing and monitoring incidents

In this category, the following main findings were identified:

- Prescribing the wrong dose was the most common type of incident identified (18%), followed by prescribing the wrong item (14%) and unsafe prescribing (13%).
- Most patient deaths resulted from prescribing a known allergy of medication to a patient (n = 3/9, 33%).
- Antithrombotic agents, mostly warfarin (n = 63), and opioid analgesics (n = 60) were the most frequent medications involved in incidents.
- Antithrombotic agents (n = 6), high-ceiling diuretics (n = 3) and NSAIDs (n = 3) were the most involved medications with patient outcome of severe harm or death from 18 incidents (67%).
- The three key issues or areas identified needing improvement for which I recommended intervention ideas were:
    - Active failures due to insufficient protocols, workforce and equipment
    - Inadequate procedures for implementing medication changes at transfer of care between settings
    - Need for improved staff education and training
- The interventions recommended (which were summarised and presented in a driver diagram), included: quality assurance approaches such as checklists, assessment tools and trigger

reviews; using automation to reduce errors associated with the active failures due to insufficient protocols, workforce and equipment; standardised electronic discharge summaries with a pharmacist follow up; standardised electronic patients' healthcare records across all care settings; direct personalised feedback; and, provision of regular training and education for continued professional development to staff. Some of the recommendations had evidence of efficacy, although, not always at a high level. See Figure 4.3 for the full list of interventions recommended for every priority area identified, visually.

4.10.2 Dispensing incidents

In this category, the following main findings were identified:

- The most frequent type of incident was dispensing the wrong medication (35%) followed by dispensing the wrong strength (28%).
- The top two incident types were also responsible for the majority of serious harm incidents (n = 238/353, 67%).
- Antidepressants (n = 439) were the most frequently involved medications.
- Antithrombotic agents had the highest proportion of reports with serious harm outcomes (n = 36/91, 40%).
- The five key issues or areas identified needing improvement for which I recommended intervention ideas were:
    - Medication similarity oversights

  - Lack of adequate or implemented protocols
  - Suboptimal working environment
  - Need for improved staff education and training
  - Inadequate procedures for implementing medication changes at transfer of care between settings

- The interventions recommended (which were presented in a driver diagram) included: the use of barcoding technology; redesigning the layouts of the dispensary; standardisation of SOPs across the board; creation of distraction free zone; ensuring adequate provision of staff to ensure balanced workload; and, providing regular training and education for continued professional development to staff. However, there were a lack of evidence of efficacy of these recommendations in this setting. See Figure 4.4 for the full list of interventions recommended for every priority area identified, visually.

4.10.3 Administration incidents

In this category, the following main findings were identified:

- The most common type of administration incident was omission of medication (22%), followed by administration of wrong dose (19%), mostly overdose.
- All patient deaths were as a result of wrong dose administration (n = 6/6, 100%) with two involving opioids.
- Insulin was the most frequent medication type involved with administration incidents (n = 156).

- The five key issues or areas identified needing improvement for which I recommended intervention ideas were:
    - Active failures due to insufficient protocols, workforce and equipment
    - Inadequate administrative practices
    - Inadequate procedures for implementing medication changes at transfer of care between settings
    - Insufficient communication of medicines information to patients
    - Need for improved staff education and training
- The interventions recommended (which were presented in a driver diagram) included: using technology to reduce errors such as smart pump, barcode technology and smart phone app; introduction of electronic MAR; using automation for patient allocation and staff reminders to attend; pharmacist-led discussion with patient during transition of care and follow up; and, introduction of medication cards to patients in easy to understand language. Similar interventions from the other medication use process areas described earlier were also recommended where the priority area is similar. Again, some of the recommendations had evidence of efficacy, although, not always at a high level. See Figure 4.5 for the full list of interventions recommended for every priority area identified, visually.

For all three categories, risk reduction strategies and interventions were suggested and mapped to the priority areas identified using driver diagrams following literature synthesis of interventions and subjective knowledge from reading thousands of incident reports.

In the next chapter, I will discuss my findings.

Chapter 5 Discussion of findings, recommendations and conclusions

5.1 Overview of chapter

This chapter will discuss the main findings of the descriptive analysis and the three medication incident categories described in the previous chapter of this thesis in relation to the current literature. The implications of these findings for practice and policy will then be explored. Furthermore, the strengths and weaknesses of the project will be described and recommendations for future research will then be presented before conclusions are drawn.

5.2 Main findings from thesis

Prior to this study, no studies had analysed national data on all primary care medication safety incidents beyond their characteristics or presented recommendations for improvement strategies based on findings and substantiated with literature for the priority areas identified.

In this study, an existing empirical approach to classifying patient safety incidents (PISA classification system) was used to classify medication incidents from primary care. With this, an advancement was made on the PISA classification tool (developed using the same NRLS data source) as it has not been previously applied with a specific focus on primary care medication safety incidents in the past. This allowed the opportunity to add value by updating and refining the tool in relation to medication safety incidents. Following the WHO Safer Primary Care

Expert group's recognition of the need to develop and improve better approaches to understanding patient safety in primary care, this advancement is set to improve the methodological rigour of the newly developed PISA classification system.

Using methods outlined in chapter 2, I have described the characteristics and categorised the associated harm severities of primary care medication safety incidents using reports submitted to the NRLS between 2003 and 2013; this is the largest analysis of medication safety incident reports from primary care. By using a structured approach to review the free-text content of reports, medication incident types and other categorical information that were submitted as part of the reports could be corroborated, but also highlight instances where the system is used for unintended purposes or where the system could be enhanced. For example, some reports were found to not contain a medication incident but were submitted as such. Furthermore, 99.6% (n = 4,997) of reports identified incidents that occurred and reached the patient, which implies that near miss incidents are uncommonly reported to the NRLS or are not captured accurately in the database. By comparison, in the prospective study by Ashcroft et al. (which used similar definitions to this study), 84.8% of reported incidents were near miss incidents [70].

I have additionally categorised the medication safety incidents according to the medication use processes in primary care (Objectives 1-3). Through a combination of descriptive and thematic analysis examining the relationships between incident types, their contributory

factors and outcomes, I have identified themes that reflect the priority areas or issues within the medication use process needing improvement (Objective 4). These include both those specific to one medication use process and those relevant to more than one, thereby identifying opportunities for change across the whole system (medication use processes in primary care). I have also identified and recommended interventions which were informed by current literature and have summarised those findings in the form of a driver diagram (i.e.: a plan to improve priority issues) (Objective 5).

Dispensing incidents were the most frequent medication safety incidents found in primary care with 67%. However, medication incidents with a higher degree of harm were more likely to originate from general practice or involve doctors. Furthermore, there were more medication incidents reported for female than male patients, although male patients were more likely to be associated with severe harm or death incidents. Antidepressants, antithrombotic agents (mostly warfarin), insulins and opioid analgesics were amongst the most common medicines described, which were involved with most of the incidents to have resulted in a serious harm to patients.

Prescribing the wrong dose (18%) was the most frequent prescribing incident identified in this study. Picking errors of the wrong medication, strength and formulation made up the majority of dispensing incidents identified, with 70.5% of dispensing incident reports. In administration incident reports, omission of medication was the most frequent incident

identified (22%) and insulins were the most commonly involved medications associated with these.

Following the application of the PISA classification, staff-related factors (50.3%) were the most frequent contributory factors identified in medication incidents with more than half of the reported factors across all incidents. This was followed by service-related factors (26.8%) and patient-related factors (11.2%). Some of the most frequently identified factors included similarity of medication names and appearances, being overloaded with work, distractions and failure to adhere to guidelines. Communication issues amongst healthcare professionals and care settings were also commonly identified as contributing to medication incidents.

Following further analysis, areas specific to prescribing, dispensing and administration processes were identified and prioritised for improvement. Some of the priority areas were common between the different medication use process areas. The following priorities were identified in Chapter 4 during the medication use processes for improving medication patient safety across primary care:

- Active failures due to insufficient protocols, workforce and equipment during prescribing, monitoring and administration processes
- Inadequate procedures for implementing medication changes at transfer of care between settings. This was an issue across all process areas

- Need for improved staff education and training across all process areas about the knowledge and skills required to provide safe care
- Medication similarity oversights (sound-alike and look-alike medicines) mostly affecting the dispensing process
- Lack of adequate or implemented protocols during dispensing process
- Suboptimal working environment in community pharmacy setting
- Inadequate administrative practices during administration of medications
- Insufficient communication of medicines information (such as indication, dose, side effects or changes) to patients affecting administration of medications

Although interventions were identified from existing literature in the previous chapter, there is a lack of existing quality improvement interventions designed specifically for primary care to test efficacies of interventions that could address the priority areas identified, particularly relating to dispensing and administration of medications. Intervention strategies from studies in secondary care were also considered when making suggestions for addressing the issues identified in primary care as summarised in Figures 4.3, 4.4 and 4.5.

5.3 Discussion of findings in relation to current literature

5.3.1 Characteristics of medication incidents

This study investigated the characteristics of medication safety incidents in primary care and found dispensing processes to be the most common source of medication safety incidents in primary care, accounting for 67% (n = 3380) of the reports. This indicates the importance of dispensing practices for improving medication safety in primary care. Various studies have described the epidemiology of medication incidents at different stages of the medication use process (i.e. prescribing, dispensing, administration and monitoring) in primary care (described in Chapter 1). However, there is a lack of such studies that use the same data source as in this study. In the first Safety in Doses document published by the NPSA in 2007, medication incidents were found to be the second most common type of incident reported to the NRLS between January 2005 and June 2006. However, only 4.9% of these were from primary care setting with more than 80% coming from hospitals [49]. The second document in the series, published in 2009, saw only 14% of the medication incidents reported to the NRLS in 2007 coming from primary care with 76% from hospitals [33]. Furthermore, in Cousin et al.'s review of medication incidents reported to the NRLS between 2005 and 2010, administration incidents were the most common incidents, described in 50% of reports. However, the study included secondary care, which was responsible for more than 75% of the reports used in the study [5]. Other studies that included secondary care (with the majority of reports) also found administration

incidents to be the most frequent incidents described [6, 85]. These study findings are, however, all skewed towards secondary care, with this setting having the majority of input in the results; this may indicate strategies to improve medication safety in primary care could require a different and tailored approach to those developed for secondary care.

5.3.1.1 Types of medication incidents

Of the 467 prescribing and monitoring incidents identified, wrong dose (n = 82, 17.6%), wrong medication (n = 67, 14.3%) and unsafe medication being prescribed (n = 62, 13.3%) were the most common types of incident identified. Medication overdose was the most frequent wrong dose issue identified (n= 58/82, 70.7%). In the PRACtICe study by Avery et al. [66], a retrospective review of medication items prescribed over a 12 month period in general practices in England was conducted to identify prescribing and monitoring errors. Wrong dose or strength errors were amongst the most common prescribing error identified with 17.8% of their sample. Other similar incidents such as wrong drug and contraindicated (unsafe) drug were also identified. Although different methods and definitions were used to identify incidents in my research, which makes it difficult to compare results, similar findings were identified. Of the 467 incidents, 36 (7.7%) were monitoring incidents, which included lack of monitoring and lack of adjustment of dose following monitoring; this was similar to the findings of the PRACtICe study.

Picking errors, i.e. wrong medication (34.9%), wrong strength (28.4%) and wrong formulation (7.2%) made up just over 70% of dispensing

incidents identified in this study, followed by dispensing the wrong dose (7.2%) or to the wrong patient (5.7%). Selection or picking error (60%) was also found to be the most common cause of dispensing incident in a prospective study about dispensing errors in UK community pharmacies conducted by Ashcroft and colleagues [70]. In the literature review of the incidence, types and causes of dispensing errors conducted by James and colleagues; a total of 60 research papers were included in the review, with only 19 papers investigating dispensing errors in community pharmacy. Of these, five papers investigated the types of dispensing incidents in UK community pharmacies. This highlights the scarcity of research in this setting compared to secondary care setting. The five UK studies reported the supply of wrong drug, wrong strength and wrong formulation to also be the most common types of both prevented and unprevented dispensing incidents [89].

Of the 760 administration incidents identified, omission of medication (n = 164, 22%) was the most common incident identified followed by administration of wrong dose, mostly overdose (n = 140, 18%). Patients also administered overdose of their medication inadvertently by themselves (n = 67, 9%). In the CHUM's study by Barber and colleagues [39], omissions were also responsible for 49.1% of administration incidents identified and 21.6% were wrong dose, similar ranking to findings in this study. However, it is important to note that the CHUM's study only included care homes, whereas this study also

included private residences, which may account for the minor differences in the incidence found.

5.3.1.2 Care settings of occurrence and healthcare professionals involved

Incident reports were submitted from all primary care settings; not necessarily from the care setting where the incident occurred. However, this applied to only a small proportion of reports. In total, 7.2% of the community pharmacy incidents were reported from the general practice and community nursing. However, 41.6% of general practice incidents were reported from hospitals, community nursing and community pharmacies. This may have contributed to the lack of depth of free-text descriptions, such as contributory factors being described in these reports. Incidents reported by nurses were generally longer and more detailed than those reported by other healthcare professionals. Nursing care is mostly provided by nurses and carers and this is reflected by their involvement in administration incidents; these incident reports were often more detailed than those for other incident categories. Community pharmacy reports were often the shortest in length compared to reports from other settings. This may be due to the time consuming nature of filling out a report in detail which community pharmacy staff may not have.

Although dispensing incidents were described most frequently, prescribing and monitoring incidents, mostly reported from general practice, were shown to have a higher proportion of reported serious harm outcomes (96 of 311 reports, 30.9%) including the most deaths

compared to dispensing incidents (353 of 1651 reports, 21.4%); amongst those with confirmed severity of harm. Furthermore, a higher proportion of dispensing incidents reported from general practice resulted in serious harm outcomes (17 of 42 reports, 40.5%) compared to those from community pharmacy (334 of 1592 reports, 21.0%). This was consistent with the finding that 7.5% (25 of 335 reports) of the incidents involving doctors specifically resulted in an outcome of severe harm or death. This was a higher proportion for any of the involved healthcare professional and was responsible for at least 32% of the total incidents causing severe harm or death (25 0f 77 reports). This may indicate that incidents from general practice causing serious harm are more likely to be reported to the NRLS than those resulting in no or mild harm, which may reflect the incident reporting culture in general practice. This is consistent with findings from other studies [85, 254]. As part of the aims of their study, Alrwisan and colleagues wanted to quantify the proportion of reported incidents according to the reporters' profession in NHS facilities in the north east of Scotland. Using retrospective data from an online reporting system, they found physicians and dentist to have reported a greater proportion of incidents that have resulted in patient harm (14.8%) compared to other professional groups like nursing and pharmacy (5.8%). However, once again this study involved both primary and secondary care settings with the majority of reports originating from secondary care; therefore, it may not completely reflect on the situation in primary care settings [85].

Sarvadikar and colleagues additionally aimed to investigate the attitudes of healthcare professionals towards reporting medication errors. They used questionnaires with clinical scenarios and questions with an ascending order of worsening patient outcome; using a Likert scale to describe likelihood of reporting. They found that doctors were unlikely to report less serious medication errors (median value of 2) compared to nurses and pharmacists (median value of 5), even with the fear of retribution. However, this study was also conducted in a hospital setting in Scotland [254]. In another retrospective study of incidents reported to an on-line incident reporting scheme in a hospital in the UK, doctors were also found to report the least number of medication incidents (9.1%) compared to pharmacists (51.9%) and nursing staff (37.6%) [6]. Despite the difference in care settings between these studies and the current study, there are similarities in the findings. This could, in part, explain why there are considerably higher number of reports, inclusive of no harm and low harm outcomes, from community pharmacy and community nursing compared to general practice (where incidents are more likely to be reported when patients' outcomes are worse). It is, however, unclear whether this is due to fewer less serious incidents or an unwillingness to report them in this setting.

5.3.1.3 Gender of patients

In this study, female patients were more commonly involved with medication safety incidents (62.3%) where gender could be established; however, male patients were more frequently described in incidents with severe harm or death outcomes (n = 25/40, 62.5%). This

finding was similar for the medication incident categories described in Chapter 4 with the exception of administration incident category: prescribing and monitoring incidents (8/13, 61.5%), dispensing incidents (9/12, 75%) and administration incidents (n = 3/6, 50%). However, this finding may not be fully reliable as gender could only be established in just over 37% (n = 1865) of the whole sample population.

A study by Roe et al. [255] found women to be more likely to use several classes of medicines compared to men. This included antidepressants, antianxiety and pain medications. This finding is consistent with the findings of this study (Chapter 3) in that more than 60% of reports involved females. The PRACtICe study [66] found risk of errors to be more associated with male gender; which was different to the findings of this research. This could be due to the study looking specifically at prescribing errors (9% of the total reports used in this study) in general practice. However, the study by Guthrie et al. in Scottish primary care showed the female gender to have a smaller positive association with high risk prescribing, similar to this study [72]. Although the study also looked at prescribing errors, it focused on specific patient demographic, which was those vulnerable to adverse drug events because of their characteristics. This may explain the difference in findings when compared to the PRACtICe study. Another study in USA using national data also found the risk of adverse drug events to be higher for females [71]. No studies were found to explore the relationship between medication-related harm severity outcomes and gender.

5.3.1.4 Age of patients

Patient age was described in 51.8% (n = 2598) of the total incident reports with the number of incidents mostly increasing with age from 18 to 85 years. Similar trends were seen in all the different medication incident categories described in Chapter 4. This is consistent with patients' expected use of medication according to age [255-257] which makes older patients receiving more medications for a longer period more susceptible to medication errors and incidents including a higher level of severity. The frequency then decreases for patients of over 85 years of age. Although patients in this age group are likely to use more medications than younger patients, the decrease in frequency is consistent with the population of people in this age group being smaller than other age groups [168]. This explains the higher proportion of the population of over 85 years experiencing an incident compared to 85 years and under.

5.3.1.5 Medicines involved in incidents

Antidepressants were the most frequently reported medicines involved with dispensing incidents, whilst antithrombotic agents and opioids were frequently reported with prescribing and monitoring incidents. Meanwhile, insulins were the most frequent medicines described in administration incident reports. Although there are studies that have identified the most common medicines implicated in incidents [5, 85], the majority of these are heavily influenced by secondary care. A recent study about primary care antidepressant prescribing used a large primary care database containing general practice patient records

across the UK, to calculate prevalence and incidence rates [258]. It showed an increased incidence rate of antidepressant prescribing in patients aged 12-17 years by more than double between 2005 and 2017. This demonstrates the increased use of antidepressants over time which correlates with the high involvement of this class of medication in incidents, especially during dispensing. The study also showed female patients to have a much higher incidence rate than male patients as discussed earlier. Another study has also demonstrated the increased rate of prescribing of opioids in primary care in England between 2010 and 2014, which, again, correlates with their increased involvement in medication safety incidents [259]. In the retrospective study using an online reporting system by Alrwisan and colleagues described earlier, insulin preparations, paracetamol and morphine were the most frequent medications implicated in patient harm [85]. However, almost three quarters of the incidents identified in the study originated from acute hospitals with the majority of incidents being administration incidents (59%). In Cousin's review of NRLS data on medication incidents, opioids, antibiotics, warfarin, low molecular weight heparin and insulin were the top five medications implicated in incidents that resulted in an outcome of severe harm or death. Three quarters of incidents (75%) also originated from acute general hospitals with majority being administration incidents (50%) [5]. Although these studies identified similar medication involvement, they involved an unweighted sample of incidents from secondary care which may affect the results and not be a true representation from primary care. This

may explain some of the differences seen. Until now, medication safety studies identifying the most frequent medicines involved in primary care incidents only were lacking, which makes it difficult to compare results. Such evidence is vital in directing strategies to improve patient safety when dealing with specific medicines or medicine groups.

5.3.1.6 Contributory factors to incidents

At least one contributory factor was described in more than 69% of the reports (these are presented in Chapter 3). Similar contributory factors were reported in all the incident categories described in Chapter 4, irrespective of harm. Contributory factors are the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident (the so-called holes in Reason's slices of cheese) described in Chapter 1. Although these factors can exist in multiple slices (stages of medication use process for example) at the same time, the variation in frequency identified in my study suggests they are more problematic for some processes than others (or, put simply, the holes may be bigger in some slices compared to others). In the study by Ashcroft et al. [70], they found similar causes for dispensing errors and near misses in community pharmacies. They found the majority of the causes to be misreading the prescription (24.5%), similar drug names (16.8%), using patient's PMR to select medication or dose of medication (11.4%) and similar packaging (7.6%). The most common contributory factors associated with dispensing incidents found in this study were similar medication names or appearances (17.9%), being busy or overloaded

with work (10.8%) and medication storage issues (9.9%). Failure to follow procedures (7.6%) and distractions (7.5%) were also commonly described. Although, there are similar contributory factors identified, my research employs a larger sample - with 3380 dispensing incidents analysed compared to 330 dispensing incidents in Ashcroft et al.'s study. Therefore, my findings provide more reliable data and are more likely to better represent the population.

Whilst errors can potentially lead to a harmful outcome and near misses do not, it is important to learn from both incidents and near misses, irrespective of harm outcome to improve the safety of medication use. The analysis of near misses has proven to be an effective learning process, as demonstrated in other industries such as the aviation sector [260].

5.3.2 Learning from medication safety incidents

The majority of safety incidents are caused by two issues: active failures and latent conditions (as described in the Swiss cheese model of error causation in Chapter 1). Errors tend to appear in very similar guises across a wide range of mental activities [54, 73]. Therefore, it is not surprising that similar factors and causes of medication incidents were found across the different incident categories in Chapter 4, albeit some being more prominent in a particular category than others.

Following the analyses of reports, priority areas were identified for each of the medication incident categories described in Chapter 4 that were based on the medication use process stages (Chapter 1). These were

informed by the contributory factors and incidents, and the relationships between them, described in the reports. However, for dispensing incidents, due to the large volume of reports, clusters of like phenomena were initially segregated and thematically analysed before identifying the priority areas. Similar issues were eventually identified across the clusters.

The Community Pharmacy Patient Safety Group is an organisation made up of different community pharmacy organisations that openly share and learn from patient safety incidents. They also achieve this through analysing clusters of like phenomena and learning from serious or recurring patient safety incidents [261], as employed in this study for dispensing incidents. This is a useful way of identifying important areas before further analysis is conducted.

For example, incidents involving Multi-Compartment Compliance Aids (MCCAs) (identified as part of the dispensing incidents in this study) may have the potential to cause or contribute to serious harm to patients, which may be due to the type of patients using MCCA devices. The majority of patients on MCCA devices were described as older and frail with multiple co-morbidities. As people are living longer, it is inevitable that more patients are using MCCA devices for ease of medication administration. Therefore, it is important to minimise the potential errors especially during dispensing of said devices. Age, care home residency and the presence of polypharmacy, could also be used to isolate incidents involving more vulnerable patients.

Some of the priority issues identified were similar in all categories whilst others were more specific to the incident category. For example, sound-alike and look-alike medicines and suboptimal working environments, were predominantly an issue during dispensing. During such incidents, one of the co-factors of suboptimal working environment included being busy or overloaded with work. Lack of staff (e.g. due to sickness or holidays) was sometimes described alongside this; therefore, this may suggest that staff taking on extra roles at certain times contributed to the feeling of work overload. These have been previously described as well-established contributory factors to dispensing incidents [70, 89, 262]. However, studies of effective mitigating strategies to address these factors are lacking.

Issues relating to the procedures for implementing medication changes at transfer of care between settings were found to be present in all incident categories. This may suggest a need for improved inter-professional collaborations to improve medication safety. Failures in communication processes have previously been reported to account for a substantial amount of discharge-related safety incidents [263-265], similar to my findings. Need for improved staff education and training was also found to be an issue across all incident categories.

During the administration stage, insufficient information communicated to patients or their representatives was found to be an issue that contributed to administration incidents. This did not only lead to self-administration of overdose or omissions but also contributed to

administration errors by nurses or carers which were unchallenged by the patient due to lack of knowledge.

Interventions in the current literature and their effectiveness at addressing the priority areas identified have been discussed in the previous chapter. There is a lack of intervention studies focusing on primary care, especially related to dispensing and administration of medicines, although, a few studies have looked at the causes of some of these incidents (see Section 1.4.3 in Chapter 1). Interventions identified from the literature, alongside analysis of the incident reports, informed the improvement ideas for addressing the priority areas (illustrated in the driver diagrams in Chapter 4) to improve the safety of medication use in primary care.

However, it is important to be aware that these new ideas for improving medication safety may come with new issues that need to be addressed. For example, electronic prescribing has already been shown to reduce prescribing errors and improve patient safety, but could also introduce unintended consequences and new medication safety issues [266]. Furthermore, drug safety alerts, a feature of electronic medical records are valuable tools for reducing prescribing incidents. However, alert fatigue (when users become overwhelmed and unresponsive to alerts), is also a threat to patient safety. A system to override alerts based on previous use was developed to reduce alert fatigue and allow users to focus on more vital alerts, thereby improving patient safety [267]. A similar idea was used to optimise smart pump technology by reducing clinically insignificant alerts, reducing alert

fatigue and increasing critical alerts, thereby increasing the effectiveness of the pumps [268].

5.4 Strengths and limitations of study

This is the first study to systematically analyse primary care-specific medication safety incident reports submitted to the NRLS. However, notable limitations exist and largely relate to the quality of the NRLS data and reporting biases. Reporting systems such as the NRLS rely on healthcare staff and patients or representatives to report details of incidents retrospectively, in order to generate the learning required to improve medication safety. When details such as contributory factors are not described in reports, this represents a missed opportunity to learn from the incident and identify potential areas for intervention. Furthermore, retrospective recording of incident is subjective and can be affected by recall biases on the part of the reporter. However, having such a large volume of reports from different origins describing similar issues that arise from incidents provides strong evidence for the existence of said issues. Various other limitations of the data were identified and are discussed below, these can be used as opportunities to improve the quality of incident reports uploaded to a reporting system.

Around 30% of the reports in this study did not contain any description of contributory factors or apparent causes as per NRLS taxonomy. This may have provided a missed opportunity to identify other important issues that may require intervention or provide further evidence and

other contextual factors on the issues already identified. Harm severity allocation of incidents was found to be poor following re-classification. For example, death was being reported as the harm outcome using NRLS taxonomy when the actual harm of the incident was not death (see Table 3.3 in Chapter 3). This may be explained by reporters selecting potential harm outcome rather than actual harm outcome. Using the harm severities described by the reporter would have introduced systematic error which may have resulted in inaccurate results. This was mitigated by reclassification of the harm severities as previously described.

Some incidents were reported via a different care setting from which they occurred, which contributed to the wrong care setting being reported in incident reports. This could be due to the selection of the wrong care setting of occurrence from the list at the time of reporting because the incident is not being reported from the setting it occurred. This would make it confusing when tracking incidents to tailor improvement strategies to specific care settings. To get around this issue, care setting was amended as part of the data cleaning process.

Gender was not provided as a structured categorical variable. It was however provided inconsistently in the free-text descriptions of reports and was present in only 37% of reports. This low percentage may not provide a statistically significant result but demonstrated gender trends associated with medication incidents. This is an area which may require further research to ascertain the full effects of gender on medication safety incidents.

Following the cleaning of data, some categorical information in the database such as age, and medicines involved were poorly recorded. This information was sometimes identified in the free-text description. The age of patients was present in only 52% of the sampled reports. Knowing the age of patients is important in identifying potentially vulnerable patients of certain age to medication incidents and their harmful effects. This could be important when designing interventions for a targeted population. Some incident reports, especially those from community pharmacies, had a distinct lack of detail compared to other care settings which may indicate some difference in reporting cultures in different care settings. This lack of detail may also present a missed opportunity as previously discussed. Finally, the total number of reports excluded from the analysis may suggest sub-optimal use of the reporting system, this may be due to lack of knowledge of how best to use the system.

Under-reporting of incidents is a well-recognised issue in patient safety studies [7, 9, 11] and may have been an issue in this study as well considering the proportion of incident reports to the number of medicines used in the same time frame [20, 269], and the reported error rates described in Chapter 1. Some of the reasons or barriers to reporting include the fear of blame [270-272] and length of time it takes to fill a report form [273]. Additionally, cultural barriers such as the feeling of the inevitability of error and the purpose of reporting, rejection of bureaucracy and managerial scrutiny, and divergent occupational responsibilities and expertise also contribute to under reporting [273].

Other factors include complexity of incident, access to reporting system, delays between when the error was made and when it was identified and the responsibility to report including who and when to report [9, 270]. In this study, no reports were identified to have been submitted by a patient or their representative. As discussed in the previous section, increasing the awareness of the system and its importance to patients and their representatives as well as encouraging them to use the system may improve the number of reports from them. Regardless of the limitations from under-reporting and reporting biases, analyses of thousands of incident reports provides an opportunity to generate valuable learning and identify areas needing interventions to prevent harmful outcomes with medication use as demonstrated in this study.

There were also some limitations associated with analysis of secondary data which may have affected this study. This include the lack of availability of some information required by the researcher. There is also a lack of control over the process and type of data being collected, which may lead to inconsistencies. For example, sex of patients is not recorded in the NRLS data but was eluded to in certain instances. This compromises the scientific rigour by reducing the accuracy of the data on sex in the NRLS dataset as presented earlier on. Furthermore, any doubts on biases whilst collecting the data may not be checked as is possible for primary data.

However, secondary analysis of data can be seen as a strength of this study, as there are many known advantages, these include the potential for resource saving as compared to primary analysis.

Research using a large sample of primary data can be extremely costly and time-consuming, therefore secondary analysis provides a flexible opportunity to analyse a large sample whilst saving time and costs. Secondary analysis may also identify biases that may have occurred when the original data was being collected. Secondary data also increases the accessibility to do research with less difficulty. Using a national database for the secondary analysis of data as in this study, provides an opportunity to conduct a much more extensive analysis whilst obtaining a nationally representative sample which makes for easy comparisons. Hence, secondary analysis of an existing national data like the NRLS is very valuable in descriptive and exploratory studies whilst allowing for meaningful conclusions to be drawn from the large sample size used [128].

From the methods used in this study, the contents of the free text descriptions of reports were also analysed using codes in stage one of data analysis. This provided both strengths and limitations to the study. Some of the limitations included the time consuming nature of doing this particularly when dealing with complex texts, and an inherently reductive process which does not capture the context in which an incident occurred. The coding process was very time consuming and it took between three and twenty minutes to code a single incident depending on the complexity of the written text. A total of 5,556 incident reports were coded during this study, requiring many months to complete. An advantage of classifying free-text data using codes is that it provides an opportunity to interpret texts written by the reporter in a

systematic way, thereby allowing development of expert knowledge from the reports. It helps to provide an insight into complex models of human thoughts and language use [128].

By using the PISA classification, the texts were coded to represent what was explicitly stated in the narratives. This helped prevent confirmation bias based on the coder's clinical experience and limited the potential for reviewer subjectivity during the coding process. This helped maintain a high level of consistency and reliability in the results, which may not have been possible with other classification systems. This classification tool also allowed the steps preceding and leading to a primary incident in a report to be identified, thereby allowing the identification of contributory incidents as well as contributory factors to be considered. This was instrumental in identifying priority areas and may not have been possible to identify with other types of classification systems. For example, the NCC MERP classification system classifies medication incidents based on severity of the outcome. This classification is about the outcomes and not the causes; therefore, it is not as helpful in terms of identifying potential preventative measures.

Furthermore, harm severity was re-coded in this study based on the structured approach described and this may have presented further limitations. Despite explicit evidence being required to justify the changes, there is a risk that the precision of harm severity results were compromised. This is due to the number of incident reports that were excluded from further analysis of the harm severity variable, as well as the possibility for wrongful reclassification. Overall, this could have

decreased the precision of the sample for harm severity results. However, modern patient safety theories acknowledge that the same incidents and contributory factors can result in a no harm or near miss in one context and a catastrophic death in another.

Some data presented in the incident reports were also double-checked and cleaned according to the methods, this ensured reliability and accuracy of results, which was a strength of this study.

As described in Chapter 1, efforts are currently being made to develop a new upgraded and improved reporting system which will replace the NRLS. This new system may address some of the limitations of the current system and hopefully encourage and improve incident reporting. The new system aims to make it easier to record data from across different healthcare setting by adopting a user-centred approach, it will also collect data that is better suited to learning for improvement. The data will also be made easier to access to support improvement work locally, and provide better feedback [51].

A strength of this study is that by using national data, it provides an appropriate representation of the medication safety incidents being reported nationally incorporating the geographical variations, thereby making it possible for generalisation across the nation but as well could filter incident reports from a specific area for further analysis where needed.

In this study, bias was minimised during stage 1 of the analysis by adhering to the nine rules of the Recursive Model of Incident Analysis

described in Chapter 2 and allocating codes based on what was explicitly stated in reports. Rigour was also ensured through double-coding of 20% of reports and keeping an audit trail of coding-related decisions during discordance meetings with the second coder. This showed a high level of concordance as described in Chapter 2, representing consistent application of coding frameworks.

Being a qualified and practicing pharmacist in UK and encountering medication safety incidents regularly, provided me with the appropriate background on medication safety incidents to be able to take on this study. My clinical expertise and judgement guided my interpretation of reports at stage 3 of data analysis steered by results from the exploratory descriptive analysis (stage 2). However, my experience of being a community pharmacist may have introduced researcher bias into the study. For instance, a researcher without a background in healthcare, a GP or a community nurse may all interpret findings differently, bringing their individual experiences to the study.

5.5 Implications for practice and policy

This research has demonstrated how medication incident reports can be used to generate recommendations for improving patient safety. However, the successful implementation of any intervention may be affected by many contextual factors present in day to day practice, which may differ locally [274]. It is therefore important for stakeholders responsible for medication safety improvements to consider the local context when designing interventions.

In 2017, the WHO announced an initiative to reduce severe avoidable harm from medication-related errors in all countries by 50% over the subsequent five years [50]. It aims to address weaknesses in health systems that lead to medication errors and the harm that results from them. This research, having identified some of these weaknesses or priority areas relating to medication incidents and how they might be addressed, could inform changes in practice that support the WHO objective. For example, the data analysis methods used here could be utilised by service providers to identify priority medication safety issues in need of action within their organisation.

One of the areas identified in this research was the need for improved staff education and training. This was an issue identified during prescribing, dispensing and administration of medicines due to inadequacies in knowledge and skills being frequently reported as contributing to incidents. Stakeholders could prioritise providing an improved regular training and education of staff for continued professional development, as recommended in this study. This could be achieved through direct personalised feedback and regular discussions and sharing of learnings from previous medication safety incidents. Strong evidence for effectiveness of this intervention has been demonstrated for prescribing and administration incidents in the driver diagrams presented. Although evidence shows educational interventions to be effective in improving the safety of medication use, they may only have short-term effects [275]. Therefore, to achieve

sustained results, stakeholders implementing such interventions may need to consider continuous or regular education programmes.

The potential under-reporting of medication incidents (discussed in Section 5.4 above) suggests that healthcare professionals in primary care may benefit from educational interventions on the importance of incident reporting in promoting patient safety. Staff should also be made aware of the procedures used for reporting incidents within their practice; for example, Carson-Stevens and Donaldson's practical guide for reporting and learning from patient safety incidents in general practice [276]. Patients and their representatives should likewise be educated and encouraged to use the NRLS system available to them to report any safety incidents they are involved in, which could give a different perspective and contribute to the learning generated from incident reports. Meanwhile, policy makers could encourage the reporting of patient safety incidents by removing the fear of retribution and promoting incident reports.

The NHS recently published their plans for the healthcare system over the next 10 years [51]. Strategies include investments to improve healthcare services, with particular emphasis on those provided in primary care. Many of these involved Information Technology (IT) improvements of all types, such as those to support integration of care. This could be effective in reducing medication incidents since this research demonstrated that inefficient communication between settings could result in various types of incidents. Some IT improvements have been suggested in the driver diagrams presented in this study (Section

4.9, Chapter 4). Stakeholders could use these evidence-based suggestions to plan quality improvement projects addressing IT improvements in line with the planned NHS investments to better the healthcare system.

For example, inadequate procedures for implementing medication changes at transfer of care between care settings was another area identified to require intervention for improved medication safety in all the medication use processes described. One of the key IT intervention recommended in this study was to standardise patient's healthcare record electronically, which enables data-linkage, across all care settings. By implementing this intervention, issues relating to communication during patient care between settings could be reduced significantly, which will in turn, lead to improved patient safety during prescribing, dispensing and administration of medicines. Another IT improvement recommendation was the development of an IT system that could automatically allocate patients to staff where healthcare professionals (mostly nurses) are required to make visits in order to administer medications to patients. This would also set automatic reminders to staff to ensure visits are carried out in time by the right person. This would potentially help improve the inadequate administrative practices which were identified to be an important area requiring change in the administration of medications process.

The use of barcoding technology was suggested as an intervention to tackle medication errors as a result of similarity of medication names and appearances especially during the dispensing process. This would

aim to allow the selection of medicines using a barcode instead of the current practice. Picking or selection errors were responsible for 70.5% of dispensing incidents identified in this study; more than half of these incidents that reported contributory factors described the similarity of medication names or appearance as contributing to the incidents. This is another IT improvement that could significantly improve the safety of medication use in primary care when designed appropriately.

However, when implementing changes such as linking data or standardising electronic health records between care settings, it is important to consider the medication use processes (as previously described) in order to avoid incidents resulting from the transfer of errors between settings. Other factors to consider for successful implementation include usability, performance and integration (with existing processes), adaptability and flexibility - as described by Cresswell and Sheikh in their recommendations for successful implementation and adoption of NHS Care Record Service (NHS CRS). These include attitudes, motivations, resistance and expectations of stakeholders as well as training and support and user input in designing the quality improvement concept [277]. For example, an Australian study aimed to gather the perspectives of patients and clinicians following implementation of an intervention of an integrated electronic prescribing and dispensing system in a hospital. The majority of patients and clinicians reported a positive impact of the intervention on safety and efficiency. This allows for further implementation of intervention on other sites whilst allowing for enhancements on

system's features that have been identified to need some improvement by the stakeholders [278].

In order to reduce patient harm and the associated costs, the NHS plan identified patient safety as a priority. To further improve medication safety, the NHS requires healthcare providers to implement electronic prescribing systems to reduce errors by up to 30% over the next five years [51]. It additionally pledges to design new medication safety improvement programmes in the future. This research offers the opportunity for stakeholders to prioritise areas and garner ideas to inform these medication safety improvement programmes by using the driver diagrams presented in this research. However, complex interventions involving more than one type of intervention demonstrated a strong level of evidence for effectiveness as discussed in Chapter 4. Therefore, future improvement programmes should focus on addressing and minimising risk for future patients for the priority areas identified in this study.

Antithrombotic agents and opioid analgesics have been identified as the drug classes associated with the most death outcomes when involved in an incident. Therefore, additional safety nets should be considered in practice when dealing with these classes of medications to promote medication safety. Other commonly involved medication classes that may be targeted for safety interventions include antidepressants, antiepileptics and insulin analogues. Furthermore, Patients aged 56 years and older were shown to be involved with a higher proportion of medication incidents to result in serious (moderate,

severe and death) harm, especially during prescribing and dispensing. Therefore, patients in this age category could specifically be a priority target for intervention in the first instance before expanding to other age categories.

The recent focus on medication safety in national and international policy has positioned this research at the forefront of the healthcare agenda. Disseminating these findings as widely as possible will be valuable to healthcare professionals, policy makers and other stakeholders in understanding and improving medication safety. This could be achieved by utilisation of this research as evidence for health policy and service planning decisions by the stakeholders when planning quality improvement projects. Knowledge mobilisation, which is a process for ensuring that different forms of available evidence are considered when making important policy decisions, is important when quality improvement approaches are being implemented. The driver diagrams presented in Chapter 4 offer evidence-based and focused quality improvement project suggestions, which could be used alongside contextual issues to design, test and evaluate future intervention programmes to improve the safety of medication use in primary care that related organisations can easily learn from.

5.6 Recommendations for future research

Throughout this chapter and thesis as a whole, potential areas for future research and development have been discussed. These include the following:

There is a lack of literature looking at medication administration incidents specific to primary care, research focused in this area is needed to gain additional insights into primary care medication safety. This would benefit nurses and carers responsible for administering medications in primary care by ensuring improved safety measures are developed when administering medications.

No studies were found to explore the relationship between harm severity of medication incidents and gender. Although not statistically tested, this thesis identified a relationship between harm severity and gender but did not seek to understand or explain this relationship. Therefore, further studies are needed to explore this relationship in order to identify factors to consider, if any, in developing interventions. This could be achieved by ensuring that the gender variable is considered in the design phase of future medication safety research. Also, a gender variable should be incorporated into the minimal dataset of safety incident reporting systems. This will enable future secondary analysis of reports to also consider gender and the relationships with other variables.

There needs to be improved and effective inter-professional collaborations amongst healthcare professionals in order to improve medication patient safety. For example, a more effective form of communication between doctors and pharmacists, and pharmacist and nurses may need to be explored for improved communication when prescribing, dispensing and administration of medications to patients. This could include, for example, a centralised patient information

system accessible to all healthcare professionals which would allow them to work together to provide care for shared patients. For instance, a prescriber should be able to communicate with a pharmacist when prescribing a medication that they are not very conversant with regarding appropriateness and dosage instructions, or with a nurse regarding appropriate administration of the medication. These could be achieved through research into the design and testing of an appropriate system, and ensuring its use was mandatory. Therefore, IT interventions that have been recommended in this study such as standardising patient's healthcare record electronically across all care settings should be developed and investigated for improved effectiveness of communication between healthcare professionals. New interventions are needed to address the system (medication use processes) as a whole, as well as parts of it. This could be achieved through the development of complex interventions by combining current effective interventions looking at individual stages of the process to address all areas of the medication related processes. For example, successful interventions that address prescribing incidents only, dispensing incidents only, and administration incidents only within different healthcare settings (such as pharmacies, care homes and general practices), may be combined to form a complex intervention to address the medication use system as a whole. This could then be tried and tested for effectiveness in practice. Complex interventions have been shown to be amongst the most effective in preventing medication errors and improving medication safety.

In this study, interventions have been recommended for the different medication use process areas based on the priority areas identified, some of which did not have strong evidence of efficacy. Further research is needed to implement and evaluate the effectiveness of the recommended changes in the driver diagrams within this thesis before incorporating into a complex intervention. These include quality assurance approaches such as assessment tools and trigger reviews especially during dispensing and administration of medicines. Others include distribution of medication health cards to patients, direct personalised feedback to healthcare professionals, a standardised layout of a dispensary which includes a distraction free zone and allowing patients to access their medical records. Furthermore, investigation of contextual factors associated with incidents is needed for the successful implementation of the change ideas described.

In order to maximise the impact of the reports created within the replacement NRLS system, research is needed to develop a quicker and more automated coding process for the reports. This will enable findings to be generated regularly and disseminated to practice settings to improve patient safety.

The methods employed in this study can be utilised in future research on medication safety incidents where ideas for improvement could be identified based on the study findings both at local and national levels. Several studies within other healthcare disciplines have already used similar methods to explore patient safety incidents [161, 162].

5.7 Conclusions

This thesis aimed to describe the nature, range and severity of primary care medication safety incidents reported to the NRLS. It sought to identify areas of priority in which to improve medication safety and to make recommendations about interventions to address these issues. This is the first study to systematically analyse primary care-specific medication safety incident reports submitted to the NRLS. To achieve the thesis aim, quantitative analysis methods with some qualitative analysis principles were employed to analyse this national-level data and generate learning to inform future improvement activity.

The descriptive characteristics of these incidents, including types, frequency, location, medicines involved, contributory factors and some patient characteristics were presented in Chapter 3. Thematic analysis was conducted alongside descriptive analysis to gain contextual understanding before identifying potential priority areas or issues. These included active failures due to insufficient protocols, workforce and equipment; inadequate procedures for implementing medication changes at transfer of care between settings; need for improved staff education and training; medication similarity (look-alike and sound-alike) oversights; lack of adequate or implemented protocols; suboptimal working environment; inadequate administrative practices; and insufficient communication of medicines information to patients. Recommendations were made following the synthesis of interventions from the literature alongside insights garnered from reading the reports. Some of the recommended ideas for change included various IT

improvements such as standardising patients' electronic healthcare records across all care settings and using automation to allocate staff to a place of work. This conforms to the new NHS long term plan published in 2019 [51].

Although limitations of incident reporting system data exist, important recommendations for interventions to improve medication safety have been generated from this research. These recommendations now need further research in order to develop, implement and evaluate them in clinical practice.

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Appendices

Appendix 1 – Data variable fields in the NRLS

Category	Code name	Description
RP01	Unique ID	Numerical
RP02	Care setting	Structured
RP05	Local reference ID	Numerical
RP07	Trust organisation code	Numerical
PD01	Patient age	Numerical
PD05	Speciality	Structured
PD09	Clinical outcome/ Degree of harm	Structured
IN01	Date of incident	Date
IN03	Location	Structured
IN05	Incident category	Structured
IN06	Contributory factors	Unstructured
IN07	Free-text description of incident	Unstructured
IN10	Reoccurrence prevention	Unstructured
MD01	Medication process	Structured
MD02	Medication error category	Structured
MD05	Approved drug name	Unstructured
MD06	Proprietary drug name	Unstructured

Appendix 2 – Coding frameworks used – developed by PISA

Incident Descriptor Framework (Version 33)

0. Incorrect use of system
   - 0.1. Defensive reporting
     - 0.1.1. Patient Refusing Care
   - 0.2. Irrelevant
     - 0.2.1. No harm from primary care
   - 0.3. Insufficient detail
     - 0.3.1. No details
   - 0.4. Reporting death *Use of the reporting system to report death not related to healthcare*
     - 0.4.1. Suicide *Use of the reporting system to report patient suicides or attempted suicide*
     - 0.4.2. Suspicious death *Use of the reporting system to report suspicious deaths*
     - 0.4.3. Unexpected death *Use of the reporting system to report unexpected deaths*
     - 0.4.4. Other death *Expected death, or death not otherwise specified*
   - 0.5. Reporting 'incident' *Use of the reporting system to report incident not related to healthcare*
     - 0.5.1. Patient fall *Use of the reporting system to report patient fall*
     - 0.5.2. *Patient self—harmed*
     - 0.5.3. *Act of violence by patient or healthcare user*
   - 0.6. Pressure Ulcer
   - 0.7. Healthcare associated infection
   - 0.8. Complaint/Coroner investigation *Use of the reporting system to alert of complaint or coronial investigation*
   - 0.9. Appropriate breach of confidentiality
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*

1.4 *P*ayment *Errors in the process of healthcare payment systems*

1.5 Ability to access physician/ Healthcare professional *Patient delayed or unable to see/ speak to physician or HCP*

1.5.1 Home Visits *Physician delayed/ unable to visit patient at home*

1.5.2 Returning Phone Calls *Physician delayed/ unable to return phone call*

1.6 Transfer of Patient Information during discharge–incorrect or inefficient transfer of patient information across healthcare systems (includes all errors of communication that occur at a system-level).

1.6.1 Between care settings *Errors in communication between healthcare settings*

1.6.1.1 From primary to secondary care *Errors in communication of information 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 *Errors in communication of information 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

Errors in communication between different settings within primary care

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

2 Documentation

2.1 Medical Records *Incorrect documentation or availability of medical records*

2.1.1 Record(s) unavailable *Records could not be accessed when needed*

2.1.1.1 *Red book (personal held record)*

2.1.1.2 *GP records (the GP surgery's own records)*

2.1.1.3 *Child health records (public health department records)*

2.1.1.4 *Lost medical records*

2.1.2 Care given but not documented *Care provided was not documented*

2.1.3 Record not up to date or complete *Item(s) of information missing from records*

2.1.3.1 *Discrepancies between vaccine records*

2.1.3.1.1 *Red book not up to date (personal held record)*

2.1.3.1.2 *GP records not up to date (GP surgery's own records)*

2.1.3.1.3 *Child health records not up to date (public health department records)*

2.1.4 Inaccurate or unclear medical records / medical record error

2.1.4.1 Red book (personal held record)

2.1.4.2 GP records (GP surgery's own records)

2.1.4.3 Child health records (public health department records)

2.2 Death Certificates *Any problem arising from death certification*

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 …to secondary care *Errors in the timely referral of*

patients to secondary care

3.1.1.1.2 …to specialist care *Errors in the timely referral of patients to specialist care*

3.1.1.1.3 …to emergency care *Errors in the timely referral of patients to 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 GP

3.1.1.2 Referral not made when appropriate *Errors in the decisions of referring a patient from primary care*

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 GP

3.1.1.3 No follow up arranged *Did not follow-up patient or were not asked to follow-up*

3.1.2 Incomplete /Incorrect referral

3.1.3 Illegible referral

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*

3.2.3.1 Sent to Wrong Place *Sent to incorrect office of physician*

3.2.3.2 Lost to Follow Up *Patient referral not followed-up by office*

3.2.4 Not acted upon *Referral successful but patient not seen by physician*

3.2.4.1 Refused *Patient referral refused by receiving office or physician*

3.2.5 Inappropriate Referral *Referral made erroneously at office level*

3.2.6 Social Work Referral Issues *Error in referral to social work*

3.3 Errors in Transfer *Errors related to the process related to the moving (transfer) of patients from one location to another*

3.3.1 Patient inappropriately transferred *Patient transferred when not required, or to the wrong location*

3.3.2 Patient not transferred in a timely manner *Patient's transfer delayed or did not occur when required*

4 Diagnosis & Assessment

4.1 Diagnosis

4.1.1 Missed diagnosis

4.1.2 Wrong diagnosis

4.1.3 Delayed diagnosis

4.1.3.1 Cancer *Cancer diagnosis delayed*

4.1.3.2 Emergency condition *Diagnosis of an emergency condition delayed*

4.2 Insufficient assessment *Error in the process of assessing a patient*

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 acute clinical conditions *Errors in the process of identifying patients with acute, serious conditions*
- 4.2.5 Emergency vehicle use *Inappropriate transfer vehicle used (e.g. private vehicle instead of ambulance)*
- 4.2.6 Identifying 'at risk' patients *Errors in the process of identifying vulnerable patients or patients at high risk*
  - 4.2.6.1 Identifying Patients at risk of deterioration *Errors in the process of identifying patients at risk of deteriorating*
  - 4.2.6.2 Mental Health *Errors in the process of identifying patients at risk due to mental health problems*
  - 4.2.6.3 Failure to recognise signs of abuse
- 4.2.7 Discharge planning Includes premature discharge and poor discharge planning i.e. *Patient discharged home when not appropriate or safe to do so*

4.3 Delayed Assessment – a delay in assessment for care or care adjunct

4.4 Refusal to do home visit – *any healthcare professional that refuses to do a home visit*

5 Treatment & Procedure (excludes drugs/vaccines)

5.1 Clinical Treatment Decision *Errors in the treatment decision-making process*

- 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 other 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*

6 Medication/Vaccines (Drugs only)
6.1 Clinical Treatment Decision *Errors in the treatment decision-making process*
6.1.1 No treatment given *No treatment given when appropriate*
6.1.2 Insufficient Treatment Given *Insufficient treatment given*
6.1.3 Wrong treatment given *Wrong treatment decision* Medications *Errors in the process of treating with medications*
6.2 Prescribing medications *Wrong medication or wrong dose of medication prescribed or medication not prescribed when appropriate*
6.2.0 Wrong medication *Wrong medication prescribed*
6.2.1 Wrong patient *Medication prescribed for wrong patient*
6.2.2 Wrong dose *Incorrect dose of medication prescribed*
6.2.3 Wrong route *Incorrect route prescribed for medication*
6.2.4 Wrong time *Incorrect timing of medication prescribed*
6.2.5 Unsafe medication *Medication prescribed which is unsafe for the patient*
6.2.6 Teratogenic *Medication with adverse foetal effects prescribed to a pregnant woman*
6.2.7 Contra-indicated *Medication prescribed for patient which is contra-indicated by patient's medical or drug history*
6.2.8 Allergy *Medication prescribed for patient who is known to be allergic*
6.2.9
6.2.10 Wrong formulation
6.2.11 Wrong no of doses *Prescription issued for 2 weeks when should have supplied a month's worth of medication*
6.3 Dispensing medication orders *Error in the process of delivering a medication order or inappropriate medication order by a provider working under physician supervision*

6.3.1 Wrong medication *Incorrect medication dispensed*
6.3.2 Wrong patient *Medication dispensed to incorrect patient*
6.3.3 Wrong dose *Medication dispensed at incorrect dose*
6.3.4 Wrong route *Medication dispensed for incorrect route*
6.3.5 Wrong time *Medication dispensed at incorrect time*
6.3.6 Wrong formulation
6.3.7 Not dispensed *Medication not dispensed*
6.3.8 Allergy *Medication dispensed to a patient who is known to be allergic*
6.3.9 Out of date – *Medication dispensed out of date*
6.3.10 Wrong label
6.3.11 Wrong number of doses
6.3.12 Inappropriate medication

6.4 Administering medications *Error in the process of administering medication to a patient*
6.4.1 Wrong medication Incorrect m*edication administered*
6.4.2 Wrong patient *Medication administered to incorrect patient*
6.4.3 Wrong dose *Medication administered at incorrect dose*
6.4.4 Wrong route *Medication administered via incorrect route*
6.4.5 Wrong time *Medication administered at incorrect time*
6.4.6 Wrong formulation
6.4.7 Out of date *Medication administered out of date*
6.4.8 Allergy *Medication administered to a patient with a known allergy*

6.5 Monitoring Medication *Error in the process of monitoring dose-dependent medications, or those with side effects*
6.5.1 Lack of monitoring *Monitoring not commenced*
6.5.2 Adjusting treatment based on monitoring *Medication dose not adjusted as a result of monitoring, when appropriate*

6.6 Adverse Event *Patient suffered a complication as a result of medication*
6.6.1 Allergy *Patient suffered an 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 *Unintentional drug overdose by patient (self-administered)*

6.9 Incorrect storage *Medication incorrectly stored*
6.10 Medication Timeliness *Medication not commenced in a timely fashion*

6.11 Vaccine

6.11.1 Vaccine Prescribing

6.11.1.1Wrong vaccine
6.11.1.2Wrong patient
6.11.1.3Wrong dose
6.11.1.4Wrong route
6.11.1.5Wrong time
6.11.1.6Contraindicated
6.11.1.7Wrong formulation
6.11.1.8Wrong number of doses

6.11.2 Vaccine Dispensing
6.11.2.1Wrong vaccine
6.11.2.2Wrong patient
6.11.2.3Wrong dose
6.11.2.4Wrong route
6.11.2.5Wrong time
6.11.2.6Wrong number of doses
6.11.2.7Stored incorrectly
6.11.2.8Out of date
6.11.2.9Not dispensed
6.11.2.10 Wrong formulation
6.11.2.11 Wrong label
6.11.2.12 Contraindicated

6.11.3 Vaccine Administration
6.11.3.1Wrong vaccine
6.11.3.2Wrong patient
6.11.3.3Wrong dose
6.11.3.4Wrong route
6.11.3.5Wrong time
6.11.3.6Wrong amount (wrong no. doses)
6.11.3.7Stored Incorrectly
6.11.3.8Out of date
6.11.3.9Contraindicated 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 Vaccine timeliness (delay in receiving vaccine)

6.11.7 Batch recall

7 Investigations *Errors in the process of investigating a patient's condition*

7.1 Laboratory *Errors in the process of laboratory investigations*

7.1.1 Ordering laboratory investigations *Wrong test ordered or test not ordered when appropriate*

7.1.1.1 Failure to consider the value

7.1.2 Implementing laboratory investigations *Errors in the process of obtaining or processing a laboratory specimen*

7.1.3 Reporting laboratory investigations *Errors in the process of physician receiving accurate laboratory results including errors of delay* Responding to results *Inappropriate response to an laboratory result*

7.1.3.1 General investigations *Of routine laboratory investigations*

7.1.3.2 Dose dependent drugs *Of investigations of dose-dependent drug levels and toxicity*

7.2 Diagnostic Imaging *Errors in the process of diagnostic imaging investigations*

7.2.1 Ordering diagnostic imaging *Wrong test ordered or test not ordered when appropriate*

7.2.2 Implementing diagnostic imaging *Errors in the process of obtaining or processing of a diagnostic image*

7.2.3 Reporting diagnostic imaging *Error in the process of physician receiving accurate results of a diagnostic image including errors of delay*

7.2.4 Responding to diagnostic imaging results *Inappropriate response to an laboratory result*

7.3 Other investigations *Errors in the process of other investigations*

7.3.1 Ordering other investigations *Wrong test ordered or test not ordered when appropriate*

7.3.2 Implementing other investigations *Errors in the process of obtaining or processing of other diagnostic investigation*

7.3.3 Reporting other investigations *Error in the process of physician receiving accurate test results or other investigations including errors of delay*

7.3.4 Responding to results of other investigations *Inappropriate response to an result of other investigations*

8 Communication Failures or Breakdowns of communication. These are human failures, and do not include breakdowns in the systems that are used to communicate information, but do include the face-to-face or telephone direct transfer of information relating to patient care.

8.1 With patients *Errors in communication between physicians or healthcare professionals and patients*

8.1.1 Wrong Advice Given to Patient / Caregiver– Incorrect or Incomplete Advice Given to Patients / caregivers, 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 e.g. by receptionist

8.1.2 Failure to Convey Seriousness/Urgency of Patient Condition – Failure to communicate or emphasise the need for immediate or fast care

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 – Failure to communicate or emphasise the need for immediate or fast care

8.3 Between Healthcare and Non-Healthcare Professionals *Errors in communication between healthcare professionals and other professionals*

9 Equipment

9.1 Therapeutic Adjunct Provision Therapeutic *adjunct not prescribed, dispensed or administered.*

9.1.1 Not prescribed or ordered

9.1.2 Not dispensed

9.1.3 Not utilized

9.1.4 Delay in dispensing

9.2 Insufficient supply

9.3 Failure of equipment (Taken from Contributory Factors)

9.3.1 Damaged

9.3.2 Faulty

9.3.3 Misused

10 Other

10.1 Professionalism *Errors in the professional conduct of healthcare professionals*

10.1.1 Breach of Confidentiality *Errors of confidentiality arising from the professional conduct of healthcare professionals*

10.1.2 Documentation. *Falsifying documentation*

10.1.3 Failure to Respect Patient's / caregiver Wishes – Including Advanced Decisions

10.2 Environmental Hazard

10.3 Errors in Transport *Logistics of transport (e.g. ambulance delayed after 2 hours window]*

10.3.1 *Emergency transport Errors associated with the attendance of an emergency vehicle in an emergency situation*

Contributory Factors Framework (Version17)

1. Patient 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 – *difficulties accessing healthcare or services because of geography*
   - 1.2. Language – *patient unable to communicate in English*
   - 1.3. Behaviour –*the way in which patients act or conduct themselves*
     - 1.3.1. Non-compliance – *patient does not follow advice or instructions*
       - 1.3.1.1. Takes own discharge – *patient discharges themselves against medical advice*
       - *1.3.1.2.* Medication – *patient does not take medication as instructed or advised*
       - 1.3.1.3. Non-disclosure
       - 1.3.1.4. Violent
   - 1.4. Pathophysiological – *factors related to the patient's physical and medical well-being and health*
     - 1.4.1. Frailty – *reduced physiological reserve, fragile*
     - 1.4.2. Disability- *a physical or mental condition that limits a person's movements, senses, or activities.*
     - 1.4.3. Allergy
     - 1.4.4 Immuno-compromised
     - 1.4.5 Coagulation problems
     - 1.4.6 Pregnant
   - 1.5. Knowledge- *patient or parent of child has poor understanding*
   - 1.6. Looked after child– *child is in foster care*

2. Staff factors
   - 2.1. Physical and mental wellbeing
     - 2.1.1. Fatigue - *extreme tiredness resulting from mental or physical exertion or illness*
   - 2.2. Task-*a piece of work to be done or undertaken.*
     - 2.2.1. Failure to follow protocol - *failure to adhere to procedures or regulation.*
       - *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
2.3.2. 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
3.1. Poor equipment design – *the design of equipment is impractical, faulty or in some way inadequate*
3.2. Medication storage
3.2.1 Medication packaging

4. Organisation
4.1. Protocols/Policies/Standards/Guidelines – *inadequate, inefficient absent or not available*
4.1.1. Infection Control Protocol – *Policies for preventing the incidence and spread of infection within a healthcare environment*
4.1.2. High-Risk or Acutely Unwell Patients
4.1.3. Mental Health protocol
4.1.4. Vulnerable Patients / Patients at risk of Abuse
4.1.5. Chronic Conditions
4.1.6. Medications
4.1.6.1. New protocol
4.1.6.2. Dose-Dependent
4.1.7. Investigations
4.1.8. Referrals
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 – *staff have not been made aware of a patient by colleagues*
4.3.2. Within Primary Care – *e.g. when a patient is seen by multiple GPs within the same practice and there is therefore a resulting failure to recognise a pattern or increasing severity of patient symptoms*
4.3.2.1. Out of Hours Service
4.3.2.2. Registering with a GP
4.3.3. Between Secondary and Primary Care
4.3.4. Access block – *can't move a patient on because there's no space to put them*
4.4. Working conditions
4.4.1. Staffing levels– *provision of healthcare staff*
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 -*the ideas and, customs of staff in a the working environment and team*
4.4.2.2. Inadequate Leadership
4.4.2.3. Disagreement amongst teams
4.4.2.4. Staff behaviour
4.4.3. Busy/overloaded by work

4.5. Education & Training
4.5.1. Supervision
4.5.2. Knowledge of others roles

4.6. Service unavailable
4.7. Long wait for service – *for example long waiting list or long wait in A&E or delay in accessing crisis teams*
4.7.1. Routine
4.7.2. Urgent
4.7.3. Cancer
4.7.4. Emergency

Incident Outcomes Framework (Version 11)

0. No outcome
   0.1No patient
   0.2No outcome described
   0.3Incident occurred but no outcome
   1.1.1.1. Patient clinical harm Pathophysiological/disease-related Pain
   1.1.2. Swelling
   1.1.3. Rash
   1.1.4. Nausea
   1.1.5. Redness
   1.1.6. Bruising
   1.1.7. Discomfort/pain
   1.1.8. Dizziness
   1.1.9. Fainting/ LOC
   1.1.10. Bleeding
   1.1.11. Vasovagal
   1.1.12. Changes in physiological parameters
   1.1.13. General deterioration/progression of condition
   1.1.14. Pressure Ulcer
      1.1.14.1 Pressure ulcer developed
         1.1.14.1.1 Sacrum
         1.1.14.1.2 Heel
         1.1.14.1.3 Other location
      1.1.14.2 Pressure ulcer deteriorated
         1.1.14.2.1 Sacrum
         1.1.14.2.2 Heel
         1.1.14.2.3 Other location
   1.1.15. Other wound/ulcer
      1.1.15.1 Arterial ulcer *(Arterial leg ulcer, arterial ulcer- non leg)*
      1.1.15.2 Diabetic ulcer *(Diabetic ulcer, diabetic foot ulcer, diabetic foot wound or diabetic wound)*
      1.1.15.3 Foot/ Heel ulcer (Nonspecific feet wound or Foot wound, Heel ulcer or Heel wound)
      1.1.15.4 Ischaemic ulcer *(Ischaemic wound or ischaemic ulcer)*
      1.1.15.5 Mixed ulcer *(Arterio-venous leg ulcer, arterio-venous ulcer or arterio-venous wound)*
      1.1,15,6 Chronic wound (Non-specific ulcer, skin ulcer or skin wound)
      1.1.15.7 Varicose ulcer (Varicose ulcer, varicose wound or varicosis)
      1.1.15.8 Venous ulcer *(Venous leg ulcer, venous ulcer-non leg)*

1.1.16 Fits/ Seizure

1.1.17 Infection

1.1.18 Thrombosis

1.1.19 Falls

1.1.20 Anaphylaxis

1.1.21 Amputation

1.2. Injury
  1.2.1. Laceration
  1.2.2. Perforation
  1.2.3. Fracture
  1.2.4. Skin tear
  1.2.5. Pain
  1.2.6. Swelling
  1.2.7. Redness
  1.2.8. Bruising
  1.2.9. Discomfort
  1.2.10. Dizziness
  1.2.11. Bleeding
  1.2.12. Needle stick
1.3. Psychological / emotional distress
1.4. Death
1.5. Cardio-respiratory arrest

2. Inconvenience to patient (non-clinical)
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 health care providers
2.6. Unnecessary treatment
2.7. Increased length of stay -*Patient's length of admission extended*
2.8. Hospital admission/ ED attendance-*Patient required to attend an ED or be admitted to hospital*

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

Appendix 3 – Nine rules for applying the Recursive model of incident analysis

Rule	Example
1. An incident has a set of contributing factors.	The wrong vaccine was administered (Incident) because the child's 'red book' was not available (CF) and the computer records were not up to date (CF).
2. An incident can be a contributing factor to another incident.	Records not up to date (Incident and CF), the wrong vaccine was administered (Incident).
3. Some contributing factors cannot be incidents in their own right.	A mistake (CF not an incident) led to the wrong prescribed medication dose (Incident).
4. An incident has a set of outcomes.	Wrong vaccine administered (Incident) requiring the correct vaccine to be administered (Outcome).
5. An incident can be an outcome of another incident.	Records not up to date (Incident) leading to the wrong number of vaccine doses (Incident and Outcome).
6. Some outcomes cannot be incidents in their own right.	Admission to hospital (Outcome) after wrong prescribed medication (Incident).
7. An outcome of an incident could be a contributing factor to another incident.	Communication error between health care professionals (Incident) led to records not being up to date (Incident and Outcome) which led to a vaccine-related error (Incident).
8. An incident type can be designated the 'Principal Incident Type' that is the incident proximal to the descriptive patient outcome.	Communication error (Incident) led to inaccurate records (Incident) and results in the incorrect vaccine administration (Principal Incident Type).
9. The outcome of a Principal Incident Type cannot be an incident.	Admission to hospital (Outcome) after failure to access relevant health care professional (Principal Incident Type).

Appendix 4 – Ethical review documentation

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Aneurin Bevan University Health Board

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Research and Development Department – Research Risk Review Committee

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Dr Andrew Carson-Stevens
Institute of Primary Care & Public Health
Cardiff University School of Medicine
Neuadd Meirionnydd
Heath Park
Cardiff CF14 4YS

26th November 2013

Dear Dr Carson-Stevens,

Title: Characterising the nature of primary care patient safety incident reports in England and Wales: mixed methods study.

Chief Investigator: Dr Andrew Carson-Stevens
Principle Investigator: Professor Adrian Edwards
ABHB R&D Reference Number: SA/410/13

The Chairman considered your project on the 26th November 2013.

The Chairman agreed that your study did not appear to pose any risk to the Health Board & agreed that your study be given a favourable opinion.

The Chairman also agreed that the study does not require approval by the Research Ethics Committee.

If you require any further assistance please do not hesitate to contact the Research and Development Office.

Yours sincerely

Mrs Jeanette Wells
Research and Development Manager
Research Risk Review Committee

Bwrdd Iechyd Aneurin Bevan yw enw gweithredol Bwrdd Iechyd Lleol Aneurin Bevan
Aneurin Bevan Health Board is the operational name of Aneurin Bevan Local Health Board

Appendix 5 – Other types of incidents and harm severity allocation (n = 190)

Incident types	Re-coded harm severity						Total (%)
	No	Low	Moderate	Severe	Death	Unclear	
Medication timeliness – not commenced in a timely fashion	4	30	11	3	2	21	**71 (37.4)**
Lost medication	6	3	0	0	0	13	**22 (11.6)**
lost by healthcare professional	4	1	0	0	0	1	6
lost by patient	0	0	0	0	0	3	3
not specified	2	2	0	0	0	9	13
Prescription handling – e.g. lost or accidental shredding	6	2	0	0	0	13	**21 (11.1)**
Inappropriate medication supply - e.g. illegal supply	15	0	0	0	0	4	**19 (10.0)**
Incorrect storage - Medication incorrectly stored	7	1	0	0	0	7	**15 (7.9)**
Medication unavailable	2	2	0	0	0	5	**9 (4.7)**
Unsuitable medication taken by patient	0	0	1	0	0	2	**3 (1.6)**
Vaccines incorrectly stored	3	0	0	0	0	0	**3 (1.6)**
Error during OTC supply	0	0	0	0	0	1	**1 (0.5)**
Medication/vaccine incidents otherwise not specified	2	8	8	0	0	8	**26 (13.7)**
Total	**45**	**46**	**20**	**3**	**2**	**74**	**190(100.0)**

Appendix 6 – List of all reported contributory factors with parent-child hierarchical codes used from the contributory factors coding framework and harm severity allocation (n = 6688)

Contributory factors	Re-coded harm severity						Total (%)
	No	Low	Moderate	Severe	Death	Unclear	
1. Patient factors	**55**	**245**	**208**	**17**	**37**	**185**	**748 (11.1)**
1.1. Geography: the area where patients live including its characteristics	2	3	1	0	2	3	11 (0.2)
1.1.1. Out of area: patient new to area	1	2	1	1	0	6	11 (0.2)
1.1.2. Access difficulties: difficulties accessing healthcare or services because of geography	0	1	0	0	0	1	2 (0.0)
1.1.3. Holiday - Patient recently on holiday abroad	0	0	1	0	0	0	1 (0.0)
1.2. Language: patient unable to communicate in English	0	5	1	0	0	2	8 (0.1)
1.3. Behaviour: the way in which patients/family act or conduct themselves	1	2	2	0	0	6	11 (0.2)
1.3.1. Non-compliance: patient does not follow advice or instructions	2	0	3	0	0	4	9 (0.1)
1.3.1.1. Takes own discharge: patient discharges themselves against medical advice	0	1	0	0	0	0	1 (0.0)
1.3.1.2. Medication: patient does not take medication as instructed or advised	1	6	4	0	1	4	16 (0.2)
1.3.1.3. Non-disclosure	0	1	2	0	0	4	7 (0.1)
1.3.1.4. Violent	0	0	0	0	0	4	4 (0.1)
1.3.2 Fraudulent behaviour	5	3	0	0	0	4	12 (0.2)
1.4. Pathophysiological: factors related to the	1	10	6	1	0	6	24 (0.4)

patient's physical and medical well-being and health							
1.4.1. Frailty Reduced physiological reserve, fragile	0	6	15	0	9	1	31 (0.5)
1.4.2. Disability: a physical or mental condition that limits a person's movements, senses, or activities.	2	2	6	0	1	6	17 (0.3)
1.4.3. Allergy	1	45	37	1	6	5	95 (1.4)
1.4.6 Pregnant	0	7	0	0	0	5	12 (0.2)
1.4.8 child	0	2	2	0	0	2	6 (0.1)
1.4.9 Concomitant use of other medication	3	17	24	3	6	3	56 (0.8)
1.4.10 Family history	0	0	1	0	0	0	1 (0.0)
1.4.11 Smoker	0	0	1	0	0	0	1 (0.0)
1.4.12 Palliative care patient	3	25	8	1	0	17	54 (0.8)
1.4.13 Unable to self-administer medication	1	2	0	0	0	2	5 (0.1)
1.4.14 Drug interaction	1	11	15	1	1	3	32 (0.5)
1.4.15 Renal function	0	2	0	1	1	0	4 (0.1)
1.4.16 Previous health/ medication history	7	23	23	6	3	18	80 (1.2)
1.5. Knowledge: patient or parent of child has poor understanding	8	43	32	1	2	44	130 (1.9)
1.5.1 False information	0	0	1	0	0	0	1 (0.0)
1.7 Nursing home patient	2	3	7	0	0	10	22 (0.3)
1.8 Patient Age	7	11	13	1	5	7	44 (0.7)
Appendix PC medication: Drug abuse patient	4	3	1	0	0	8	16 (0.2)
Appendix unwell children-1.7 child	0	1	1	0	0	1	3 (0.0)

Appendix OOH Project - 1.4.8 - Terminally ill patient / requiring palliative care	0	6	0	0	0	1	7 (0.1)
Appendix PC medication: Co-morbidities	0	0	0	0	1	0	1 (0.0)
Other patient factors	3	2	0	0	0	8	13 (0.2)
2. Staff factors	**515**	**785**	**386**	**30**	**15**	**1608**	**3338 (50.0)**
2.1. Physical and mental wellbeing	2	0	2	0	0	0	4 (0.1)
2.1.1. Fatigue - extreme tiredness resulting from mental or physical exertion or illness	2	0	1	0	0	3	6 (0.1)
2.2. Task-a piece of work to be done or undertaken.	5	24	6	2	0	29	66 (1.0)
2.2.1. Failure to follow protocol - failure to adhere to procedures or regulation.	65	122	67	3	2	235	494 (7.4)
2.2.1.2 No Patient Information Leaflet (PIL) supplied	1	2	3	0	0	1	7 (0.1)
2.2.2. Inadequate skill set/ knowledge	56	76	39	6	5	97	279 (4.2)
2.2.2.1 Wrong professional carries out task. E.g. Admin clerk filling out prescriptions.	8	3	1	0	0	11	23 (0.3)
2.3. Cognitive: includes abilities such as perception, learning, memory, language, concept formation, problem solving, and thinking.	0	0	0	0	0	1	1 (0.0)
2.3.1. Mistakes, slips & lapses	42	63	48	4	1	73	231 (3.5)
2.3.1.1. Distraction/ Inattention/ Oversight/ Forgot -	69	124	44	4	1	211	453 (6.8)
2.3.1.2. Similar medication names / appearances confused	95	199	70	5	1	494	864 (12.9)

2.3.1.3. Similar patient names	13	4	1	0	0	23	41 (0.6)
2.3.1.4. Haste/ Poor time management	11	6	13	1	0	31	62 (0.9)
2.3.1.5. Misread/ Did not read	17	12	10	0	2	56	97 (1.4)
2.3.1.6 Multi-compliance compartment aids errors	39	47	46	2	0	103	237 (3.5)
2.3.2. Violation: Deliberate breaking of a rule	0	0	0	0	0	1	1 (0.0)
2.3.3. Stress: Mental or emotional strain	0	2	0	0	0	3	5 (0.1)
2.3.4. No or Poor supervision or assistance of staff	0	7	4	1	0	11	23 (0.3)
2.3.5 Staff language barrier	0	1	0	0	0	0	1 (0.0)
2.3.6 Hand writing	10	8	6	0	1	22	47 (0.7)
Appendix PC medication: Dispensing medication from label	7	12	2	0	0	23	44 (0.7)
Appendix PC medication: Dispensing medication from Patient Medication Record	16	8	3	0	0	28	55 (0.8)
Appendix PC medication: Medication delivery	26	20	11	2	1	45	105 (1.6)
Appendix PC medication: No double check	30	42	8	0	0	104	184 (2.7)
Appendix unwell children-4.4.4 interruptions	1	1	0	0	0	2	4 (0.1)
Other staff factors	0	2	1	0	0	1	4 (0.1)
3. Equipment	**96**	**162**	**59**	**7**	**2**	**382**	**708 (10.6)**
3.1. Poor equipment design: The design of equipment is impractical, faulty or in some way inadequate	6	12	6	1	0	9	34 (0.5)
3.2. Medication storage	49	95	28	3	1	294	470 (7.0)
3.2.1 Medication packaging	21	28	9	0	0	42	100 (1.5)

3.3 Equipment maintenance	1	0	0	0	0	0	1 (0.0)
3.4 Manufacturing problem	2	7	3	1	0	5	18 (0.3)
3.5 Lack of stock	10	11	4	1	0	20	46 (0.7)
3.5.1 Ordered but not received from wholesalers	1	2	0	0	0	4	7 (0.1)
Other equipment factors	6	7	9	1	1	8	32 (0.5)
4. Organisation	**235**	**418**	**204**	**14**	**16**	**871**	**1758 (26.3)**
4.1. Protocols/ Policies/ Standards/ Guidelines inadequate, inefficient absent or not available	44	72	44	5	6	206	377 (5.6)
4.1.1. Infection Control Protocol: Policies for preventing the incidence and spread of infection within a healthcare environment	1	0	0	0	0	0	1 (0.0)
4.1.2. High-Risk or Acutely Unwell Patients	0	1	4	0	1	0	6 (0.1)
4.1.2.1 Acutely deteriorating patient	0	4	0	0	0	0	4 (0.1)
4.1.3. Mental Health protocol	0	1	1	0	0	0	2 (0.0)
4.1.4. Vulnerable Patients / Patients at risk of Abuse	0	1	0	0	0	3	4 (0.1)
4.1.5. Chronic Conditions	0	0	1	0	0	0	1 (0.0)
4.1.6. Medications	2	12	10	1	0	10	35 (0.5)
4.1.6.1. New protocol	1	0	0	0	0	3	4 (0.1)
4.1.6.2. Dose-Dependent	0	0	1	0	1	0	2 (0.0)
4.1.6.3 repeat prescribing	8	13	10	0	1	20	52 (0.8)
4.1.7. Investigations	0	2	0	0	0	0	2 (0.0)
4.2. Interpreter services: Communication aids to reduce language barriers	0	1	0	0	0	0	1 (0.0)
4.3. Continuity of care - the delivery of a 'seamless service' through integration, coordination	2	2	2	0	1	5	12 (0.2)

and the sharing of information between different providers							
4.3.2. Within Primary Care e.g. when a patient is seen by multiple GPs within the same practice and there is therefore a resulting failure to recognise a pattern or increasing severity of patient symptoms	17	30	13	0	1	52	113 (1.7)
4.3.2.1. Out of Hours Service	1	6	2	0	1	2	12 (0.2)
4.3.2.2. Registering with a GP	0	0	0	0	0	1	1 (0.0)
4.3.3. Between Secondary and Primary Care	13	29	20	3	0	42	107 (1.6)
4.3.5 Locum/ agency staff	16	26	15	0	0	56	113 (1.7)
4.4. Working conditions	0	4	1	0	0	6	11 (0.2)
4.4.1. Staffing levels: Provision of healthcare staff	0	1	2	0	0	3	6 (0.1)
4.4.1.1. Shift pattern	0	4	1	0	0	1	6 (0.1)
4.4.1.2. Insufficient numbers of staff	20	26	5	2	0	68	121 (1.8)
4.4.1.2.1. Doctors	0	1	0	0	0	0	1 (0.0)
4.4.1.3. Sickness	2	2	1	0	0	12	17 (0.3)
4.4.2.1. Culture -the ideas and, customs of staff in a the working environment and team	0	0	0	0	0	1	1 (0.0)
4.4.2.3. Disagreement amongst teams	1	0	0	0	0	1	2 (0.0)
4.4.2.4. Staff behaviour	4	1	0	0	0	2	7 (0.1)
4.4.3. Busy/ overloaded by work	75	129	31	3	2	284	524 (7.8)
4.5. Education & Training	7	17	11	0	2	29	66 (1.0)
4.5.2. Knowledge of others roles	0	1	1	0	0	1	3 (0.0)
4.6 Service Unavailable	0	0	1	0	0	0	1 (0.0)

4.7 Long wait for service - for example long waiting list or long wait in A&E or delay in accessing crisis teams	0	0	1	0	0	1	2 (0.0)
4.7.4 Emergency	2	2	1	0	0	7	12 (0.2)
Appendix PC medication: Owed medication	4	12	2	0	0	13	31 (0.5)
Appendix PC medication: Transposed labels	4	5	3	0	0	8	20 (0.3)
Appendix PC medication: Specials order	2	1	5	0	0	3	11 (0.2)
Appendix PC medication: Medication not ordered	2	3	2	0	0	3	10 (0.1)
Appendix PC medication: medication order by pharmacy	1	2	4	0	0	9	16 (0.2)
Other organisational factors	6	7	9	0	0	19	41 (0.6)
5. Other factors	**16**	**52**	**15**	**2**	**2**	**49**	**136 (2.0)**
Appendix OOH Project - 1.4.9 - Patient requires syringe driver	3	33	6	1	1	20	64 (1.0)
Appendix contraceptive – use of generic drug name	7	9	1	0	0	19	36 (0.5)
Appendix PC medication: Off license use of medication	3	3	0	1	0	1	8 (0.1)
Appendix unwell children- 2.3.1.6 chose wrong patient's sticky label	1	3	0	0	0	4	8 (0.1)
Appendix PC medication: Old duplicate prescription	0	1	1	0	0	2	4 (0.1)
Appendix PC medication: Lack of support	1	0	3	0	0	0	4 (0.1)
Appendix PC medication: Morphine conversion calculation error	0	2	1	0	0	1	4 (0.1)
Appendix PC medication: Long term treatment	0	0	1	0	1	0	2 (0.0)
Appendix PC medication: Rare use of drug/strength	0	1	0	0	0	1	2 (0.0)

Appendix unwell children-4.1.13 mental health care plan	1	0	1	0	0	0	2 (0.0)
Appendix unwell children-3.1.1 CPOE (order entry)	0	0	1	0	0	0	1 (0.0)
Appendix unwell children 4.1.11 school care plan	0	0	0	0	0	1	1 (0.0)
Total	**917**	**1662**	**872**	**70**	**72**	**3095**	**6688 (100.0)**

Appendix 7 – ATC level 1 (anatomical) and 2 (therapeutic) medicine classes described in all analysed reports

ATC Level 1	ATC Level 2		Total
Alimentary tract and metabolism	Stomatological preparations	5	942
	Drugs for acid related disorders	165	
	Drugs for functional gastrointestinal disorders	69	
	Antiemetics and antinauseants	1	
	Bile and liver therapy	1	
	Laxatives	42	
	Antidiarrheals, intestinal antiinflammatory/antiinfective agents	29	
	Antiobesity preparations, excluding diet products	1	
	Drugs used in diabetes	561	
	Vitamins	16	
	Mineral supplements	52	
Blood and blood forming organs	Antithrombotic agents	329	404
	Antihemorrhagics	5	
	Antianemic preparations	62	
	Plasma substitutes and perfusion solutions	8	
Cardiovascular system	Cardiac therapy	156	1412
	Antihypertensives	42	
	Diuretics	211	
	Peripheral vasodilators	1	
	Vasoprotectives	3	
	Beta blocking agents	244	
	Calcium channel blockers	254	
	Agents acting on the renin angiotensin system	295	
	Lipid modifying agents	206	
Dermatologicals	Antifungals for dermatological use	21	97

	Emollients and protectives	6	
	Antipruritics, including antihistamines, anaesthetics, etc.	2	
	Antipsoriatics	8	
	Antibiotics and chemotherapeutics for dermatological use	13	
	Corticosteroids, dermatological preparations	25	
	Antiseptics and disinfectants	3	
	Medicated dressings	4	
	Anti - acne preparations	14	
	Other dermatological preparations	1	
Genito urinary system and sex hormones	Gynecological antiinfectives and antiseptics	9	215
	Other gynecologicals	4	
	Sex hormones and modulators of the genital system	126	
	Urologicals	76	
Systemic hormonal prep, excluding sex hormones	Pituitary and hypothalamic hormones	9	241
	Corticosteroids for systemic use	105	
	Thyroid therapy	127	
General antiinfectives for systemic use	Antibacterials for systemic use	325	578
	Antimycotics for systemic use	7	
	Antimycobacterials	5	
	Antivirals for systemic use	16	
	Immune sera and immunoglobulins	7	
	Vaccines	218	
Antineoplastic and immunomodulating agents	Antineoplastic agents	21	129
	Endocrine therapy	24	

	Immunomodulating agents	17	
	Immunosuppressive agents	67	
Musculo-skeletal system	Antiinflammatory and antirheumatic products	129	228
	Topical products for joint and muscluar pain	19	
	Muscle relaxants	13	
	Antigout preparations	41	
	Drugs for treatment of bone diseases	26	
Nervous system	Anesthetics	21	2387
	Analgesics	592	
	Antiepileptics	398	
	Anti - parkinson drugs	133	
	Psycholeptics	482	
	Psychoanaleptics	544	
	Other nervous system drugs	217	
Antiparasitic products	Antiprotozoals	25	26
	Anthelmintics	1	
Respiratory system	Nasal preparations	15	289
	Anti-asthmatics	204	
	Cough and cold preparations	34	
	Antihistamines for systemic use	36	
Sensory organs	Ophthalmologicals	197	221
	Otologicals	21	
	Ophthalmological and otological preparations	3	
Various	All other therapeutic products	21	71

	Diagnostic agents 17 General nutrients 33	
Total		**7240**

Appendix 8 – ATC level 1 (anatomical) and 3 (pharmacological) medicine classes described in all analysed reports

ATC Level 1	ATC Level 3		Total
Alimentary tract and metabolism	Stomatological preparations	5	942
	Antacids	7	
	Drugs for treatment of peptic ulcer	158	
	Drugs for functional bowel disorders	11	
	Belladonna and derivatives, plain	18	
	Antipasmodics in combination with analgesics	2	
	Propulsives	38	
	Antiemetics and antinauseants	1	
	Bile therapy	1	
	Laxatives	42	
	Intestinal antiinfectives	5	
	Antipropulsives	10	
	Intestinal antiinflammatory agents	14	
	Antiobesity preparations, excluding diet products	1	
	Insulins and analogues	373	
	Blood glucose lowering drugs, excluding insulins	188	
	Vitamin A and D, including combinations of the two	12	
	Vitamin B1, plain and in combination with vitamin B6 and B12	1	
	Vitamin B-complex, including combinations	1	
	Other plain vitamin preparations	2	
	Calcium	31	
	Potassium	10	
	Other mineral supplements	11	
Blood and blood forming organs	Antithrombotic agents	329	404
	Antifibrinolytics	4	
	Vitamin K and other hemostatics	1	
	Iron preparations	21	
	Vitamin B12 and folic acid	26	

	Other antianemic preparations	15	
	Irrigating solutions	2	
	I.V. solution additives	6	
Cardiovascular system	Cardiac glycosides	51	1412
	Antiarrhythmics, class I and III	37	
	Cardiac stimulants excl. Cardiac glycosides	5	
	Vasodilators used in cardiac disease	62	
	Other cardiac preparations	1	
	Antiadrenergic agents, centrally acting	7	
	Antiadrenergic agents, peripherally acting	21	
	Arteriolar smooth muscle, agents acting on	14	
	Low-ceiling diuretics, thiazides	54	
	Low-ceiling diuretics, excluding diuretics	21	
	High-ceiling diuretics	86	
	Potassium-sparing agents	42	
	Diuretics and potassium-sparing agents in combination	8	
	Peripheral vasodilators	1	
	Agents for treatment of haemorrhoids and anal fissures for topical use	3	
	Beta blocking agents, plain	242	
	Beta blocking agents and other diuretics	2	
	Selective calcium channel blockers with mainly vascular effects	195	
	Selective calcium channel blockers with direct cardiac effects	59	
	ACE inhibitors, plain	168	
	ACE inhibitors, combinations	3	
	Angiotensin II antagonists, plain	107	
	Angiotensin II antagonists, combinations	17	
	Lipid modifying agents, plain	204	
	Lipid modifying agents, combinations	2	
Dermatologicals	Antifungals for topical use	9	97
	Antifungals for systemic use	12	
	Emollients and protectives	6	

	Antipruritics, including antihistamines, anaesthetics, etc.	2	
	Antipsoriatics for topical use	7	
	Antipsoriatics for systemic use	1	
	Antibiotics for topical use	5	
	Chemotherapeutics for topical use	8	
	Corticosteroids, plain	22	
	Corticosteroids, combinations with antibiotics	2	
	Corticosteroids, other combinations	1	
	Antiseptics and disinfectants	3	
	Medicated dressings	4	
	Anti-acne prepartions for topical use	13	
	Anti-acne preparations for systemic use	1	
	Other dermatological preparations	1	
Genito urinary system and sex hormones	Antiinfectives and antiseptics excluding combination with corticosteroids	9	215
	Contraceptives for topical use	3	
	Other gynecologicals	1	
	Hormonal contraceptives for systemic use	43	
	Androgens	3	
	Estrogens	43	
	Progestogens	14	
	Progestogens and estrogens in combination	17	
	Gonadotropins and other ovulation stimulants	5	
	Antiandrogens	1	
	Other urologicals, including antispasmodics	36	
	Drugs used in benign prostatic hypertrophy	40	
Systemic hormonal prep, excluding sex hormones	Anterior pituitary lobe hormones	3	241
	Posterior pituitary lobe hormones	4	
	Hypothalamic hormones	2	
	Corticosteroids for systemic use, plain	102	
	Corticosteroids for systemic use, combinations	3	
	Thyroid preparations	117	
	Antithyroid preparations	10	

General antiinfectives for systemic use	Tetracyclines	19	578
	Beta-lactam antibacterials, penicillins	144	
	Other beta- beta lactam antibacterials	23	
	Sulfonamides and trimethoprim	40	
	Macrolides and lincosamides	66	
	Quinolone antibacterials	15	
	Other antibacterials	18	
	Antimycotics for systemic use	7	
	Drugs for treatment of tuberculosis	5	
	Agents affecting the virus directly	16	
	Immunoglobulins	7	
	Bacterial vaccines	72	
	Viral vaccines	103	
	Bacterial and viral vaccines, combined	43	
Antineoplastic and immunomodulating agents	Alkylating agents	2	129
	Antimetabolites	8	
	Cytotoxic antibiotics	3	
	Other antineoplastic agents	8	
	Hormones and related agents	12	
	Hormone antagonists and related agents	12	
	Immunostimulating agents	17	
	Immunosuppressive agents	67	
Musculo-skeletal system	Antiinflammatory and antirheumatic products, non-steroids	127	228
	Specific antirheumatic agents	2	
	Topical products for joint and muscluar pain	19	
	Muscle relaxants, centrally acting agents	11	
	Muscle relaxants, directly acting agents	2	
	Antigout preparations	41	
	Drugs affecting bone structure and mineralization	26	
Nervous system	Anesthetics, general	2	2387
	Anesthetics, local	19	
	Opioids	429	
	Other analgesics and antipyretics	120	

	Antimigraine preparations	43	
	Antiepileptics	398	
	Anticholinergic agents	39	
	Dopaminergic agents	94	
	Antipsychotics	278	
	Anxiolytics	95	
	Hypnotics and sedatives	109	
	Antidepressants	477	
	Psychostimulants	33	
	Anti-dementia drugs	34	
	Parasympathomimetics	1	
	Drugs used in addictive disorders	207	
	Antivertigo preparations	9	
Antiparasitic products	Agents against amoebiasis and other protozoal diseases	5	26
	Antimalarials	20	
	Antinematodal agents	1	
Respiratory system	Nasal decongestants for topical use	13	289
	Nasal decongestants for systemic use	2	
	Adrenergics, inhalants	51	
	Other drugs for obstructive airway diseases, inhalants	126	
	Adrenergics for systemic use	5	
	Other systemic drugs for obstructive airway diseases	22	
	Expectorants, excluding combinations with antitussives	6	
	Antitussives, excluding combinations with expectorants	28	
	Antihistamines for systemic use	36	
Sensory organs	Antiinfectives	49	221
	Antiinflammatory agents	10	
	Antiinflammatory agents and antiinfectives in combination	6	
	Antiglaucoma preparations and miotics	113	
	Mydriatics and cycloplegics	7	

	Decongestants and antiallergics	1	
	Local anesthetics	1	
	Surgical aids	1	
	Other ophthalmologicals	28	
	Corticosteroids and antiinfectives in combination	1	
	Other otologicals	2	
	Corticosteroids	1	
	Corticosteroids and antiinfectives in combination	1	
Various	All other therapeutic products	21	71
	Other diagnostic agents	17	
	Protein supplements	2	
	Infant formulas	15	
	Other nutrients	16	
Total			**7240**

Appendix 9 – ATC level 1 (anatomical) and 2 (therapeutic) medicine classes described in prescribing and monitoring reports

ATC Level 1	ATC Level 2		Total
Alimentary tract and metabolism	Stomatological preparations	1	49
	Drugs for acid related disorders	3	
	Drugs for functional gastrointestinal disorders	5	
	Antidiarrheals, intestinal antiinflammatory/antiinfective agents	5	
	Antiobesity preparations, excluding diet products	1	
	Drugs used in diabetes	31	
	Vitamins	2	
	Mineral supplements	1	
Blood and blood forming organs	Antithrombotic agents	63	72
	Antihemorrhagics	2	
	Antianemic preparations	7	
Cardiovascular system	Cardiac therapy	11	79
	Antihypertensives	2	
	Diuretics	27	
	Beta blocking agents	10	
	Calcium channel blockers	9	
	Agents acting on the renin angiotensin system	11	
	Lipid modifying agents	9	
Dermatologicals	Antifungals for dermatological use	1	9
	Antipsoriatics	1	
	Antibiotics and chemotherapeutics for dermatological use	2	
	Corticosteroids, dermatological preparations	4	
	Anti - acne preparations	1	

Genito urinary system and sex hormones	Sex hormones and modulators of the genital system	15	20
	Urologicals	5	
Systemic hormonal prep, excluding sex hormones	Pituitary and hypothalamic hormones	3	16
	Corticosteroids for systemic use	9	
	Thyroid therapy	4	
General antiinfectives for systemic use	Antibacterials for systemic use	56	68
	Antimycobacterials	5	
	Antivirals for systemic use	6	
	Vaccines	1	
Antineoplastic and immunomodulating agents	Antineoplastic agents	5	19
	Endocrine therapy	1	
	Immunosuppressive agents	13	
Musculo-skeletal system	Antiinflammatory and antirheumatic products	20	26
	Antigout preparations	1	
	Drugs for treatment of bone diseases	5	
Nervous system	Analgesics	71	185
	Antiepileptics	14	
	Anti - parkinson drugs	6	
	Psycholeptics	51	
	Psychoanaleptics	22	
	Other nervous system drugs	21	

Antiparasitic products	Antiprotozoals	2	2
Respiratory system	Nasal preparations	1	14
	Anti-asthmatics	5	
	Cough and cold preparations	5	
	Antihistamines for systemic use	3	
Sensory organs	Ophthalmologicals	4	5
	Otologicals	1	
Various	All other therapeutic products	2	8
	Diagnostic agents	1	
	General nutrients	5	
Total			**572**

Appendix 10 – ATC level 1 (anatomical) and 3 (pharmacological) medicine classes described in prescribing and monitoring reports

ATC Level 1	ATC Level 3		Total
Alimentary tract and metabolism	Stomatological preparations	1	49
	Antacids	1	
	Drugs for treatment of peptic ulcer	2	
	Belladonna and derivatives, plain	1	
	Propulsives	4	
	Intestinal antiinfectives	1	
	Antipropulsives	1	
	Intestinal antiinflammatory agents	3	
	Antiobesity preparations, excluding diet products	1	
	Insulins and analogues	26	
	Blood glucose lowering drugs, excluding insulins	5	
	Vitamin A and D, including combinations of the two	2	
	Potassium	1	
Blood and blood forming organs	Antithrombotic agents	63	72
	Antifibrinolytics	1	
	Vitamin K and other hemostatics	1	
	Iron preparations	5	
	Vitamin B12 and folic acid	1	
	Other antianemic preparations	1	
Cardiovascular system	Cardiac glycosides	3	79
	Antiarrhythmics, class I and III	4	
	Vasodilators used in cardiac disease	3	
	Other cardiac preparations	1	
	Antiadrenergic agents, peripherally acting	1	
	Arteriolar smooth muscle, agents acting on	1	
	Low-ceiling diuretics, thiazides	3	
	Low-ceiling diuretics, excluding diuretics	1	
	High-ceiling diuretics	19	

	Potassium-sparing agents	4	
	Beta blocking agents, plain	10	
	Selective calcium channel blockers with mainly vascular effects	5	
	Selective calcium channel blockers with direct cardiac effects	4	
	ACE inhibitors, plain	11	
	Lipid modifying agents, plain	9	
Dermatologicals	Antifungals for systemic use	1	9
	Antipsoriatics for topical use	1	
	Antibiotics for topical use	1	
	Chemotherapeutics for topical use	1	
	Corticosteroids, plain	4	
	Anti-acne preparations for systemic use	1	
Genito urinary system and sex hormones	Hormonal contraceptives for systemic use	5	20
	Estrogens	4	
	Progestogens	1	
	Progestogens and estrogens in combination	1	
	Gonadotropins and other ovulation stimulants	4	
	Other urologicals, including antispasmodics	3	
	Drugs used in benign prostatic hypertrophy	2	
Systemic hormonal prep, excluding sex hormones	Anterior pituitary lobe hormones	2	16
	Posterior pituitary lobe hormones	1	
	Corticosteroids for systemic use, plain	9	
	Thyroid preparations	4	
General antiinfectives for systemic use	Tetracyclines	4	68
	Beta-lactam antibacterials, penicillins	19	
	Other beta- beta lactam antibacterials	6	
	Sulfonamides and trimethoprim	16	
	Macrolides and lincosamides	7	
	Other antibacterials	4	
	Drugs for treatment of tuberculosis	5	
	Agents affecting the virus directly	6	

	Viral vaccines	1	
Antineoplastic and immunomodulating agents	Antimetabolites	2	19
	Cytotoxic antibiotics	3	
	Hormone antagonists and related agents	1	
	Immunosuppressive agents	13	
Musculo-skeletal system	Antiinflammatory and antirheumatic products, non-steroids	19	26
	Specific antirheumatic agents	1	
	Antigout preparations	1	
	Drugs affecting bone structure and mineralization	5	
Nervous system	Opioids	60	185
	Other analgesics and antipyretics	11	
	Antiepileptics	14	
	Anticholinergic agents	2	
	Dopaminergic agents	4	
	Antipsychotics	27	
	Anxiolytics	12	
	Hypnotics and sedatives	12	
	Antidepressants	16	
	Psychostimulants	1	
	Anti-dementia drugs	5	
	Drugs used in addictive disorders	21	
Antiparasitic products	Agents against amoebiasis and other protozoal diseases	2	2
Respiratory system	Nasal decongestants for systemic use	1	14
	Adrenergics, inhalants	3	
	Other drugs for obstructive airway diseases, inhalants	2	
	Expectorants, excluding combinations with antitussives	3	
	Antitussives, excluding combinations with expectorants	2	
	Antihistamines for systemic use	3	
Sensory organs	Antiinfectives	2	5

	Antiinflammatory agents	1	
	Antiinflammatory agents and antiinfectives in combination	1	
	Antiglaucoma preparations and miotics	1	
Various	All other therapeutic products	2	8
	Other diagnostic agents	1	
	Protein supplements	1	
	Other nutrients	4	
Total			**572**

Appendix 11 – ATC level 1 (anatomical) and 2 (therapeutic) medicine classes described in dispensing reports

ATC Level 1	ATC Level 2		Total
Alimentary tract and metabolism	Stomatological preparations	3	672
	Drugs for acid related disorders	153	
	Drugs for functional gastrointestinal disorders	43	
	Bile and liver therapy	1	
	Laxatives	36	
	Antidiarrheals, intestinal antiinflammatory/antiinfective agents	23	
	Drugs used in diabetes	352	
	Vitamins	14	
	Mineral supplements	47	
Blood and blood forming organs	Antithrombotic agents	153	184
	Antihemorrhagics	3	
	Antianemic preparations	25	
	Plasma substitutes and perfusion solutions	3	
Cardiovascular system	Cardiac therapy	129	1258
	Antihypertensives	37	
	Diuretics	168	
	Peripheral vasodilators	1	
	Vasoprotectives	2	
	Beta blocking agents	224	
	Calcium channel blockers	238	
	Agents acting on the renin angiotensin system	272	
	Lipid modifying agents	187	
Dermatologicals	Antifungals for dermatological use	17	75
	Emollients and protectives	6	
	Antipsoriatics	7	

	Antibiotics and chemotherapeutics for dermatological use	10	
	Corticosteroids, dermatological preparations	21	
	Antiseptics and disinfectants	1	
	Medicated dressings	2	
	Anti - acne preparations	10	
	Other dermatological preparations	1	
Genito urinary system and sex hormones	Gynecological antiinfectives and antiseptics	8	179
	Other gynecologicals	3	
	Sex hormones and modulators of the genital system	101	
	Urologicals	67	
Systemic hormonal prep, excluding sex hormones	Pituitary and hypothalamic hormones	4	194
	Corticosteroids for systemic use	75	
	Thyroid therapy	115	
General antiinfectives for systemic use	Antibacterials for systemic use	223	235
	Antimycotics for systemic use	5	
	Antivirals for systemic use	6	
	Vaccines	1	
Antineoplastic and immunomodulating agents	Antineoplastic agents	12	70
	Endocrine therapy	16	
	Immunosuppressive agents	42	
Musculo-skeletal system	Antiinflammatory and antirheumatic products	95	182
	Topical products for joint and muscluar pain	19	
	Muscle relaxants	12	
	Antigout preparations	38	

	Drugs for treatment of bone diseases	18	
Nervous system	Analgesics	388	1872
	Antiepileptics	351	
	Anti - parkinson drugs	114	
	Psycholeptics	361	
	Psychoanaleptics	492	
	Other nervous system drugs	166	
Antiparasitic products	Antiprotozoals	22	23
	Anthelmintics	1	
Respiratory system	Nasal preparations	12	259
	Anti-asthmatics	191	
	Cough and cold preparations	25	
	Antihistamines for systemic use	31	
Sensory organs	Ophthalmologicals	181	203
	Otologicals	19	
	Ophthalmological and otological preparations	3	
Various	All other therapeutic products	17	54
	Diagnostic agents	13	
	General nutrients	24	
Total			**5460**

Appendix 12 – ATC level 1 (anatomical) and 3 (pharmacological) medicine classes described in dispensing reports

ATC Level 1	ATC Level 3		Total
Alimentary tract and metabolism	Stomatological preparations	3	672
	Antacids	6	
	Drugs for treatment of peptic ulcer	147	
	Drugs for functional bowel disorders	7	
	Belladonna and derivatives, plain	7	
	Antipasmodics in combination with analgesics	2	
	Propulsives	27	
	Bile therapy	1	
	Laxatives	36	
	Intestinal antiinfectives	4	
	Antipropulsives	8	
	Intestinal antiinflammatory agents	11	
	Insulins and analogues	181	
	Blood glucose lowering drugs, excluding insulins	171	
	Vitamin A and D, including combinations of the two	10	
	Vitamin B1, plain and in combination with vitamin B6 and B12	1	
	Vitamin B-complex, including combinations	1	
	Other plain vitamin preparations	2	
	Calcium	29	
	Potassium	8	
	Other mineral supplements	10	
Blood and blood forming organs	Antithrombotic agents	153	184
	Antifibrinolytics	3	
	Iron preparations	13	
	Vitamin B12 and folic acid	11	
	Other antianemic preparations	1	
	Irrigating solutions	1	
	I.V. solution additives	2	

Cardiovascular system	Cardiac glycosides	40	1258
	Antiarrhythmics, class I and III	29	
	Cardiac stimulants excl. Cardiac glycosides	3	
	Vasodilators used in cardiac disease	57	
	Antiadrenergic agents, centrally acting	6	
	Antiadrenergic agents, peripherally acting	19	
	Arteriolar smooth muscle, agents acting on	12	
	Low-ceiling diuretics, thiazides	49	
	Low-ceiling diuretics, excluding diuretics	19	
	High-ceiling diuretics	58	
	Potassium-sparing agents	35	
	Diuretics and potassium-sparing agents in combination	7	
	Peripheral vasodilators	1	
	Agents for treatment of haemorrhoids and anal fissures for topical use	2	
	Beta blocking agents, plain	222	
	Beta blocking agents and other diuretics	2	
	Selective calcium channel blockers with mainly vascular effects	183	
	Selective calcium channel blockers with direct cardiac effects	55	
	ACE inhibitors, plain	147	
	ACE inhibitors, combinations	3	
	Angiotensin II antagonists, plain	105	
	Angiotensin II antagonists, combinations	17	
	Lipid modifying agents, plain	185	
	Lipid modifying agents, combinations	2	
Dermatologicals	Antifungals for topical use	8	75
	Antifungals for systemic use	9	
	Emollients and protectives	6	
	Antipsoriatics for topical use	6	
	Antipsoriatics for systemic use	1	
	Antibiotics for topical use	3	
	Chemotherapeutics for topical use	7	
	Corticosteroids, plain	18	

	Corticosteroids, combinations with antibiotics	2	
	Corticosteroids, other combinations	1	
	Antiseptics and disinfectants	1	
	Medicated dressings	2	
	Anti-acne prepartions for topical use	10	
	Other dermatological preparations	1	
Genito urinary system and sex hormones	Antiinfectives and antiseptics excluding combination with corticosteroids	8	179
	Contraceptives for topical use	2	
	Other gynecologicals	1	
	Hormonal contraceptives for systemic use	35	
	Estrogens	38	
	Progestogens	10	
	Progestogens and estrogens in combination	16	
	Gonadotropins and other ovulation stimulants	1	
	Antiandrogens	1	
	Other urologicals, including antispasmodics	33	
	Drugs used in benign prostatic hypertrophy	34	
Systemic hormonal prep, excluding sex hormones	Anterior pituitary lobe hormones	1	194
	Posterior pituitary lobe hormones	3	
	Corticosteroids for systemic use, plain	75	
	Thyroid preparations	105	
	Antithyroid preparations	10	
General antiinfectives for systemic use	Tetracyclines	12	235
	Beta-lactam antibacterials, penicillins	104	
	Other beta- beta lactam antibacterials	11	
	Sulfonamides and trimethoprim	18	
	Macrolides and lincosamides	54	
	Quinolone antibacterials	14	
	Other antibacterials	10	
	Antimycotics for systemic use	5	
	Agents affecting the virus directly	6	
	Viral vaccines	1	

Antineoplastic and immunomodulating agents	Alkylating agents	2	70
	Antimetabolites	3	
	Other antineoplastic agents	7	
	Hormones and related agents	5	
	Hormone antagonists and related agents	11	
	Immunosuppressive agents	42	
Musculo-skeletal system	Antiinflammatory and antirheumatic products, non-steroids	95	182
	Topical products for joint and muscluar pain	19	
	Muscle relaxants, centrally acting agents	10	
	Muscle relaxants, directly acting agents	2	
	Antigout preparations	38	
	Drugs affecting bone structure and mineralization	18	
Nervous system	Opioids	256	1872
	Other analgesics and antipyretics	90	
	Antimigraine preparations	42	
	Antiepileptics	351	
	Anticholinergic agents	36	
	Dopaminergic agents	78	
	Antipsychotics	223	
	Anxiolytics	73	
	Hypnotics and sedatives	65	
	Antidepressants	439	
	Psychostimulants	29	
	Anti-dementia drugs	24	
	Parasympathomimetics	1	
	Drugs used in addictive disorders	157	
	Antivertigo preparations	8	
Antiparasitic products	Agents against amoebiasis and other protozoal diseases	2	23
	Antimalarials	20	
	Antinematodal agents	1	
Respiratory system	Nasal decongestants for topical use	12	259
	Adrenergics, inhalants	47	

	Other drugs for obstructive airway diseases, inhalants	120	
	Adrenergics for systemic use	3	
	Other systemic drugs for obstructive airway diseases	21	
	Antitussives, excluding combinations with expectorants	25	
	Antihistamines for systemic use	31	
Sensory organs	Antiinfectives	41	203
	Antiinflammatory agents	8	
	Antiinflammatory agents and antiinfectives in combination	4	
	Antiglaucoma preparations and miotics	109	
	Mydriatics and cycloplegics	6	
	Decongestants and antiallergics	1	
	Local anesthetics	1	
	Surgical aids	1	
	Other ophthalmologicals	27	
	Corticosteroids and antiinfectives in combination	1	
	Other otologicals	2	
	Corticosteroids	1	
	Corticosteroids and antiinfectives in combination	1	
Various	All other therapeutic products	17	54
	Other diagnostic agents	13	
	Protein supplements	1	
	Infant formulas	15	
	Other nutrients	8	
Total			**5460**

Appendix 13 – ATC level 1 (anatomical) and 2 (therapeutic) medicine classes described in administration reports

ATC Level 1	ATC Level 2		Total
Alimentary tract and metabolism	Drugs for acid related disorders	3	182
	Drugs for functional gastrointestinal disorders	11	
	Antiemetics and antinauseants	1	
	Laxatives	1	
	Antidiarrheals, intestinal antiinflammatory/antiinfective agents	1	
	Drugs used in diabetes	162	
	Mineral supplements	3	
Blood and blood forming organs	Antithrombotic agents	85	117
	Antianemic preparations	28	
	Plasma substitutes and perfusion solutions	4	
Cardiovascular system	Cardiac therapy	7	32
	Diuretics	8	
	Beta blocking agents	6	
	Calcium channel blockers	6	
	Agents acting on the renin angiotensin system	3	
	Lipid modifying agents	2	
Dermatologicals	Antibiotics and chemotherapeutics for dermatological use	1	2
	Antiseptics and disinfectants	1	
Genito urinary system and sex hormones	Gynecological antiinfectives and antiseptics	1	11
	Other gynecologicals	1	
	Sex hormones and modulators of the genital system	6	
	Urologicals	3	

Systemic hormonal prep, excluding sex hormones	Pituitary and hypothalamic hormones	2	21
	Corticosteroids for systemic use	12	
	Thyroid therapy	7	
General antiinfectives for systemic use	Antibacterials for systemic use	15	189
	Immune sera and immunoglobulins	4	
	Vaccines	170	
Antineoplastic and immunomodulating agents	Antineoplastic agents	2	32
	Endocrine therapy	6	
	Immunomodulating agents	16	
	Immunosuppressive agents	8	
Musculo-skeletal system	Antiinflammatory and antirheumatic products	2	6
	Muscle relaxants	1	
	Drugs for treatment of bone diseases	3	
Nervous system	Anesthetics	3	195
	Analgesics	91	
	Antiepileptics	16	
	Anti - parkinson drugs	11	
	Psycholeptics	44	
	Psychoanaleptics	23	
	Other nervous system drugs	7	
Antiparasitic products	Antiprotozoals	1	1
Respiratory system	Anti-asthmatics	5	9

	Cough and cold preparations	2	
	Antihistamines for systemic use	2	
Sensory organs	Ophthalmologicals	5	6
	Otologicals	1	
Various	All other therapeutic products	2	6
	Diagnostic agents	2	
	General nutrients	2	
Total			**809**

Appendix 14 – ATC level 1 (anatomical) and 3 (pharmacological) medicine classes described in administration reports

ATC Level 1	ATC Level 3		Total
Alimentary tract and metabolism	Drugs for treatment of peptic ulcer	3	182
	Drugs for functional bowel disorders	1	
	Belladonna and derivatives, plain	5	
	Propulsives	5	
	Antiemetics and antinauseants	1	
	Laxatives	1	
	Antipropulsives	1	
	Insulins and analogues	156	
	Blood glucose lowering drugs, excluding insulins	6	
	Calcium	2	
	Potassium	1	
Blood and blood forming organs	Antithrombotic agents	85	117
	Iron preparations	2	
	Vitamin B12 and folic acid	13	
	Other antianemic preparations	13	
	Irrigating solutions	1	
	I.V. solution additives	3	
Cardiovascular system	Cardiac glycosides	5	32
	Vasodilators used in cardiac disease	2	
	Low-ceiling diuretics, thiazides	2	
	High-ceiling diuretics	5	
	Potassium-sparing agents	1	
	Beta blocking agents, plain	6	
	Selective calcium channel blockers with mainly vascular effects	6	
	ACE inhibitors, plain	3	
	Lipid modifying agents, plain	2	
Dermatologicals	Antibiotics for topical use	1	2
	Antiseptics and disinfectants	1	

Genito urinary system and sex hormones	Antiinfectives and antiseptics excluding combination with corticosteroids	1	11
	Contraceptives for topical use	1	
	Androgens	3	
	Estrogens	1	
	Progestogens	2	
	Drugs used in benign prostatic hypertrophy	3	
Systemic hormonal prep, excluding sex hormones	Hypothalamic hormones	2	21
	Corticosteroids for systemic use, plain	12	
	Thyroid preparations	7	
General antiinfectives for systemic use	Tetracyclines	1	189
	Beta-lactam antibacterials, penicillins	5	
	Other beta- beta lactam antibacterials	3	
	Sulfonamides and trimethoprim	2	
	Macrolides and lincosamides	2	
	Other antibacterials	2	
	Immunoglobulins	4	
	Bacterial vaccines	66	
	Viral vaccines	70	
	Bacterial and viral vaccines, combined	34	
Antineoplastic and immunomodulating agents	Antimetabolites	1	32
	Other antineoplastic agents	1	
	Hormones and related agents	6	
	Immunostimulating agents	16	
	Immunosuppressive agents	8	
Musculo-skeletal system	Antiinflammatory and antirheumatic products, non-steroids	2	6
	Muscle relaxants, centrally acting agents	1	
	Drugs affecting bone structure and mineralization	3	
Nervous system	Anesthetics, general	1	195
	Anesthetics, local	2	

	Opioids	78	
	Other analgesics and antipyretics	13	
	Antiepileptics	16	
	Anticholinergic agents	1	
	Dopaminergic agents	10	
	Antipsychotics	22	
	Anxiolytics	4	
	Hypnotics and sedatives	18	
	Antidepressants	16	
	Psychostimulants	2	
	Anti-dementia drugs	5	
	Drugs used in addictive disorders	6	
	Antivertigo preparations	1	
Antiparasitic products	Agents against amoebiasis and other protozoal diseases	1	1
Respiratory system	Adrenergics, inhalants	1	9
	Other drugs for obstructive airway diseases, inhalants	3	
	Adrenergics for systemic use	1	
	Expectorants, excluding combinations with antitussives	1	
	Antitussives, excluding combinations with expectorants	1	
	Antihistamines for systemic use	2	
Sensory organs	Antiinfectives	4	6
	Antiglaucoma preparations and miotics	2	
Various	All other therapeutic products	2	6
	Other diagnostic agents	2	
	Other nutrients	2	
Total			**809**