An Examination of the Role of Communication in Paediatric Medication Errors

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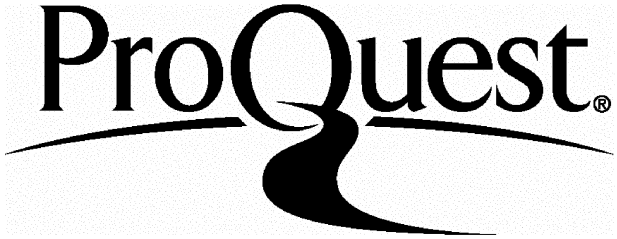

ABSTRACT

This thesis examines the varied roles that communication plays within paediatric medication safety. This is a complex area, because it is such a new field, and because communication is at the heart of every part of this research area. Communication is the cause of many errors and is the key to resolving such incidents.

My thesis relies on three new pieces of research. Firstly, an examination of the US and UK medication systems. My research examined how each system works and associated problems, and looked at how solutions could be developed, and turned into policy in the UK- how to maximize benefit through clear communication.

The second is a secondary analysis of data from a multi-centre trial carried out in Boston, Massachusetts where I examined the link between the prescribing advice provided to parents and the likelihood of errors occurring during the home administration process. My data suggest no such apparent link, but do find that the advice given is inadequate and parents want more. To my knowledge, this has not been studied previously.

My final piece of research is an attempt to look at how the public opinion is formed on paediatric medication safety. Patient safety is not an area of erudite study; each error has repercussions for real individuals. Only if the developments and new thinking patterns are communicated to the public can we hope to change the public mentality and achieve truly safer systems, moving away from a culture of blame to one of safety. This research identified that newspapers covered a wide range of themes including research findings and did so fairly, more often framed in a culture of safety rather than blame.

This thesis shows how fundamental communication is the rapidly emerging area of patient safety and in particular paediatric medication safety.

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William Elves Pub August 12th 1811

Jack, hove down-with a Grog Blossom Fever

Charicature shows a doctor and a sailor, both speak in their own language such that it is incomprehensible to the other.

The doctor "'hold - I must stop your Grog Jack-it excites those impulses, and concussions of the Thorax, which a company [sic] sternutation by which mean you are in a sort of kind of Situation - that your head must be Shaved – I shall take from you only - 20ozs of Blood – then swallow this Draught and Box of Pills, and I shall administer to you a Clyster'".

The sailor " 'Stop my Grog. – Belay there Doctor –Shiver me timbers but your lingo bothers me – You May batter my Hull as long as you like, but I'll be damn'd if ever you board me with your Glyster pipe'".

I CONFIRM THAT THE WORK PRESENTED IN THIS THESIS IS MY OWN WORK.

C. Lemer 14/12/07

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List of Abbreviations

AAP	American Academy of Paediatrics
AAFP	American Academy of Family Practioners
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
CDSS	Clinical Decision Support Systems
CPOE	Computerised Physician Order Entry
FHL	Functional Health Literacy
HISS	Hospital Information Support System
HMP	Harvard Medical Practice
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
ISMP	Institute for Safe Medication Practice
JCAHO	Joint Commission on Accreditations of Healthcare Organizations
LES	Limited English Speaking
ME	Medication Error
PICU	Paediatric Intensive Care Unit
POP	Paediatric Outpatient Prescribing Study
PRN	As required
SHO	Senior House Officer
UK	United Kingdom
USA	United States of America

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I have been enormously lucky that every step of my career has been supported by extraordinary individuals, prepared to go that extra mile for me, for which I thank them. Dr Colin Stern has been a wonderful mentor for many years, Dr Rainu Kaushal has given of her time, and energy unstintingly this year, Carol Keohane for her constant support, and Cathy Yoon for making SAS less scary, John Orav and Garrett Fitzmaurice for making statistics fun and finally to Don Goldman and Sharon Muret-Wagstaff who took me under their wing.

"To err is human; to forgive, divine"

Alexander Pope 1711

"To err is human; to fail to learn is inexcusable"

Susan Sheridan, Vice President, Consumers Advancing Patient Safety 2004

Chapter 1 Introduction

1.1 Introduction-The importance of communication in medication safety

Hippocrates was the first to outline the guiding principles of medicine:

"Declare the past, diagnose the present, foretell the future; practice these acts. As to diseases, make a habit of two things—to help, or at least to do no harm."

Epidemics, Bk. I, Sect. XI

These principles are as true today. Over the last 40 years there has been a renewed attempt to identify sources of error within medicine and develop strategies to minimize the risk to patients.

During my Senior House Officer years I was struck time and time again by how unsafe the medication system seemed. I distinctly remember calculating maximum intravenous potassium concentrations, on the back of a piece of paper at three in the morning, with constant interruptions and worrying all the time that I was making a mistake. I started to think that there must be safer ways to do things. I started to read and search for other like-minded people. I soon discovered there was a wealth of literature on the evolving field of patient safety, a vast tranche of data on medication safety and a small but rapidly growing field of paediatric medication safety. The more that I read, the more I realised that the common theme of all this work is communication. Each error that has occurred or mechanism that prevents such errors has at its heart communication. My example of the potassium challenge, could so easily have been avoided had a senior doctor had time to sit down with me and help, or if clear protocols communicating to professionals in training how to do such calculations, had existed. So this set me to thinking how best I could highlight the importance of communication in medication safety particularly paediatric medication safety. This thesis is the culmination of this journey. I was immensely lucky to be awarded a Harkness-Health Foundation Fellowship in 2004-5 to pursue this burgeoning interest.

This thesis grew from the work that I was able to carry out within the Center of Excellence in Patient Safety, Brigham and Women's Hospital in Boston, under the expert guidance of Professor David Bates and Dr Rainu Kaushal. This thesis is my attempt to start to build the case for the importance of communication in patient safety, but particularly within medication safety and my area of expertise paediatrics. The thesis grew from my journey to understand what is known and what needs to be known, within the limitations of being a researcher in training. I started by reading everything that I could. I found that there is a wealth of literature examining the extremely complex area of communication and medicine, but less of it focused on paediatrics. I found that there is a burgeoning literature on medication safety, but to date no real attempt has been made to integrate the two, despite numerous references to the importance of communication to patient safety. [1;2] My findings in this area, the positive information that we currently possess and the gaping holes that need to be examined further became the basis for my research, and form the basis of the first chapter of this thesis. This chapter is an attempt to understand the patient safety literature and the communication literature and identify the importance of research combining the two. Whilst examining the patient safety and in particular the medication safety literature it became apparent that not only was this literature needed to see how communication fitted in, but was in itself a source of multiple failures of communication. Firstly the often confusing and non-universal definitions, secondly the varying methodologies used in medication safety research, which are often not clearly explained to the reader leading to confusion between ostensibly contradictory results from different studies; which may in fact be explained by the differing methodologies used. Finally, the different ways of expressing the frequency of errors also leads to potential confusion in interpretation of results, another failure of communication.

Research has not only focused on defining the nature and scale of the problem, it has also developed and tested solutions. Each of key areas that have been identified has at their core mechanisms to improve communication, either between health professional or patients and professionals. Therefore, the second part of this chapter focuses on how communication is involved in the development of solutions. The chapter also identifies how communication plays a vital role in the process of coping with errors, by both professionals and patients or their families. Whilst my natural home is paediatrics, and whilst it is definitely true that paediatrics is a particularly challenging area with regard to medication safety, it is also true that this is a relatively poorly studied area and therefore it is both necessary and useful to examine the adult literature first and then use this to enhance the limited knowledgebase of the paediatric literature.

My exposure to a new culture in the USA, a new way of practicing medicine, a system with different quirks, failings and successes set me to thinking about the constant re-duplication of efforts, not just internationally but also within countries; although it is more apparent perhaps with international comparisons. I began to realize that huge amounts of work have been carried out around the globe on how to make healthcare safer and follow Hippocrates' first principle. Yet this information so often fails to be disseminated properly and so re-duplication occurs. The third chapter of this thesis is an attempt to understand and perhaps influence this. As the UK develops perhaps the most ambitious program of computerization ever carried out by a healthcare system, it is fundamental that part of this process involves reviewing successful and failed attempts that have been carried out elsewhere. This chapter is an analysis of these previous efforts and an attempt to graft this knowledge onto the United Kingdom (UK) system, which differs immensely from other systems worldwide. This is an attempt to show how communicating key lessons learned through integrating and correct application could help to develop policy while minimising the chance of repeated similar failings.

The department that I was based in, in the USA, carries out some of the largest multi-centre patient safety studies in the world, using ground breaking but well accepted methodologies.[3;4]At the time that I arrived Phase 1 of the Paediatric Outpatient Prescribing Study (POP) [5] had just finished. POP is a 3-year research study funded by the Agency for Health Care Research and Quality (AHRQ). The aim of which was to examine the nature of medication incidents occurring in the outpatient paediatric setting in Boston, Massachusetts and to examine whether computerised prescribing reduces such incidents. I became involved with this study just after the primary data collection had occurred. This raw data provided a rich and at the time untapped resource for answering questions about medication safety in the outpatient or ambulatory setting. This provided me with the opportunity to start to answer the question that I was interested in – how does communication affect medication safety (this time in the ambulatory or outpatient setting) whilst honing my methodological skills. I wanted to know, how the nature of advice given to parents (and other home-care givers such as guardians or grandparents) during the medication system process (the sequence of prescribing, dispensing and administration) affected the incidence of medication incidents. Essentially, I was asking how does the way we as healthcare professionals interact with patients and their families affect medication safety. This is examined in the fourth chapter of this thesis.

As I started to gather the data for this part of my research, I started to think about how the parents in the POP study would consider medication safety. Would they be horrified that medicine was not perfect, or would they accept that risk was part of medicine? This led me to start to wonder how such thoughts were developed within people; what influences our opinion of medicine. I thought long and hard about how I could start to answer this question. Given my limited resources and my desire to learn as many new research methodologies as possible it seemed that this would be a wonderful opportunity to learn some basic qualitative skills. So I

started to read about how others had looked at opinion generation, and I found a huge literature from the world of cigarette smoking. Researchers have developed a meticulous methodology for attempting to look at the coverage of the tobacco industry over time. My area of interest was different in many ways from this topic, primarily because it is a new area of discussion and a relatively small one compared to the tobacco industry. However, I scoured this literature so that I could develop a methodology to allow me to ask a new question – Does the written media present the paediatric medication safety to the public in a fair manner, or is the slant of the articles biased? This was an immensely complex question requiring learning of many new qualitative skills and the results are presented in chapter five.

This thesis is my journey to understand communication in patient safety. The process has been enormously pleasurable, but it also required a huge amount of learning. In the course of this time, I have come to understand a little better an immensely important and currently undervalued area of healthcare. As one of the seven key attributes to improving the quality of medical care as defined by the Institute of Medicine's (IOM's) landmark report- Crossing the Quality Chasm, it is an area which is rapidly evolving.[6] I hope that this thesis will be a small step in understanding how important communication is to this topic.

1.2 Background to Medication Safety

Before being able to answer my first question- what does the current evidence show about the role of communication in medication safety, I had first to start to understand why errors occurred and how these complex failings are described.

1.21 Why do errors occur?

James Reason has written extensively on error theory and its relevance to healthcare; he proposes two approaches to the question of why errors occur. Errors can either be the result of individual error or alternatively systems may make errors more likely.[7] Historically individuals have been seen as the main cause of error in medicine but more recently systems have received more attention.[8] The person approach focuses attention on the individual involved in the error. The mistake occurred because the individual did or did not do something. In contrast, the systems approach looks more widely at causes of error. This approach appreciates that the individual does not work in isolation and a myriad of contributory factors, often beyond the individuals control, coalesce to produce the error. Reason's model, is that of Swiss cheese; only if all the problems in the system line up to create a contiguous "hole in the cheese" do hidden problems within the system become visible.[7] In the person approach, the individual is accountable and there develops a culture of blame. Accountability in the systems approach means thorough investigation of all the contributory factors through a root cause analysis. This leads to a culture of safety, where mistakes are treated as opportunities for learning.[8]

1.22 Definitions

Part of the complexity of understanding how communication plays a role in medication safety stems from the language used to describe incidents of harm or potential harm. This is therefore rather ironically the first step in which communication plays a role. The terminology that has developed to explain and understand the field of patient safety is an attempt to communicate complex ideas regarding harm, and potential harm that can occur during the medication process. The first concept that requires explanation is that of a mistake or an error in general. The IOM's seminal report on Patient Safety adopted Reason's definition of error:[9]

"The failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim."[10]

This encapsulates the general principle of mistakes. The IOM define safety as one of the key indicators of quality. However, there is much disagreement about what constitutes patient safety. Does overuse of medications particularly antibiotics constitute a safety problem or is it a quality problem?[9] More specific terminology is required to understand and study the field of medication safety. As the field of medication safety has developed one of the major complications has been variation in the terminology used. The broadest definition of medication use resulting in harm to the patient is that of Bates et al; they define an Adverse Drug Event (ADE) as:

"An injury or injuries resulting from medication use."[11]

Sometimes people have used –adverse drug reaction (ADR) in place of ADE.[12;13] However the World Health Organization defines an ADR as:

"Any noxious, unintended and undesired effect of a drug, which occurs at doses used for prophylaxis, diagnosis or therapy."[14]

This definition does not include complications from medications, which are used at the incorrect doses. An adverse drug reaction is an unwanted consequence of a correctly prescribed, dispensed and administered medication. An ADR is a sub-type of an ADE.

ADEs have been further subdivided according to preventability. (Figure 1) A non-preventable adverse event occurs when there is harm to the patient but there has been no mistake in the medication process. An ADR is an example of a non-preventable adverse event, e.g. if an

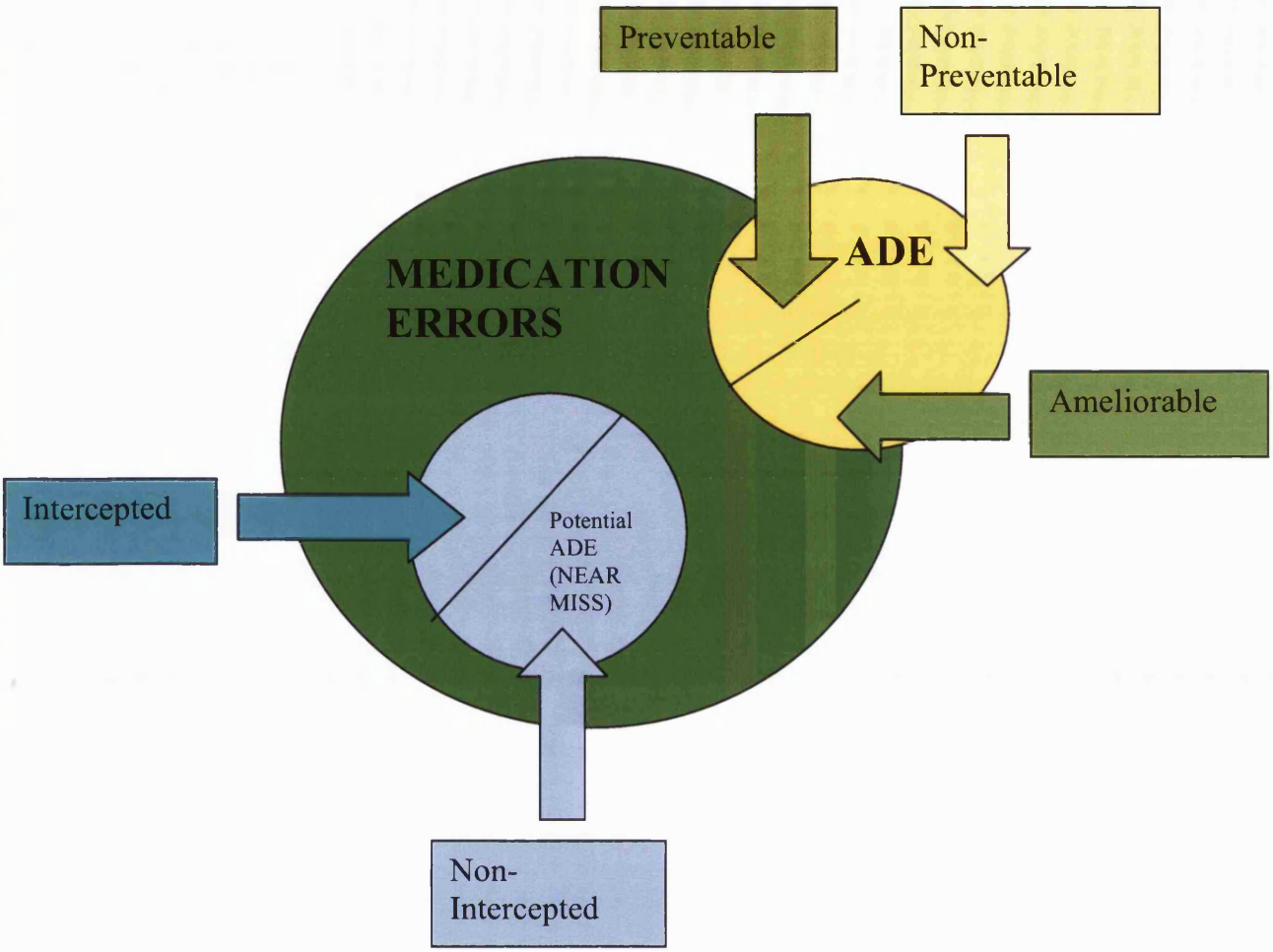


Figure 1 Relationship between ADEs and MEs. Reproduced with kind permission from the Centre of Excellence For Patient Safety Research and Practice Terminology Training Manual.

antibiotic is given for the first time and the patient develops an allergic reaction. A preventable adverse event describes harm that occurs to a patient as a result of a mistake in the medication process. An example is a neonate administered a ten-fold overdose of morphine due to a calculation error, resulting in a respiratory arrest. A further and newer subtype of ADEs is the

ameliorable ADE. This is where the harm that has occurred to the patient could have been lessened. An example is a child prescribed an antibiotic, which resulted in diarrhoea, and no contact was made with a doctor. If contact had been made the course or severity of the diarrhoea might have been altered.[11]

ADEs may also be classified according to the stage in the medication process at which they occur. The first step is prescription, followed by verification and dispensing. This is completed by administration and in the case of some drug categories, follow up monitoring. The causes of errors at each stage and the subsequent strategies necessary to reduce these errors vary widely.[15;16]

ADEs describe situations in which harm occurs to the patient. The majority of errors that occur in the medication process do not reach the patient. [4;17] Medication errors (MEs) are mistakes in the medication process that do not lead to actual harm to the patient; one example of a ME at the administration stage would be a single missed dose. This should not occur but there is not likely to be a harmful consequence for the patient. Medication errors are distinct from rule violations - where the exact letter of the law is not followed but the risk to the patient is very low; an example would be a medication prescribed for as required use (PRN) and no reason for use is noted. Thus an ADE may occur as a result of a medication error but does not always do so; non-preventable adverse drug events are an example of harm occurring and yet the absence of a medication error.

Even the term ME has been subject to confusion. MEs are now accepted to be mistakes in the process compared to normal standard practice. In some of the earliest studies the definitions of errors were:

"Deviations from the physician's order on the patient's chart"[18]

This is a very different concept and so care must be taken when comparing prevalence figures based on differing definitions.

In an attempt to focus on the most important group of MEs i.e. those with the most likelihood of harm a subgroup has been defined – a potential ADE or near miss is a medication error that did not result in an ADE, but could have. These near misses are important because, if identified they allow opportunities to alter the medication process before harm occurs. These may be sub-divided further into a potential ADE-intercepted, and non-intercepted. An example of a potential ADE – intercepted is a patient with a known penicillin allergy is prescribed ampicillin, but the pharmacist notices the error and prevents the possibility of harm, by altering the prescription. A non-intercepted potential ADE is a medication error that reaches the patient but fortuitously does not produce harm, e.g. a patient known to be allergic to penicillin is prescribed a cephalosporin but no harm occurs.

Finally both medication errors and ADEs can be classified according to severity, i.e. serious, significant and life threatening are the commonly used subtypes.[11]

This classification therefore serves two purposes. Firstly, it acts as a glossary for future reference in this thesis. Secondly, it serves to highlight how important clarity in communication is, particularly when trying to describe in crucial detail very complex situations. Without clear definitions, which have worldwide meaning, research and translation of this research into practice is very difficult. Therefore, not only do definitions provide a useful starting point to understanding the literature, they provide the first example of how important good clear

communication is. This is an increasingly recognized concern and researchers are attempting to standardize the taxonomy. [19;20]

1.23 Modern history of medication safety

Understanding the research and policy background to the current interest in medication and indeed patient safety is vital. It was through this work that the original suggestions about the importance of communication were made. In addition as with the definitions, the history is itself an example of poor communication and why communication is so important.

In the 1960's epidemiological studies were carried out in the US and UK to ascertain the prevalence of mistakes in the medication process, however these studies used very different terminology and the medication systems in place were also dissimilar. These studies focused on rates of medication errors within the hospital setting. Barker et al in the United States found a 15% error rate.[21]Hill et al in the UK found 15.3% of orders for drugs given in a single hospital study contained an error.[22] These studies utilized direct observation of the medication process to identify errors. In an attempt to reduce these error rates the two countries' hospitals developed divergent methodologies.

Another defining moment in medication safety was the Harvard Medical Practice Study (HMP). This study estimated the numbers of adverse events occurring in hospitals in the state of New York. The study utilized a sample of over 30,000 records from a population of more that 2 million patients discharged in 1984. Teams of trained reviewers made the assessment of harm. This study estimated the occurrence of adverse events at 3.7 % of hospitalizations, and the prevalence of ADEs as 19% of the total.[23] This permitted the realization that a large number of these errors were potentially preventable. [24] The Utah and Colorado based study further

investigated the preventability of adverse events and determined that 57.7% of the events detected were preventable. The study estimated the total annual US costs of these errors at $661,889,000 for events and $348,081,000 for preventable adverse events, (figures are for 1996 dollars). ADEs were the second most expensive subtype of adverse events.[25]

Further recognition of the consequences of such high rates of errors came with the publication in 2000 of the IOM report "To Err is Human."[9] The report identified that between 44,000 and 98,000 Americans die each year in hospital from adverse events. These figures were calculated by extrapolation from the prevalence figures of the HMP study and the Utah and Colorado Study. These figures were extremely controversial at time of initial publication but have become generally accepted over time.[26-28]The report also went on to set out recommendations that it hoped would be the basis of strategies to reduce the adverse events over the following 10 years.[9]

Within a few years of these seminal papers, researchers were starting to suggest the importance of communication, [29]as this recognition was growing however the very same research community was failing to heed its own advice and failures of communication were becoming apparent.

1.24 Prevalence of error

As has been examined earlier the history of medication safety is of importance to this thesis in two ways. Firstly, it is through this that an understanding of medication safety is gained and thus the role of communication within it. Secondly, the research itself is littered with examples of poor communication.

Identification of the prevalence of mistakes within the medication process depends on three factors, firstly, the methodology used,[30] secondly on the definitions used, as described previously and thirdly on the expression of the data. Some studies report data as percentages of admissions, some as percentages of orders and thus care must be taken when interpreting the data. Studies have found significantly differing error rates and it may be that the different prevalence estimates may not truly represent reality.[31;32] Therefore each of these three factors are subject to miscommunications which lead to the potential for confusion.

1.241 Adverse Events

The seminal studies in the field of adverse events, in general, have attempted to use the same methodology but each has modified the protocol for local use. These studies are based on retrospective examinations of medical charts. The essential principles are that teams of trained researchers, often nurses, identify errors from randomly selected case records and then in association with review panels, assess and categorize the errors. The first of these studies and the largest was the HMP study. As described, this found that 3.7% of admissions suffered an adverse event.[23] The Colorado and Utah study found overall rates of 2.9%.[25]In the UK Vincent et al found that 10.8% of admissions suffered adverse events, the rate rose to 11.7% if multiple adverse events were included in the analysis.[33]In Australia the rate was found to be 16.6%.[34]

An alternative methodology for examining patient safety was used by Andrews et al in the UK.[35]They utilized direct observation to assess adverse event rates within a single hospital. Direct observation uses trained researchers to watch the processes and record errors. This technique is difficult in terms of both cost and methodology. As the observers are watching errors real time there is an ethical requirement for intervention if harm is inevitable.[31]This study found that 17.7% of patients in the study had experienced an adverse event.[35] Therefore already it is

apparent that unless the type of event detection used is clearly communicated the results may be misleading or at least confusing.

1.242 Adverse Drug Events

As with adverse events, in general, studies have used a variety of methodologies to estimate ADE prevalence and so direct comparisons may be difficult. In the HMP Study Leape et al identified that 19% of the overall adverse event burden was due to drugs. This was the most common sub-group. [24] Using the data collected from direct observation Andrews et al detected that in 9.3% of patients who experienced an adverse event the cause was medication. [35] In a study at the Brigham and Women's Hospital, Bates et al found an ADE rate of 6.5% of admissions; of these, 28% were judged preventable. Of the preventable group the most common stage of error was the ordering stage (56%) followed by the administration stage (34%). This study used case reviews and panel reviews, but was prospective.[36] Classen et al used computers to identify ADEs, and found that ADEs occurred in 1.7% of the admissions. The computers searched for events based on pre-determined rules or triggers.[37] Jha et al examined these methodologies - the reliability of trigger tools vs. chart review and found that chart review identified 65% of the total ADEs found, computers using triggers found 45%, perhaps explaining some of the difference in data from Bates et al and Classen et al. [36-38] Again each type of research adds to the knowledgebase but for the new reader adds to the complexity and potential for error.

1.243 Medication Errors

Utilizing self report, chart review and panels, Bates et al identified 5.3 errors per 100 orders when they investigated medication errors at a tertiary care hospital within the USA.[11] Using a very different technique, a modified version of direct observation targeting the administration stages, Dean et al found medication error rates of 6.9% in a US hospital and 3% in the UK.[39] It is

unclear why these results were so different. Dean et al performed a similar comparison between the UK and Germany, again using the modified direct observation technique; this time the medication error rate was 8% in the UK and 5.1% in Germany. [40] Other studies in the US have found widely varying rates among institutions, [41] so perhaps these differences reflect inter-institutional differences rather than differences among countries.

1.244 Paediatric medication safety

Medication safety research began by considering adults. However, in recent years, there has been increasing focus on paediatric medication safety. Much of the research carried out on adults and the conclusions that have subsequently been reached, is valid in paediatrics.[42] It is important though to appreciate that medicating for children does have major differences compared to adults.

At the prescribing stage, paediatric medications are often based on weight or surface area. This requires more calculation than fixed dose prescribing. In addition, different systems are used to calculate weight, so adding to the potential for confusion. Furthermore the range of weights is considerable, a paediatrician may look after a neonate and a teenager, this means that without careful consideration it may not be instantly apparent to prescribers (especially inexperienced ones) that the dose is incorrect, even if it is a ten-fold error.[43] Potts and Phelan tested new residents, using a written examination that covered four areas, conversion of common units of weight and fluid volume, fluid and feed calculations and dose calculations. The mean score was 42%. The researchers compared family medicine trainees and paediatric residents and found that there was a significant difference in results, with paediatric residents scoring a mean of 57.8%. The areas of most difficulty were the conversion of units and fluid calculations.[44]A later, similar study, using a different questionnaire, found comparable poor clinical mathematical ability.

Interestingly, no correlation between length of training and likelihood of error was found. Overall, 40% of residents made at least one error and 10% made ten fold errors, additionally these residents made more errors than the rest of the sample. Both studies conclude that new residents require double-checking of calculations, and training. In addition they comment that medical schools must teach, assess mathematical clinical competence and provide remedial help before the students graduate.[45;46] This too is an example of communication failure, and Rowe et al suggest that the solution lies in improved communication i.e. teaching of prescribing skills.

Dispensing is different from adults too; often pre-made medications do not exist and so pharmacists have to create them, which is error-prone. In addition, children are more reliant on solutions than adults are. At the administration, stage children may need a caregiver to administer the medication, and given that, children spend considerable time out of the house, this may be more than one person, thus introducing new errors. Even if the medications are correctly, prescribed dispensed and administered children have different physiology and anatomy to adults and so may deal with the medication differently.[47] This is not to say that all of these problems are unique to children; many of these are faced in geriatric medicine, but they do increase the potential for error.

Furthermore, it should be noted that prescribing for children is fraught with inherent risk because so many drugs are prescribed un-licensed or off-label. [48-50]

1.2441 Prevalence of error

As with the adult prevalence studies methodologies, definitions and expressions of error rates vary making direct comparisons difficult.[47;51] Some of the first studies, as in the adult literature, examined the general rates of adverse events or medical errors. In the USA in 1996 McCormick

et al began a series of papers examining the care that children in the USA receive, using national databases. They reported that 0.8% of all paediatric discharges included a complication of medical care.[52] The HMP estimated that there was a rate of 2.7 adverse events in patients aged 5 or under, per 100 discharges.[23] Miller et al used Patient Safety Indicators which are based on work by AHRQ and found an error rate of 1.15%.[53] Analysis of the Colorado and Utah study showed that 1% of paediatric hospitalizations resulted in adverse events of which 0.6% were preventable. The authors extrapolate from this that 70,000 children per year in the USA experience an adverse event. Medication related events made up 19% of the total forming the third highest group, after birth related (29.6%) and diagnostic errors (21.3%). [54]

The methodologies utilized to examine specifically medication safety in paediatrics may be divided into two main types - first are studies, which collect data from pre-existing hospital reporting systems and second are cohort studies. Slonim et al carried out a complex nonconcurrent study, using administrative data to identify the medication error rate and found an error rate of 1.81 to 2.96 per 100 discharges, of which drug related errors ranged from 0.03 to 0.13 per 100 admissions. Whilst the data are of great importance the choice to express the data in conflicting ways as a percentage of discharges for one result and as a percentage of admissions for another makes comparison difficult.[55] In the UK Ross et al carried out a retrospective review of medication errors identified from standard reporting forms. The prevalence of errors was 0.15% of admissions; 8% of the errors involved 10 fold errors. The highest rates were found in the Neonatal Intensive Care Unit. The most common class of drug was antibiotics.[56]

Wilson et al also identified medication errors from in situ reporting systems and found a higher rate of one error per 5.8 admissions, or 65% of admissions. During the study period changes such as multi-disciplinary teaching sessions, were made to reduce errors and the incidence of errors

was found to be lower in the second than first year of the study. The authors also noted that there was an appreciable rise in error rates at times of the year when new junior doctors started. This study also identified an ADE rate of 0.6%.[57] Further studies have looked at the ADE rate. Using data from MedWatch, the FDA ADE reporting system, Moore et al determined that ADEs are a significant cause of mortality and morbidity amongst infants and children, with 238 deaths over the 38 month study period, however this study also looked at prenatal drug exposure.[58] The variation in results is considerable, and whilst this may be explained by methodological and definition differences, other factors such as the different medications systems, both within countries and between countries may also play a role.

The second methodology is that of a cohort study- two studies have examined medication errors alone. In 1987, Folli et al examined two large paediatric hospitals and found a medication error rate of 1.35, and 1.77 per 100 patient days or 4.9 and 4.5 per 1000 medication orders. The most common type of error was using the wrong dose. Patients aged less than 2 years or patients on the paediatric intensive care unit had the highest error rate. Pharmacists detected the errors in this study as part of their usual work, at the verification stage. This study also found that years' of training was inversely correlated with likelihood of making errors. [59] Marino et al studied a paediatric medication system at a US hospital. However, their definitions of error were very different from standard definitions. Thus, the main outcome that is comparable with other paediatric data are that the majority of errors occurred at the transcribing stage. [60]

There are in addition a further few studies which examine ADEs and MEs by the cohort method. Whyte et al examined the rate of adverse events using this prospective methodology; however, since this study was carried out in the UK in 1977 definitions have altered considerably. Whyte et al identified that 6.5% of patients suffered an "ADR" however his definition of an ADR is

closer to our current definition of an ADE, as it includes harm from overdosing.[13] Holdsworth et al performed a prospective review of ADEs occurring in a general paediatric unit and ICU of a single hospital. 6% of admissions suffered an ADE and in addition 8% of admissions experienced a near miss. As in other paediatric studies antibiotics was the most common group of medications causing ADEs. [61]

One of the most comprehensive studies of the prevalence of paediatric medication errors was also performed in Boston in 2001. This prospective cohort study detected a medication error rate of 5.7% and an ADE rate of 1.4%, of which 19% were preventable. This study involved nurse researchers detecting errors and ADEs and a review panel identifying the stage, severity and preventability. This study used a methodology developed in the Adverse Drug Event Prevention Study and thus direct comparison with adult data was possible. The most striking difference was the almost three times higher rate of near misses in the Paediatric study. As with previous studies, prescribing was the most common stage of error, with dosing the most common reason for error. Equally errors with the most potential for harm occurred most frequently in the neonatal intensive care unit.[17]Again and again each of these examples demonstrate that as with adult medicine the varying methodologies, ambiguous use of definitions and results expressions can lead to misinterpretation via poor communication.

One area that has received little attention to date is ambulatory paediatrics.[42] A study of parental administration of paracetemol and ibuprofen detected that 51% of the doses to be inaccurate, and that age less than one year increased the risk.[62] Kaushal et al using methodology similar to the Boston inpatient study identified that 3% of patients suffered a preventable ADE, 13% a non-preventable ADE and 26% a near miss. The majority of the ADEs were ameliorable (53%). [5]

In summary, the estimates for paediatric medication errors prevalence range from 0.5% to approx 6% of medication orders (the most common descriptive mechanism for errors). [17;59]The most common error type is a dosing error.[51] The inpatient ADE rate is between 1.3 and 6%, again expressed in the most common terminology,[17;61]and the outpatient ADE rate 16% with 26% of patients experiencing a near miss.[5] Furthermore as was demonstrated with the recent history of adult medication safety, the literature is strewn with examples of how poorly defined or expressed results or methodologies leads to potential confusion.

In summary, the exact prevalence of adverse events, adverse drug events and medication errors depends on both the definitions and the methodology used in the study. Care must be taken when interpreting results due to the different methods of expressing data, therefore extreme care must be taking when comparing between studies. Again clear communication of research findings is crucial to understanding this difficult area.

1.3 Communication and Errors

This section will attempt to examine communication in two further areas. Firstly, the resolution of the error and secondly mechanisms under development to prevent such errors occurring again. As with the research concerning medication safety much of the data are not available at present for children and so inference is needed from the adult literature.

1.31 Communication and the management of medication incidents

In the direct aftermath of a medication incident, the first step is that the acute medical needs must be handled. Although the medical management may be clear and straight forward, more

complicated and rarer events such as intrathecal Vincristine, which may result in fatalities, require utilization of a broader range of clinical resources. Gathering the necessary information to attempt to rectify the problem relies on communication. The literature may need to be accessed or conversations with experts held, in order to find the best solution to the acute problem. [63]

Secondly, there needs to be recognition that an adverse drug event has probably occurred. [36;64] Recognition relies very heavily on communication, because this relies on patient safety being high on the policy agenda at both a local and national level, and or discussed in the media. In the UK, this process started with the publication and dissemination by the Department of Health of "An Organisation with Memory" in 2000, which examined the causes of error, [65] and followed up with "Building a Safer NHS for Patients" in 2001 which examined implementation of prevention strategies [66] and "Making Amends" 2003 which looked at strategies to compensate error victims. [67] The creation of the NPSA [68] was a further step towards raising the profile of safety issues. It too has examined the causation of errors and the cost-effectiveness of strategies to reduce them.[69] But crucial to its remit is dissemination of patient safety messages to the grassroots in innovative ways, for example a campaign to reduce nosocomial infection has been initiated by using screen saver adverts on hospital PC's.[70] A recent publication "Medical Error" was mailed to over 40,000 doctors and contained very personal accounts by leading doctors about their own medical errors, in an attempt to highlight the issues, and encourage reporting of errors.[71]

Once an error has been recognized this needs to be communicated to both local and national bodies. [72] At a local level, this permits the initiation of further investigation of the causes of the error. Hospitals in the UK are currently using a traffic light system of error reporting to prioritise

such investigations. At a national level, this allows collection of data on the epidemiology of such errors, identification of trends and development of error reduction strategies. Thus, repeated occurrence of errors can be prevented with such a strategy in place. The recurrence of administration of intrathecal Vincristine, and the subsequent adverse events may have been avoided by such a system; as counter measures could have been instituted earlier if the extent of the problem had been recognized more speedily.[63]

Once a report is lodged, the process should then lead to a thorough investigation of the events leading to this incident. Various techniques-such as root cause analysis have been developed to understand the range of factors that contribute. These rely on investigators interviewing all those involved in the incident and teasing out the salient factors that led to the error.[73] These techniques are based on the principle of a "Culture of Safety" rather than "blame". [7;74] In the UK, this concept of shared responsibility is beginning to reach policy makers and local healthcare providers. For example, the development of the Medicines for Children and the Children's British National Formulary (BNF) demonstrate that the system has a responsibility to provide clear medication information to healthcare providers rather than relying on individual knowledge, and that this information should be paediatric specific.[75;76] Vincent outlines how to start the investigative process based on James Reason's error theory. First, the "unsafe act" that led directly to the incident must be identified, and then further work needs to be carried out to isolate the "latent failures" and "error producing conditions" that occurred. [77;78] For example, a child is inadvertently prescribed a penicillin based antibiotic, despite a previous allergic reaction. The "unsafe act" would be the prescribing of penicillin to a child who has probably had an allergic reaction already to such a drug. Contributory factors might include be the heavy workload, the time of day, the relative inexperience of the prescriber, and the failure of the

original doctor seeing the child to communicate clearly the potential allergic reaction to medical and nursing colleagues. Key to such a process is identification of those events that are specific to the incident and those which are more general.

The penultimate step in coping with medication incidents is talking with the family. This phase should involve three components; presentation of the results of investigation into how the incident came about, a thorough apology and information of how this will be prevented in future. [8;79] For many healthcare practioners this is a very difficult step. [80] Wu et al found in 1991 that 76% of house officers had not disclosed involvement in a serious error. [81] This is for a multitude of reasons: difficulty in formulating the communication, and or fear about the consequences. [82;83] However, this is a betrayal of patients' desires. Gallagher et al found that patients "were unanimous in their desire to be told about any error that caused them harm"; they were slightly more ambiguous in their feelings towards disclosure of near misses. [79] Data also seem to suggest that doctors' hold erroneous views that disclosure of errors will make potential financial penalties worse. Kraman et al carried out a case study in Kentucky. One of the Veteran's Administration (VA) hospitals had adopted a radical policy of full disclosure in the case of medical errors, even when the family / patient did not suspect an error. The experience of this hospital was compared to that of VA hospitals located close by, with similar characteristics but who did not adopt a policy of full disclosure. The study suggests that liability payments were comparable between institutions.[84] Disclosure may be more likely if healthcare practioners feel supported. Wu et al have coined the term the "the second victim" to describe the concept that healthcare providers are also affected by errors and need help after an event. [83]

The final step in the pathway for dealing with errors is dissemination of the findings of investigations, both to the patients and their families as mentioned and to a wider audience such

as other similar hospitals or units, both nationally and internationally. This prevents the repeated reoccurrence of similar events, which is a source of frustration to affected families, and clinicians. [85]

Examining each of these steps, it is clear that an underlying theme is communication. Communication is the key for clinicians and patients (or families) navigating the medication process and dealing with its failings. However much of the evidence for this is implied and attempts to provide clear unambiguous answers to the role of communication in the resolution of errors are just beginning with the work of researchers such as Kraman et al.[84]

1.32 How can communication prevent such medication related errors occurring?

1.321 The Patient Level-Communication Between Patients, Parents and Healthcare Professionals

At present, there is little information available that suggests that improved communication can prevent medication related incidents. However, there is evidence from projections based on analysis of the types of current errors that communication improvements could reduce errors. Fortescue et al noted that 47.4% of all inpatient medication errors could have been prevented by improved communication between doctors and patients. [2]

There is increasing evidence that whilst not all patients want more information, many do. [86] However, there is disagreement about how and when best to supply this information. [87] Some argue that doctors should act as "navigators" of the system for and with patients, others that information should be provided to allow true "shared-decision making". Some suggest that the

type of interaction and information exchange depend very much on the situation; shared decision making for example should be used in situations where there is no clear evidence base, [86-88] studies to date show that at present this ideal is not fulfilled.[89-91] Many doctors find providing information time consuming and unfeasible. Others question the benefit of providing complex data to patients- that it may actually be anxiety provoking rather than relieving. Even when doctors think they are fulfilling patient needs and supplying more information, it appears that they overestimate their ability to transfer information.[92] Increasingly the consensus is, that this information provision is crucial, not only to patients understanding their condition and or treatment, but the wider picture of uncertainty in medicine.[93] The UK has taken this very seriously, with the production of a series of initiatives aimed at improving the accessibility of medical information for the public: NHS Direct online and The National Library for Health are part of this drive.

However, in many ways the evidence base is not clear. Studies and reviews have shown benefit: for example data suggest that written reminders improve compliance with screening programmes [94] and the more personalized the written matter, the more used. [95] However, others have failed to show benefit in a range of outcomes – information for stroke patients and their families did not improve satisfaction nor did information improve psychological well being amongst cancer sufferers. [96;97] In part, the lack of clarity arises from the difficulty there is in defining the information used, in each study and in part, this is because of the heterogeneity of the situations studied.

A major factor, which can skew results, is functional health literacy (FHL). This is the term used to describe patients' / parental ability to understand everyday health related information. This factor is of paramount importance when the success of the communication depends on patients'

absorption of information.[98] FHL describes both the ability to understand verbally communicated health related information and information communicated in the written form.[99] Patients struggle with both verbal and written communication. In an American survey, 42% of patients could not understand instructions "to take medication on an empty stomach."[100] Patients with the lowest FHL have poorer health, [101] but are not easily identifiable, as there is a poor correlation between stage of schooling and functional literacy, [102] instead specific tests must be used such as Test of Functional Health Literacy in Adults (TOFHLA). [103] However, health literacy is more strongly correlated to health status than many other socioeconomic factors like employment status or educational achievement. [104]

Lack of understanding of the extent of poor FHL by healthcare providers has led to the production of written matter that is not appropriate for patients as it is beyond the average reading skills of 8th grade level. [102;105] Even on-line information is not well targeted. For example, RAND (a not for profit organisation that informs public debate by analysis and research) [106] assessed that 100% of studied websites written in English were at 9th grade or higher and six out of seven Spanish language sites presented information at, at least a high school level. [107] Furthermore Eysenbach et al noted that the quality of internet health sites is very variable. [108] Additionally, difficulties with gaining access to the required information on-line are underestimated.[109] Doctors can counter problems with FHL by identification of FHL levels, pitching information at the correct level and employing innovative alternative communication strategies such as videos, cartoons and multimedia-based tools, which have been shown to have high user satisfaction and some success in improving health outcomes.[110-112] The Department of Health is attempting to confront this issue with a number of pilots and projects. One such is "Its Your Life" a magazine aimed at young women from poorer backgrounds. Created by Dr Foster and the Department of Health, and available free through healthcare facilities and high street

outlets like beauty parlours and nail saloons. This is an attempt to not only provide correctly pitched information, but to ensure that the information is located in situations were the target group can access it. [113] This is particularly successful if young people are involved in the design process. [114]

The transfer of information is also affected by a myriad of other factors such as language spoken. Doctors may also play a role in reducing the negative consequences of language barriers by utilizing the best available source of interpretation. Failure to intervene in the negative effects of Limited English Speaking (LES) has been demonstrated to affect perception of care [115;116] and leads to increased use of services at higher costs. [117] This ideal situation is not always possible but professional interpreters improve satisfaction. [115] If professional in person interpretation is not possible, then a less clear picture emerges; patients prefer family members whereas physicians prefer telephone interpreters. [118] Language barriers are present even if both parties consider they are talking the same language; patients speak in "Everyday language" and doctors in "Medical language". Bourhis et al found that doctors thought they switched to everyday language and patients thought they switched to medical language, but neither detected the others' switch.[119] Further gains can me made even where LES is not present by training patients in communication leading to improved medical outcomes, including adherence.[120;121]

Studies suggest that improved communication is correlated with a higher recall of information, [122] and may improve compliance and reduced relapse of disease. [123;124] These are key factors in reduction of medication related incidents. Furthermore there is some evidence that the effect of communication goes beyond this to better health status [125] and reduced malpractice claims. [126] In the UK, improving communication between staff and patients has been shown to improve health hygiene -a tool kit developed by the National Patient Safety Agency (NPSA) including badges

for staff with "It's OK to ask" showed an increase in hand washing by staff. Staff were also pleased by the involvement of patients- 34% had been asked by a patient about hand washing. [127]

In paediatrics as previously stated, the doctor- patient relationship is a bi-way conversation but in paediatrics, it is a tri-way discussion. Despite evidence that communicating with the child directly, improves compliance and satisfaction [128] studies suggest that the child contributes only 10% of the consultation. [129;130] However, studies tend to concentrate on verbal communication and it may be that non-verbal communication is important to children. [130] The type of information transfer is also very different between children and their parents. Children are involved far more in information gathering than in decision making, [131]and far more in social and psychosocial issues than purely medical ones.[132] Tates et al suggest that this is because the combination of the parent and doctor align to inhibit child participation.[133] Tates goes further and suggests that whilst doctors attempt to moderate child involvement depending on the child's age, parents seem to restrict child involvement in general practice consultations "irrespective of their child's age".[134] Therefore strategies to improve this tri-way communication rely on acknowledging these constraints and overcoming them, for example by encouraging children's involvement in their health and heath care needs within the home.[135]

To summarize, during the patient physician interaction, many factors intertwine, including successful communication, to produce a successful outcome. Studies have examined many outcome measures, but as yet, the closest measure to medication error and adverse drug events appears to be adherence. This has been shown to improve if there is better information transfer and communication.

1.322 Communication between health care providers- How to reduce medication safety incidents

Identification of the scale of the problem of medication safety has led to the development of strategies and research into the best mechanisms to reduce the problem. [9;65] One of the keys to error reduction has been the change from a blame culture to culture of safety. This is a work environment in which it is accepted that actions occur as part of a system and errors occur because of a systems failure not just an individual failure.[7;74] Each of the central elements to this new model relies on improvements to communication; reporting of events and near misses (and developing systems to allow this to occur), investigation of these events, apologizing to victims, supporting staff involved, learning from errors and sharing this information.[8;136;137] As with the prevalence research, paediatrics is a few paces behind adult medicine, but increasingly where studies have replicated and or adapted adult work they have shown similar findings.

1.3221 Error reporting

Good communication underlies successful reporting systems, not just in the initial generation of reports but also in the crucial subsequent feedback to reporters of trends and solutions. Not only is this an example where communication can improve error reduction, but the very development of this idea relied on discussions with the aviation industry and subsequently extracting the relevant concepts from the aviation industry, which pioneered this idea and translating it to healthcare. The aviation industry developed reporting schemes, which are non-punitive generally voluntary and account to national regulatory bodies. If pilots report quickly, after an incident, they are eligible for limited immunity, in incidents that do not involve criminal actions. The aviation authorities decided that learning would only occur if reporting to the authorities were the norm.[138]

Within the US and the UK two very different approaches to reporting have been adopted. The IOM report considered reporting in healthcare in detail. Unlike the aviation industry's immunity the IOM report proposed that Congress enact legislation to grant peer review privilege to the data collected, in all but the most serious events.[9] The IOM also examined the type of reporting system required. The IOM proposed a nationwide mandatory reporting scheme. This was to collect standardized data, which would allow states to develop error reduction methodologies. Responsibility for data collection was to lie not with individuals but with institutions and there was to be phased introduction starting with hospitals and eventually encompassing all providers of medical care. Funds were to be made available to facilitate this. In addition, voluntary reporting was to be encouraged. It was assessed that the two reporting systems would work in symbiosis and provide complementary information. [9] These proposals were vehemently opposed by the AMA and the Institute for Safe Medical Practice (ISMP). Michael Cohen, the ISMP President, wrote that the two examples of mandatory reporting, that exist currently - the Safe Medical Devices Act of 1990 and the mandatory systems in place in some states, have not been successful. The Medical Devices Act has not achieved compliance by health care providers and the state systems use the information punitively.[139] The counter argument put forward by the IOM was that mandatory reporting is necessary for serious adverse events to permit accountability and to ensure that public confidence in the system be maintained.

Changes have yet to happen to the reporting systems currently in place within the USA. Currently, as mentioned there are multiple systems- some voluntary, some mandatory, some local and some national, some cover specific areas such as medical devices some are more comprehensive. The most similar to the IOM reports proposal is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Sentinel Events Reporting Program that

covers the full range of errors, is national but, " not entirely voluntary" because if the commission discovers non- reported events the consequences can be significant.[72]

In line with the IOM report, the American public believes that reporting should be mandatory. In the Kaiser Family Foundation survey 73% of the public felt government should require health care providers to report all serious medical errors and make the information public, while 21 % thought this should be done on a voluntary basis, to protect healthcare workers.[140]

The contrary approach has been taken in the UK. Within the UK, the NPSA launched its National Reporting and Learning System (NRLS) in February 2004. This is an anonymised voluntary reporting scheme. Data from local reporting schemes are fed directly to the NPSA; in addition, staff from health care institutions (and eventually patients) can provide reports. This allows the NPSA to "understand the 'how' rather than the 'who' and to ensure maximum learning."[141]However a recent review has recognized that whilst volumes of reports are being generated, these are of insufficient quality and furthermore there is inadequate feedback of emerging trends and solutions from these reports to the originators of the data.[142]

Whatever the type of reporting system adopted, the key to success is that reporting develops a dialogue between the reporters and the regulatory body. This must be a two way process. Reporting will be improved if conclusions from investigations are fed back to the grass roots and change as a result of the reports is seen.[72;139]

1.3222 Team Work

Research has also shown that error reduction can come from improved teamwork. At its core, this is an expression of the need for improved communication between the various professional

groups that make up any healthcare unit. Again, the healthcare system has learned from the aviation industry. Sexton et al identified that hierarchy and communication of concerns are also a factor in the healthcare arena. They noted that juniors, as in the aviation industry, in years gone by, felt too intimidated to point out potential errors, therefore putting at patients at risk. [143] The aviation industry has developed training to ensure that all those who work within the system feel empowered. Crew resource management is a technique designed to eliminate the negative effect of hierarchy and thereby reduce problems associated with poor communication. Specifically this is a technique used to breakdown communication barriers, and ensures that everyone feels that safety is their concern and it is their right to be involved. [144] It is starting to be used in medicine – in anaesthesiology, surgery and the emergency room.[145]

Other techniques have been developed to improve teamwork, for example, Leape et al re-engineered the delivery of healthcare on an intensive care unit at a tertiary referral hospital. A pharmacist began rounding with the medical and nursing team in the morning, remained on the ward during the morning and available on call the rest of the day. This was a change from previously where the pharmacist was less easily available to ward staff and primarily based within the pharmacy. Leape et al found a 66% reduction in the rate of preventable ordering ADEs in the study unit as compared with the control unit. As previously mentioned the ordering stage is the most common stage for errors in hospitalised patients.[36] Increased pharmacist involvement is one of the key recommendations of the National Quality Forum Consensus Report.[146]

Again following on from adult based research, similar interventions have been tried in paediatrics: introduction of ward-based pharmacists and improved communication between professional groups both of which were estimated to reduce errors by 86%.[2] Studies have also

looked at teamwork in emergency situations using scenarios. A prospective observational study using simulated paediatric emergency scenarios detected 17% of orders had no dose specified and 3% of orders contained a 10-fold error. In addition to ordering errors, administration errors were noted, 16% of the syringes' analyzed showed doses different from those ordered. One of the main conclusions of this paper is the need for training in scenarios and team building to ensure effective communication in real situations and improved patient safety.[147] This work follows on from a study in the ER, which identified that 10% of charts contained a medication error. In a logistic regression the risk of error was higher if the medication was prescribed by a trainee or for a seriously ill patient.[43]

Each of the examples of teamwork as an error reduction mechanism shows the importance of communication. In part, the mechanisms to improve patient safety are about breaking down professional or hierarchical barriers and ensuring that those with the most information are empowered to speak and have the opportunity to be heard by those who need to know.

1.3223 Technology

Technology is revolutionizing all stages of the medication system.[148] But whilst it is the computing power and software that are behind the benefit the reason that these new systems work is that they allow information to be accessible to those who need it more quickly and efficiently, i.e. improved communication.

At the ordering stage, the major change has been the development of Computerised Physician Order Entry Systems (CPOE) generally in association with Clinical Decision Support Systems (CDSS). Different computer systems exist which perform different functions but essentially CPOE allows automated prescription of medications. Computerization eliminates two of the

factors that contribute to error- illegible prescriptions and the need for transcription, because multiple users may utilize the information concurrently. Additionally, computers allow the insertion of prescribing rules, [137] which decrease the likelihood of error. Additionally if CDSS is enabled, targeted information may be given to prescribers, real time as they are prescribing to assist with decision-making. This may be overt such as provision of information on which antibiotic to use; or covert, such that the computer automatically assesses creatinine clearance (based on most recent laboratory results) and alters dosing choices in response to the result. Research has repeatedly demonstrated benefit from such systems, and acceptance of the benefit by users, [149]but it is important to note that whilst CPOE predominantly affects the prescribing or ordering phase some of the advantages are seen in other stages too, for example the verification stage. [150-152]

Unlike in adults there has been relatively little use of CPOE and or CDSS in paediatrics to date. Fortescue et al conducted a study in which they estimated the prevalence of medication errors in two academic medical centers. From this they extrapolated, that given that most medication errors occur at the ordering stage, CPOE with CDSS would have reduced the error rate by 76%. One study has introduced CPOE into two paediatric units of a hospital and found a 40% reduction in error rates, when comparing pre and post introduction data; however, no benefit was detected for ADEs. This is possibly because the study was not sufficiently powered to detect changes in rates of the relatively rare ADEs.[153] Information technology may provide further benefits to paediatric medication safety, specifically the development of smart pumps or computerised dose calculators. In particular, the outpatient setting may be an arena where information technology can play a role in improving health literacy. [47]

Automation is also developing at other stages of the medication process. Robots have been designed to permit automated dispensing. These systems require that medication is bar-coded, which allows the robot to identify requested medicines from a store, and present these to the pharmacist / assistant. Staff have been shown to look favourably on this new technology although there have been concerns expressed by some regarding their job security.[154] The IOM report also identified this automation as a good preventative step.[9] This system is not without problems, as yet not all medications have barcodes and so hospitals have had to invest in machines to provide these, which is time consuming and costly, but as the use of the technology spreads the impetus for universal bar coding to be provided increases. Equally there are a variety of barcode types and national standards may be required.[155;156] Bar coding and computer assisted dispensing has also been used on the wards. Here, medications are stored in cabinets that are managed by computers. Nurses either scan or type in patient details and are given access to patient medications.[157] Not only do these aid administration and reduce errors, but they also help to automate supply to the ward, again because of clearer and faster communication.[158;159] In the UK a recent Department of Health report has just confirmed the importance of bar-coding and called on clinicians, managers, industry and technology suppliers to work together to make it possible to use bar-coding in healthcare more easily.[160]

At the administration stage infusion pumps have been developed with integrated computers, which allow selection of preprogrammed options for individual drugs thus reducing calculation at the bedside. However, to date, use of these pumps has not been shown to reduce errors, but the equipment is in its infancy.[161] These pumps allow the information needed to calculate rates to be in the pump and so not dependent on the individual who is setting up the pump. Information at the fingertips, which is accurate and improves safety.

Finally, technology has been used at the monitoring stage. Clinicians require complex and up to date patient information to aid decisions, but accessing this information, particularly in a timely manner can be difficult. Poon et al looked at current practice and found that only 41% of doctors were satisfied with the current report result management[162] and Tate et al have developed systems to improve physician warning of potentially life-threatening laboratory results.[163]

Technology enables new and improved communication. [164;165] At the ordering stage it allows information to be conveyed to the prescriber real-time. Crucial information such as medication choice or dose choice is communicated along with up to date information on key patient based values. Although these are available without CPOE and CDSS, the breakthrough, is the ease with which this crucial information is available.[165] User friendliness is paramount, where CPOE implementation has failed one of the major concerns has been the lack of perceived user friendliness, leading to a lack of user buy in, in particular the possible additional time required to use the system.[166;167]Automation of dispensing systems in the pharmacy and the ward allows better communication between pharmacists and ward staff. Automation of result notification is probably especially important and can ensure that important data reaches the correct people in a timely manner, allowing faster action.[165]

It should also be remembered that whilst information technology has been shown here to demonstrate benefit in error prevention, information technology may also improve patient medication safety by enabling improved detection of medication errors and ADEs as well as allowing better communication once errors have occurred.[165] Information technology is not THE solution to medication safety; it is part of a complex and varied approach to the problem. In particular automation may bring with it new problems[168] and as the authors of a recent paper suggest, care must be taken to appreciate these new errors.[169]

1.4 Communication and medication safety

Many factors play into the production of medication related incidents, and as has been noted research is exploring a range of solutions. As this chapter has demonstrated, communication is the theme that runs throughout. The starting point of appreciating medication safety was examining the definitions and how they have emerged over time. Whilst this aids understanding, it is also the first example of the confusion that imprecise use of language can lead to. The exploration of the history of medication safety both adult and paediatric shone further light on this problem. Ambiguous use of terminology, methodology and expression of results has led to confusing data that is particularly hard for the novice or lay reader to interpret.

My examination of how the communication literature links with the patient safety research focused on two areas: the resolution of errors and secondly the prevention of errors. The data on how communication is involved in resolving incidents once errors have occurred are at the very early stages. Currently much of the information must come from inferences and from examining the results of policy changes rather than clear studies. However this is changing, work by Kraman et al looking at the effect on medical negligence payouts of a truly open apology culture in the VA system has shown clear benefit.

Work looking at the prevention of medication related incidents may be split into those involving communication between patients or families and healthcare providers and those involving inter-healthcare communication. The evidence of the benefit of communication to the former is based on inference and examination of the effect of policy introduction. Whereas, the data that form the basis of the role of communication in preventing errors involving inter-professional discussion is more robust, particularly the work on information technology.

Creating a health care system that is true to Hippocrates first principle is dependent on improving communication and understanding how communication plays a role in the development of harm.

Chapter 2 Materials and Methods

2.1 Introduction

The aim of this chapter is to describe the research methodologies used in this thesis and how these developed.

2.2 A Comparison of the US and UK Inpatient Medication Systems: Implications for Patient Safety IT and Automation

Living in a different environment was a novel experience and led to continual surprise about the differences between the US and UK healthcare systems. During the period in the USA, my research base was the Center of Excellence for Patient Safety Research, which is under the umbrella of the Division of General Medicine of the Brigham and Women's Hospital. This is a department, which has devoted enormous amounts of effort and time to patient safety research and in particular to medication safety work. Much of this work has looked at the role of automation particularly in the prescribing stage of the medication process. [4;170] Repeatedly questions were raised about the benefits of computerization and how this could be translated to the UK, given the ongoing national computerization programme in the UK- the National Program for Information Technology (now called Connecting for Health) under the leadership of the Department of Health and specifically Richard Grainger.[171] Examing the structure of the US medication systems it became clear that the lessons learned from automating this process were important for the UK, but only if the differences between how the two countries systems were structured were first investigated. It became clear that the idea of grafting innovations from one to the other required not only knowledge of the innovation but also of the two systems. It appeared that there was a paucity of such descriptions, when the literature was examined, in part because there is no one system even within each county. This then, was another example of how communication fails within the Patient Safety arena. Enormous amounts of important work have

occurred within the USA and around the world in how to integrate new automated processes into clinical practice, and yet the UK seems not to look to these in a clear fashion. It seemed that the UK might benefit from some of this work, as might the US.

A policy analysis of the different medication systems using case studies and an attempt to look at how new technological developments could be adapted for the UK, given the differences in systems seemed necessary. Furthermore, by an examination of successful and unsuccessful adoptions of technology, further insight might be gained. This would, it was hoped, be an attempt to communicate lessons learned from one system to another, in the early stages of a massive policy reconfiguration in the UK. As this is, an attempt to mould policy this does not follow the clear structure of the following two sections. The aim of this chapter is clear, but the methods used follow those of policy analysis rather than an analytical or descriptive study.

The analysis began by identifying the literature to date on medication systems in the USA and the UK. The search was limited to the inpatient system, in the main although the outpatient system is briefly described. This was done because at present most interventions have been based in this setting. [172;4;161;170] Whilst this study does not specifically address the paediatric medication system; given the additional complexities of paediatric medications the lessons learned from the adult arena are perhaps even more valid. In addition as outlined in Chapter 1 the introduction of paediatric technological solutions has been slow to date and thus, there are limited examples even within the USA.

Further to the study of the literature, visits to examples of the USA medication system were arranged: the Brigham and Women's Hospital and the Veterans Administration Hospital just outside of Boston; both leaders in the field of automation. Whilst it could be argued that these are

not sufficient to gain a full perspective of the USA system, this was not my aim. This chapter is an attempt to start a dialogue about the two different systems and in choosing hospitals and hospital systems at the leading edge and comparing them with the UK this will provoke such a debate. During the visit an attempt was made to follow the medication system from the initial stage of prescribing, through verification, dispensing and administration (in the case of inpatient medications). By discussing with health professional at each step an insight into the system was gained. This was mirrored by the development of a similar framework for the UK, based on the systems experienced as a junior doctor and the working knowledge of two senior pharmacists from the UK.

The literature search and the experiences were used to answer the question- How can the UK learn from the US experience of automation? This was based on the hypothesis that without the underlying knowledge of the systems understanding this could be difficult. With the fundamental knowledge, it would be possible to shed light on important lessons that the UK could learn. By using the well-established medication system steps, i.e. prescribing, verification, dispensing and admistration as the skeleton of a framework; each country's system was delineated. With the systems clarified, it was possible to start to examine the IT developments in the USA and to try to project the outcomes of transposing these ideas to the UK. Furthermore if examples of such translations existed these were examined to see of the predictions from the framework bore true. In particular, cases of successful and failed implementation, as defined by the authors of the case studies, were examined in an attempt to tease out the strands that lead to success.

This was my attempt to show how important trans-national comparisons and communication can be in the policy arena; if there is deep knowledge rather than a superficial grab of good ideas and ill-thought out attempts to quickly maximize benefit and is presented in Chapter 3.

2.3 Methodology for determining the role of information provision in the ambuiatory paediatric setting.

2.31 Introduction

After consideration of the literature base I realized that at present there were no clear examples from either inpatient or outpatient paediatrics of studies looking at the direct affect of communication on medication safety directly, rather than using proxies such as compliance.[94] Therefore, I started to formulate hypotheses that would allow an improved understanding of the role that communication plays in medication safety. The results of this work are found in Chapter 4. The largest study to date on paediatric medication safety was occurring in Boston at the Brigham and Women's Hospital under the guidance of Dr Rainu Kaushal. It was therefore in Boston that I based myself.

This study called Paediatric Outpatient Prescribing Study (POP) is an epidemiological study of MEs and ADEs. This was based on a similar study carried out within the same department but focusing on elderly adults. [3] POP aimed to determine the rates, types and predictors of medication errors and ADEs as well as to perform a randomised controlled trial to assess the effectiveness of an intervention to reduce prescribing errors (a computerised system). The project was to be based in 6 paired outpatient offices within the city of Boston. Offices were paired according to socio-demographics. The study was to consist of 2 phases (later extended to 3). Phase one was collection of data on current error rates and background information to help understand causation of incidents. Phase 2 was to be the implementation of the new computerised system in half the offices and reassessment of the error rates. Phase 3, which became possible after a further grant and co-development with a local investigator, is to look at the additional effect of a weight based prescribing system.

When I arrived, the project was into the second year of a 5-year grant from AHRQ. Phase 1 had just been completed. There was therefore a wealth of data, which had yet to be analyzed. However since I was not involved in the original study design the opportunities for examining my areas of interest where limited. The data that had been collected was extremely extensive, and it was therefore possible to design a secondary analysis asking the question specifically of the role of advice and information provision to parents and the affect that this had on the rates of errors occurring within the home at the administration stage. This is an area of immense importance, since most medications especially in children are taken in the home environment.

After becoming familiar with the study and the available data and in discussion with the team working on the POP study we generated a hypothesis; that effective and efficient communication of advice would reduce the prevalence of medication administration errors, in the ambulatory setting. The specific aims of the study were to analyze current advice provision by doctors and pharmacists, to parents and children regarding prescribed medications and to perform a multivariate analysis to examine if advice provision reduced reported medication related incidents, within the ambulatory setting.

The preliminary work for Phase 1 was completed in my absence; section 2.32-2.36 describes this work. Annexe 1 contains the data capture forms in the various versions that were in use at the time of my arrival.

Also prior to my arrival, the US equivalent of ethical approval was granted for the entire study.

2.32 Study Sites

In the United States unlike the UK, there is a separation of outpatient or ambulatory paediatrics and inpatient paediatrics. Children are reviewed regularly by primary care paediatricians. These are doctors who are educated to the equivalent of Senior House Officer (SHO) level in paediatrics. This means that from graduation as doctors they have worked one year as an intern (approximately equivalent to the old Junior House Officer) and two years as residents (approximately equivalent to SHOs). These doctors are based in clinics, which may be situated either in the community or occasionally still within the hospital system. These doctors act very much like British general practioners, seeing the children unless they develop either acute or chronic disease requiring more specialized intervention, when they are referred to hospitals. Practices vary in size across the country and many are increasingly using nurse practioners for routine appointments.

The POP study was conducted at 6 paediatric office practices within the Partners System and Children's Hospital System. Partners is an integrated network of care, which encompasses outpatient and inpatient facilities, including The Brigham and Women's Hospital and Massachusetts General. The Children's Hospital is one of the leading providers of care for children in the Boston area. The offices chosen where identified such that two came from each of the following neighbourhoods: poor urban, working class suburban and affluent suburb. Thus they were a stratified random sample. Two of the practices were academic i.e. they were associated with academic institutions and therefore staffed by paediatricians who had joint appointments, additionally these practices therefore had residents i.e. doctors in training, equivalent to Senior House Officers in the UK.

2.33 Study Timing

The data for this study were collected between July 2002 and April 2003. However, data were only collected from each of the paired offices for 2 months. Staffing levels meant that the two-month periods were not the same for each set of 3 pairs. Data were first collected from one pair for two months and then when this finished, the next pair was started and then the final pair.

2.34 Providers

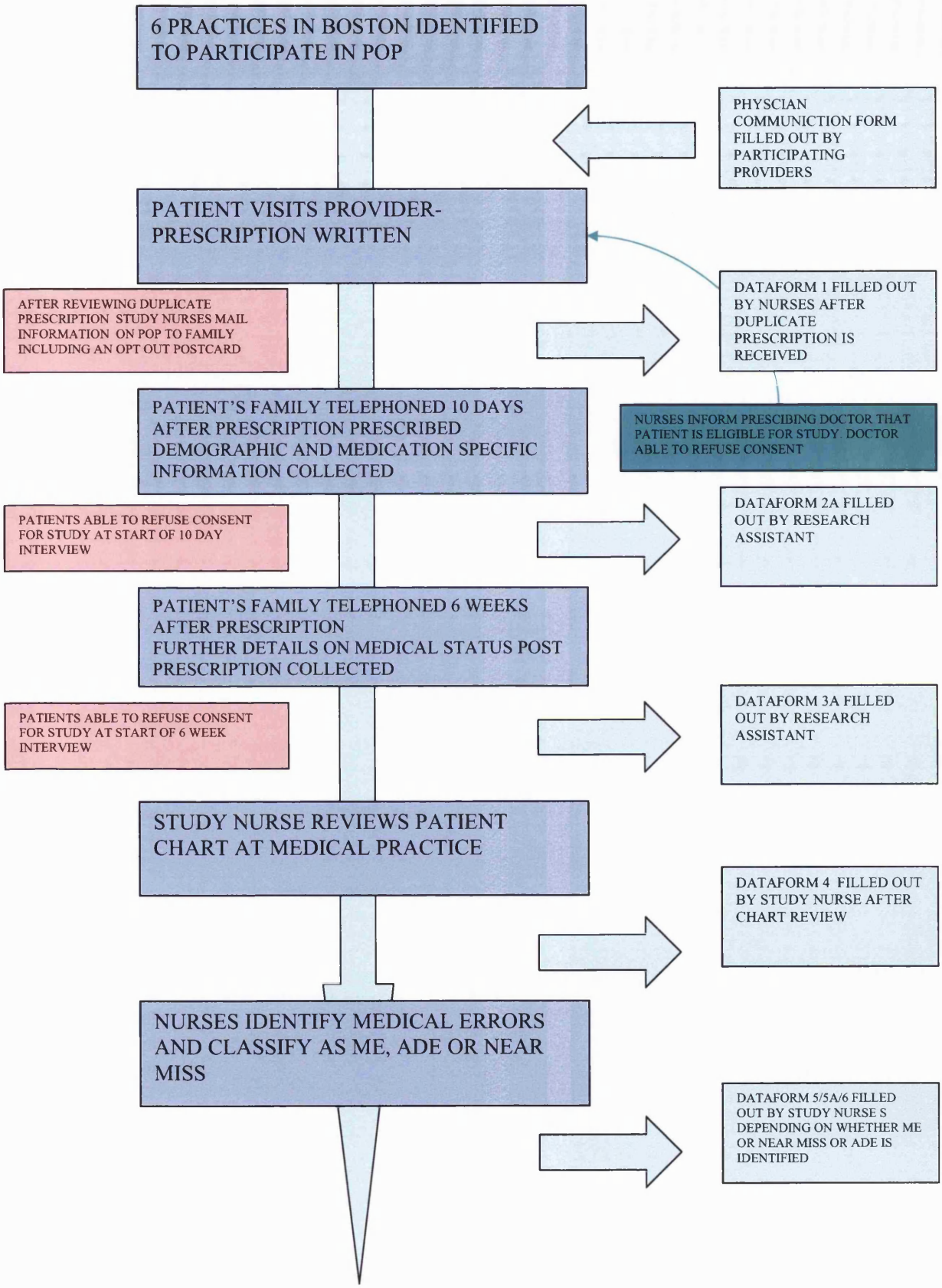
Data from analysis of the practioner make up were collected as part of the study, prior to my arrival. A questionnaire was sent to every doctor or nurse who was involved in the study, and is included in Annex 1. This questionnaire asked about the job status of the healthcare provider, i.e. whether they were a doctor or nurse practioner, years post training, and sex. As the study, involved academic practices the residents rotated through, so the number of providers was higher than might otherwise be expected. Each clinician had to consent to take part in the study.

These data were analyzed, descriptively by the team data analyst. They help to provide insight into the makeup of the providers of care, which could be relevant to the transfer of information between patient and provider. 132 physicians took part in the study, 66 (50%) were still in training, 53 (40%) had completed their training and 13 (10%) nurse practioners. Of those who had completed their training – the average was 11.7 years post training. 89 (67%) of the paediatric providers were female and the mean age was 39.8.

2.35 Study Protocol

See Figure 2 for schematic of protocol. During the study period, doctors at the participating office practices used duplicate prescription pads. A duplicate copy of each prescription written was sent to the study headquarters. The prescriptions were then reviewed by a research nurse to identify medication errors, for example unacceptable shorthand or illegibility; this was then recorded on Dataform 1 (See Annex A- Dataform 1 and Section 2.37 for further information). For all patients who met the inclusion criteria (See Section 2.36) information was sent to the parents of the patient (including a mail-in postcard to allow opting out) explaining the study, with the opportunities described to opt out.

Research assistants contacted the home caregivers, by telephone at 10 days, using Dataform 2A (See Annex A- Dataform 2A) and 6 weeks after the visit, using Dataform 3A (See Annex A- Dataform 3A) to administer structured surveys. Research assistants tried a minimum of three times, for each telephone call to contact the homecare givers for both interviews. The contact information was provided by the office practices. The research assistants were trained by the study coordinator in the necessary questionnaires, they were asked specifically to work evenings and weekends to try to ensure that telephone calls had more chance of success. Full records were kept of those who did not take part in the study and if possible there reasons for declining.


6 PRACTICES IN BOSTON IDENTIFIED TO PARTICIPATE IN POP
PHYSCIAN COMMUNICTION FORM FILLED OUT BY PARTICIPATING PR0VIDERS
PATIENT VISITS PROVIDER-PRESCRIPTION WRITTEN
AFTER REVIEWING DUPLICATE PRESCRIPTION STUDY NURSES MAIL INFORMATION ON POP TO FAMILY INCLUDING AN OPT OUT POSTCARD
DATAFORM 1 FILLED OUT BY NURSES AFTER DUPLICATE PRESCRIPTION IS RECEIVED
NURSES INFORM PRESCIBING DOCTOR THAT PATIENT IS ELIGIBLE FOR STUDY. DOCTOR ABLE TO REFUSE CONSENT
PATIENT'S FAMILY TELEPHONED 10 DAYS AFTER PRESCRIPTION PRESCRIBED DEMOGRAPHIC AND MEDICATION SPECIFIC INFORMATION COLLECTED
PATIENTS ABLE TO REFUSE CONSENT FOR STUDY AT START OF 10 DAY INTERVIEW
DATAFORM 2A FILLED OUT BY RESEARCH ASSISTANT
PATIENT'S FAMILY TELEPHONED 6 WEEKS AFTER PRESCRIPTION
FURTHER DETAILS ON MEDICAL STATUS POST PRESCRIPTION COLLECTED
PATIENTS ABLE TO REFUSE CONSENT FOR STUDY AT START OF 6 WEEK INTERVIEW
DATAFORM 3A FILLED OUT BY RESEARCH ASSISTANT
STUDY NURSE REVIEWS PATIENT CHART AT MEDICAL PRACTICE
DATAFORM 4 FILLED OUT BY STUDY NURSE AFTER CHART REVIEW
NURSES IDENTIFY MEDICAL ERRORS AND CLASSIFY AS ME, ADE OR NEAR MISS
DATAFORM 5/5A/6 FILLED OUT BY STUDY NURSE S DEPENDING ON WHETHER ME OR NEAR MISS OR ADE IS IDENTIFIED

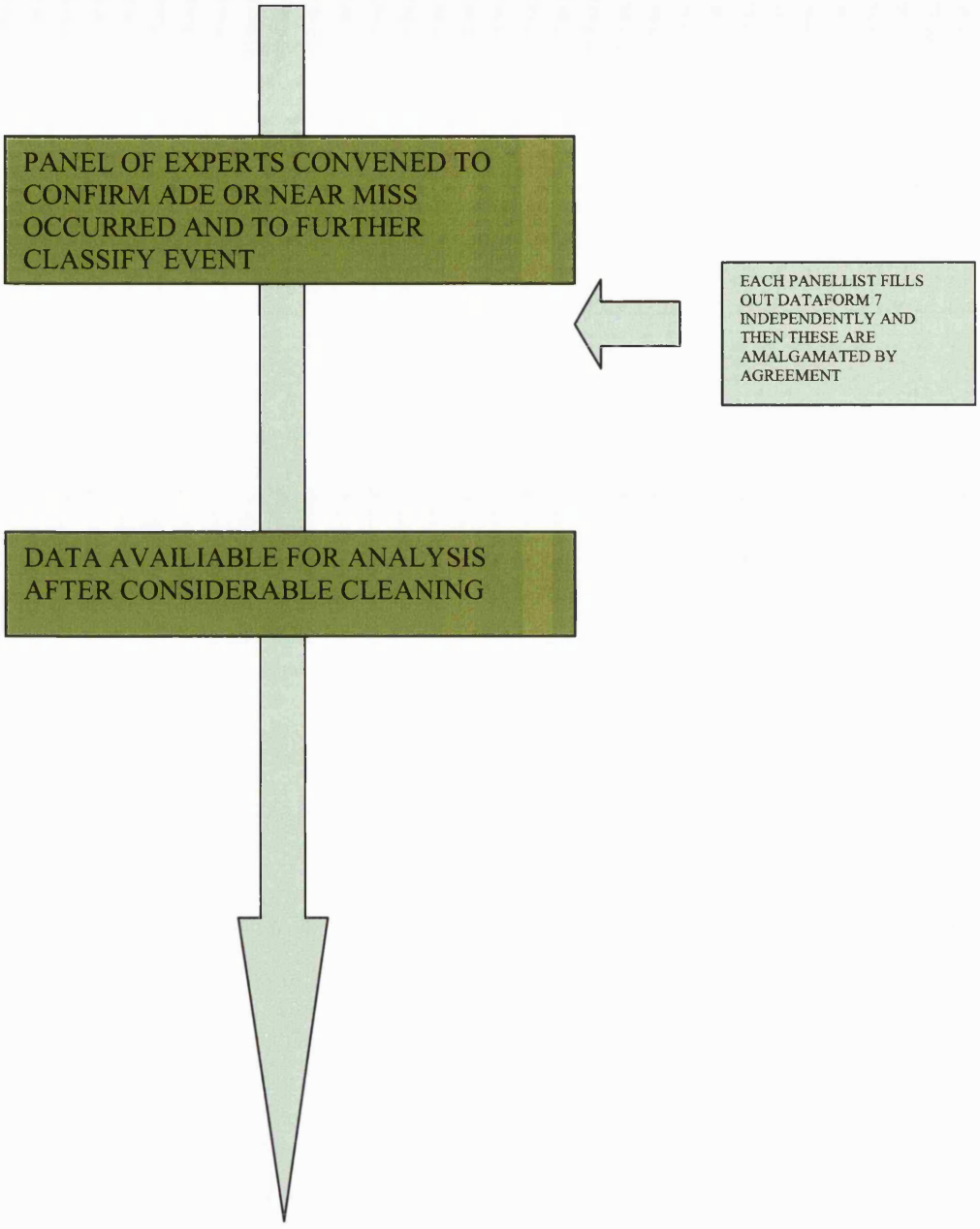


Figure 2: Diagram of the stages of data collection in POP

BLUE BOXES – DATA COLLECTION PRIOR TO MY ARRIVAL

GREEN BOXES – DATA COLLECTION AFTER MY ARRIVAL

PINK BOXES- OPPORTUNITES FOR PATIENTS TO REFUSE CONSENT

The surveys were pre-tested and refined using focus groups, prior to my arrival in Boston. The 10-day survey collected information on patient characteristics, the process of medication prescription, dispensing and administration from a caregiver perspective, and essential demographic data. The survey also asked about additional medications that the child was taking; both prescribed and "over the counter" (see Annex A -Dataform 2A). The follow-up survey at 6-weeks asked further details on potential complications from medications (See Annex A - Dataform 3). If permission was not granted by either the doctor or the patient/ parent or the exclusion criteria were met then no further data was collected.

To ensure identification of adverse drug events, research nurses reviewed the medical charts of study patients. This meant after a patient had agreed to be part of the study and had taken part ideally in the two telephone conversations, nurses visited the offices and reviewed each chart. Information was used to fill out Dataform 4 (See Annex A -Dataform 4). Whilst the original aim had been to only do this time-consuming review on cases where both telephone conversations had occurred; the difficulty with coordinating a paper based system, irregular working hours of research assistants and the need for multiple attempts to contact parents meant that some reviews were carried out which were subsequently not able to be used, because at least the first telephone conversation had not occurred. The medical reviews allowed the nurses to collect further data on patient medical histories and medication regimens.

Data were collected on medications other than those prescribed at the initial visit, for example questions were asked about ongoing medications not re-issued at the target visit. See Annex 1. However as there was not a prescription for these medicines there were limited data, thus although these medications contributed to the total number of medications that a patient was taking they could not be used or considered as index medications. These medications were

termed non-target medications, and were excluded from the logistic regression because prescribing data were not available on these medications. Although we still kept the data on these medications, for future analyses.

2.36 Subject Characteristics

Within the paediatric office practice system, patients are usually cared for until they leave full time education, although this is often negotiable. Therefore, all patients under 21 who were prescribed medication at an office during the study period were eligible for inclusion in the study. Any patient who visited the paediatrician or nurse practioner for any reason such as flu or an asthma reoccurrence was eligible to be included. During the study period, the health care professionals involved were given new prescription pads that had carbon copies. Therefore, when they prescribed a medication, such as an antibiotic a copy of the prescription was made which was then collected by the study nurses from the offices on a regular basis. The original prescription was then given to the patient in the usual way so that the script could be filled by the local pharmacist.

Exclusion criteria were prescriptions for the treatment of sexually transmitted diseases or oral contraceptives. These medications were excluded to prevent breaking patient confidentiality when parental interviews were carried out. Part of the data collection process involved collection of further demographic information and data on the medication administration technique and complication from the medications; on the patient and their family via telephone conversations with a parent or the patient if they were over 12 and chose this. It was therefore thought unethical to speak to parents/ patients concerning prescriptions which the patients may have wished to keep confidential.

Repeat visits to the physician during the study period (even if further medication was prescribed) were excluded, so as not to overburden families with repeated questionnaires. Therefore, if a patient went to see the doctor on day one of the study about a headache and was given analgesia, this triggered potential inclusion in the study. If the patient or parent agreed, then the rest of the protocol, to be described subsequently occurred. If however on day 35 of the study the patient re-presented to the doctor with an infected toe, this visit was not eligible for inclusion into the study. The study was designed like this because for each medication additional data were required from the patient or parent such as number of doses actually taken. It was felt unduly burdensome to ask families for such information twice on separate occasions, therefore subsequent visits with prescription were excluded. However if the visit was still connected with the original visit, e.g. in the case above a stronger analgesic was needed, then these data was added to the original case by the study nurses as part of the review of the medical chart (See Figure 2).

Healthcare practioners were informed daily, by email, by the study nurses who had collected the prescriptions, which patients were eligible for the study and were given the opportunity to refuse permission. Patients were also excluded from the study if they did not speak English, Spanish or Cambodian, as there was not sufficient survey staff fluent in other languages, to permit the telephone survey to be carried out, which as mentioned was required to collect administration data and demographic data. If patients did not have a home telephone, they were also excluded.

Patients and home caregivers were informed of the study at the time of the visit by information leaflets and were able to opt out of study either through returning a postcard sent out by the study nurses after a script was identified; or at the start of the telephone interview.

2.37 Incident Classification

After the nurses had completed Dataforms 1 and 4, and had received the telephone interview forms –Dataforms 2A and 3A, they were able to identify if errors had occurred, by consulting the training manual (See Annex 1) and by using the US equivalent to the BNF for children. If there were errors then Dataform 5, 5A and 6 were available (See Annex A-Dataforms 5,5A and 5). Dataform 5 was filled out if there was a medication error. Dataform 5A was used if there were multiple errors. If an ADE was suspected then Dataform 6 could also be used. Not all forms were used each time; even Dataform 6 could be filled out without any other form, if the ADE was a non-preventable ADE e.g. a patient prescribed penicillin correctly but who had their first allergic reaction to it.

All queries and all near misses and ADEs were presented by the nurse researchers to a review panel. The panel consisted of two physicians, who independently reviewed the incidents. These panels were convened when a sufficient number of incidents had been collected- approximately monthly. In general, the reviewers were physically present in the same conference room although on occasion they were done using a telephone or video conference link. The nurse researcher presenting the data would describe the incident, using Dataforms 5, 5A and or 6 and then each researcher would fill out Dataform 7 (see Annex A -Dataform 7). Each reviewer filled in his or her own independent copy of this form.

This took about 15 minutes to fill in and a separate form was used for each event. So, for example if a patient had an asthma inhaler prescribed at the index visit and the parent acknowledged giving the wrong dose and also omitting a week of treatment then two Dataform 7's would be filled out. Events were classified into ADEs, near misses or re-classified back to ME status. Further, sub-classification according to severity, stage in the process at which they

occurred and preventability occurred. The reviewers opinion on how the errors could have been prevented was also sought using tick box system (See Annex A-Dataform7). Options included CPOE, changes in training and or changes in communication. After each reviewer had independently decided on how to categorize the incident, the case was discussed and consensus reached. [11]

When I joined the program, the Phase 1 data was still being reviewed by panels and so I was taught how to be a physician reviewer using the training manual and mock reviews. I therefore participated in a large number of reviews. The reviews from Phase 1 are part of the data presented in Chapter 3. However, I also participated in panels for Phase 2. Whilst these data are not used in this thesis, participation helped improve my understanding of the complexities of medical errors.

After data had been collected and processed as above from all 6 practices the data were then sent to a data inputting firm who transferred the data to a computer database. The data was returned from the company as an interogatable Access file. However, when this data was needed for statistical analysis it was converted to a SAS file. This was then used by myself, Dr Kaushal and the data analyst- Cathy Yoon to perform the necessary analysis.

Whilst the data were a rich resource, the fact that Phase 1 had been planned and was well underway, but not yet complete, when I arrived did present a number of problems. Firstly as mentioned, I did not design the questions nor the study methodology. Secondly, as this was a project in evolution the data collection forms were subject to a number of re-writes during Phase 1 data collection, thus the data were in a confused state, for example, there were three versions of Dataform 2A in use for Phase 1 (See Annex A -Dataform 2A). This meant question numbers in

different versions did not refer to the same information, meaning that data had to be re-arranged by hand, by the data analyst and myself. Furthermore categories had been updated during revisions, for example ethnicity and so decisions had to be made about re-grouping again carried out by myself and the data analyst, in discussion with the project team.(See Annex A- Dataform 2A 3 versions)

Thirdly the data entry company had not, as anticipated been close to completely accurate and therefore the data required extensive cleaning and so I spent time returning to the original paper copies to ensure accuracy. Therefore, I checked the accuracy of data by comparing random samples and queried data with the original forms.

2.38 Statistical Analysis

All parents who completed the 10-day survey were eligible for inclusion into this analysis. Of the 1782 patients enrolled 1685 (or 95%) completed the 10-day survey and had a chart review. Only patients who completed the 10-day survey and had a chart review were included in this analysis. This was because without both the survey and chart review crucial data were lacking. Reasons for lack of chart review included unobtainability of the medical chart. Descriptive statistics were used to estimate the prevalence of medication administration errors, near misses and ADEs, and expressed as the fraction of patients who suffered a medication administration error. We also described the information provided to patients and reasons for lack of information provision.

We then performed a univariate analysis, comparing patients with administration errors to those with no administration errors. From these analyses, all variables of clinical significance were included in a multivariable analysis to determine the unique contribution of each factor in

predicting administration errors. For this analysis, the main outcome of interest was a binary response indicating the presence or absence of any medication administration error. The main predictors were the type and place of advice. We therefore examined if provision of information on medication indication, side effect and written information in either the pharmacy or the office affected the likelihood of an administration error. The model adjusted for patient attributes (e.g. race and ethnicity, proficiency in English, presence of a chronic condition and total number of current medications), parental characteristics (e.g. socio-economic status as shown by educational status and family income) and provider characteristics (e.g. type of provider, and continuity of care). Univariate analyses were carried out using chi-squared tests, and in one case Fisher's exact test because of small sample size. The multivariable analysis was by a logistic regression using SAS Software, version 8.0. $p<0.05$ was considered significant.

2.4 Methodology used for study to examine the role that the media plays in paediatric medication safety.

2.41 Introduction

The idea for the results presented in chapter 5 developed during the course of my work on the POP study. The realization grew that improving patient safety relied on a number of intertwined factors. Firstly the change from a culture of blame to a safety culture, and with this the changes and improvements described in Chapter 1. However, this was part of a delicate balance; true change had to occur within the public. Part of the driving force for the way that medicine is practiced, particularly in the USA is the need for defensive medicine to ensure that medical negligence litigation does not occur. The current systems mean that doctors try naturally to prevent mistakes occurring, perhaps by doctors acting more cautiously or ordering more tests, or even by restricting the type of patients or cases seen.[173] Rosenbach et al estimated that 20% of

surveyed doctors had changed practice as a result of medical negligence/insurance liability cost concerns.[174] This is driven by the high payouts that are provided to patients who suffer harm in the USA and thus the high premiums that doctors have to pay to protect themselves. This is not just true of the USA however; in the UK whilst the overall burden of litigation is less, the trends have been the same as for the USA or Australia. The NHS spend on clinical negligence has grown from £242 million in 1998–99 (2002 £) to £446 million in 2001–02 and continues to grow. [173] Therefore all three countries have had to actively pursue strategies to reduce this, in part by commissioning governmental policy reviews, such as in the UK – *Making Amends a review by the Chief Medical Officer.*[67] Examing the literature however it seems that other systems exist that are not just less adversarial but also perhaps more equitable. [173;174] To break the cycle of medical negligence requires a paradigm shift; not just in the legal system but also in the public's willingness to accept that errors are part of practice and should be treated as such.

This led to questions about how this could be possible, but more specifically how the public's opinion was formed. Who was getting across messages to the public, was it researchers and the painful slow steps that they made in examing and improving patient safety or was the public message being heard only that of terrible medical disasters like Wayne Jowett and his death due to intrathecal Vincristine.

Reading around the subject led to an examination of how the concepts of medication safety and in particular paediatric medication safety were communicated to the public. The decision to focus on the media came from the realization that this is a crucial mechanism through which the public are informed. Although others such as the internet or advocacy, groups are important. [175]After realizing the resource and logistical implications of such work, discussions were had

with qualitative research experts to develop a small area which would give be a manageable window into this topic.

Examing the literature on opinion generation, it became clear that similar questions had been asked about the world of cigarette smoking.[176-178] Researchers have developed a meticulous methodology for attempting to look at the newspaper coverage of the tobacco industry over time.[176] Paediatric medication safety was different in many ways from this topic, primarily because it is a new area of discussion and a relatively small one compared to the tobacco industry. However, the literature base did allow the development of a methodology to start to answer these questions. The focus for this piece of work was to be the question – Does the written media present the topic of paediatric medication safety to the public in a fair manner, or is the slant of the articles biased? This was an immensely complex question requiring learning of many new qualitative skills and the results are presented in chapter four.

The aim was therefore to understand paediatric medication safety and the media, specifically through examining newspaper coverage, to understand what the public sees.

2.42 Sample

Newspapers were chosen as the medium to be examined because it is possible to readily search published stories. News articles on the topic were located using an online version of the media part of Lexis Nexis (accessed through Countway Medical Library), an international database of news articles, which covers a wide spectrum of both newspaper types and origins. This is one of very few online resources that cover an enormous cross-section of worldwide media and is interogatable. To quote "LexisNexis® is a leading provider of information and services

solutions, including its flagship Web-based Lexis® and Nexis® research services, to a wide range of professionals in the legal, risk management, corporate, government, law enforcement, accounting and academic markets." [179] The media arm of Lexis Nexis is one of the main sources used by journalists researching new topics for articles. The availability of data defined the search criteria to some extent; as did the relative newness of the field of patient safety and particularly paediatric patient safety. The search was limited to the 10 years from 1994 and 2004, because this was the time when the field of medication safety burgeoned. All articles that were identified were located. However this database is extremely non-user friendly, the search engine was antiquated and liable to miss articles, unless meticulously searched. It was not possible, for example to search the whole of the USA, so each key word had to be searched for each region separately. Discussions with librarians with a special interest in literature searching did not reveal other more user-friendly search engines, and so the decision was taken to continue to use Lexis Nexis and accept the limitations.

The strategy used was very broad; the terms used were used in multiple combinations to try to overcome the limitations of the searching function. If available links to other articles in series were followed up to add to the total. Search terms had to be altered for each country for example "paediatric" converted to "pediatric" for North America. All newspaper articles from the USA, Canada, UK, Australia and Ireland that contained the keywords "paediatric," "infant," "child," or "adolescent" in combination with "medication," "prescribing," "dispensing, or "drug" and either "error" or "mistake" were included.

2.43 Coding Variables

The origin, date of publication, newspaper, article type (news article, editorial or letters) was noted. Furthermore, the articles were categorized by event type and article slant. Event type classified the actual story reported into four categories, negative, positive, mixed and neutral. For example, a patient death would be classified as a negative event. The article slant is the skew of the report written about the event for example; if the article overstated the event, this would be a negative slant. This methodology has been employed previously for example, by Durant et al in their examination of the formation of public opinion on smoking. [176] To account for varying country size, the total number of articles for each country was divided by the country population. The population for each country came from national census data, from websites from each of the countries national data collection agencies, for example in the UK the census data are collected by the Office for National Statistics[180]. Initially it was hoped that, it would be possible to use estimates of readership instead of the cruder use of total population, as was done by Durant et al. However, the original paper covers articles from within the USA only and thus allowed for such calculations; it was not possible to do this for a study, which covered such a wide geographic distribution. Also, and perhaps more importantly it was felt that such numbers are becoming increasingly incorrect, many newspapers absolute readership as calculated by sales is no longer representative of true readership, which includes on-line readers.

The articles were also coded using a more qualitative approach. First, articles were coded according to the four main themes (or combinations of themes): patient incident, research, policy or other. To assess overall classification reliability, a second independent researcher re-assessed a random sample of 30 of the articles. The second reviewer coded the articles according to slant and type, as well as theme. A PubMed search was also carried out using the same keywords that used for the LexisNexis Search. This permitted an approximation of the amount of published

research that has been occurring within the topic of paediatric medication safety, during the same time period, and thereby allowed a comparison of the trends in the newspapers with the trends in research.

The second part of this study was an evaluation of the content in more detail. These codes were developed from initial assessment of the news articles, using Atlasti.4.2. This is a qualitative research program, which stores data and keywords. Essentially, the user allocates keywords and highlights important areas of text. It is then possible to search the database for all the items, which share the same keywords, the articles could then be grouped by keywords. Atlasti is capable of more complex functions such as, producing hierarchies for these codes, and some qualitative researchers go on and produce nodal diagrams showing interactions between documents, to aid their understanding of the complex content. For this project, each article was key worded with initial keywords; further readings of the data allowed creation of more detailed keywords. This approach is based on the principle of qualitative research- Grounded Theory.

This allowed an assessment of the extent to which the media framed articles within the context of a culture of safety. The research examined whether the media presented the public with the three key tenets of a culture of safety. First, to what extent did the news articles portray adverse events as systems failures? Second, did the cases described in the news articles illustrate best practices for providers for dealing with adverse events? It is acknowledged that after an adverse event occurs, there should be an apology to the family or patient, a thorough investigation of why the event occurred; and institution of polices and procedures to prevent repeat occurrences.[176] This is directly linked with the final concept that examined. Third, to what extent was the concept of shared learning prominent within articles? Shared learning is the term used to explain that adverse events and near misses must be seen as opportunities for learning. Thus, not only should

the care providers directly involved with the adverse event learn from the event, but there is also a duty to disseminate this knowledge. Equally, learning cannot occur unless adverse events and near misses are reported, and we coded articles for incorporation of this concept.

2.44 Analysis

The data collected were presented in a number of ways. All the data was analysed in a descriptive manner. The numeric data on the event type and article slant were tabulated. The distribution of articles by theme, temporal relationships and distribution by nationality were presented graphically. The data from the PubMed search were also presented graphically. The qualitative data examining the content of the texts were presented as continuous prose.

Chapter 3: A Comparison of US and UK Inpatient Medication Systems: Implications for Patient Safety IT and Automation

3.1 Introduction

This chapter examines communication between researchers and policy implementers in the United States and the UK. The time that I spent in the USA and planning the research in the USA made me acutely aware of the differences in the US and the UK medication systems and the degrees of automation. This chapter examines how the information gleaned in one system could be used to influence the policy development in another, were it to be communicated correctly. This means understanding the nuances and subtleties of the system that the innovation came from and the intricacies of the new system and therefore allowing the melding to occur. Given the development of Connecting for Health in the UK, the most ambitious computerization project to date worldwide-this is an important time to understand the US medication system from which many innovations spring and how this differs from the UK system. Examining how these innovations might be altered for the UK and looking at some of the successes and failures of the US in adopting new technology, might help the UK learn without making not only the same errors, but errors due to incorrect or inappropriate transfers. This is therefore an attempt to communicate the lessons of one system to another, the US is a good domain to focus on because so much of the innovative solution work is being generated and implemented there. Many have described the US as a laboratory of innovation, due to the unique mix of well-funded health services research and the independence of the individual states.

As detailed in Chapter 1 failures of patient safety and in particular medication safety have been demonstrated to be an important and costly problem facing countries worldwide.[24;33] Both the USA and the UK amongst other countries are now grappling with how to improve patient safety and in particular medication safety. In the UK "An Organisation with Memory", focused attention on the problem and in the USA "To Err Is Human" was similarly groundbreaking. [9;65]

In the USA the National Quality Forum has produced clear guidelines aimed at reducing harm to patients.[146] In the UK the NPSA supports both research and dissemination of error reduction strategies.[68] Research on improving medication safety has now led to interventions at all stages of the medication process.[1;15;16;181]

However, the two countries are attempting to improve medication safety by changing very different medication systems. The process of prescribing, dispensing and administering medications in the hospital setting is designed to permit the transfer of the prescribers' wishes safely into action and this process has been described as the medication system.[158]

3.2 Methodology

This is a policy analysis using case studies of each country's medication system, examing technological breakthroughs and how these might be adapted for the UK given the differences in the two systems. Furthermore, by identifying successful and unsuccessful adoptions of technology, further insight can be gained which is relevant to the UK. This is an attempt to communicate lessons learned from one system to another, at a very important time in the development of the NHS – full computerization.

The analysis began by identifying the literature to date on predominantly inpatient adult medication systems in the USA and the UK. The reasons for this are expounded in the methods section -2.2. The use of the adult system is considered further in Chapter 1.
In addition to the study of the literature, the understanding of the US system was developed from visits to two leaders in the field of automation: the Brigham and Women's Hospital and the Veterans Administration Hospital just outside of Boston. This is by no means a complete

exploration of the medication systems available in the US, but these systems are leaders in the field. The case studies were developed by following the medication process from start to finish helping create an overall picture. Discussions with health professional at each step allowed further insight into the systems. The UK framework described on both my experience and that of senior pharmacists from the UK.

The literature and the case studies were used to answer the question, how can the UK learn from the US experience of automation? First, this required understanding the countries systems and then looking at areas where each country has progressed and comparing this to the other. A further development was the study of cases of failed or successful implementation, as sources for leaning valuable lessons.

This chapter is a step to improve the transfer of research and ideas from the US to the UK. This is just the beginning, since the USA is not the only country that the UK looks too, and each country has a slightly different medication system. In addition, the analysis is based very much on generic wards; specialities such as oncology have altered medication pathways.

3.3 The Medication Systems

3.31 The history

After identification of high rates of medication errors-approximately 15% in the 1960's in both the USA and the UK [21;22] providers attempted to reduce the problem, though divergent methods were used in the two countries. In the UK, efforts were directed at improved documentation, leading eventually to the combination of the prescription form and the Medical Administration Chart into a single paper document known as the Drug Chart, which streamlined the process, and

took out the transcription step. (See Annex 2 for an example) This has not been used in the US, where instead effort was focused on implementing unit dose dispensing. [39] Unit dose dispensing is still not widely used in the UK because of the success of the Drug Chart. Unit dose dispensing describes the principle that safety could be achieved by increased control by pharmacists. Every dose that was administered in the USA needed to be vetted by a pharmacist. Instead of nurses taking the necessary doses from a stock, they received the exact amount from the pharmacy for a named patient.

During the 1970's the USA's approach to the reduction of medication errors was to restrict access to medicines thereby increasing control of the medication supply, and to minimize error by providing wards with medication in a ready to administer form. These changes were partly driven by payment issues.[182] This led to the removal of medication stocks from the wards and the development of unit dose dispensing. In the 1980's with the end of fee for service the high cost and labour intensive nature of these systems led to the introduction of unit dose dispensing 24-hour cart exchange programs, a limited move back to a ward stock. Physicians continued to order drugs in the same way they ordered radiographs and pathology (on physician order sheets), which included carbon copies for the individual departments. The pharmacy generally recopied these orders, and then dispensed the individualized prescriptions and delivered them daily to the ward, to be held in drug carts. To further limit error, pharmacies dispensed drug use information with each medication. So instead of individual doses being sent to the ward when needed, limited stock was held on the ward, but still each individually checked by a pharmacist and for named patients. Pharmacies in larger hospitals were required to be open 24 hours 7 days a week to supply drugs. This also enabled them to perform other functions such as mixing all intravenous preparations at many sites. Handwritten medication administration record charts (MARs) were prepared by clerical or nursing staff transcribing details from physicians' orders

onto paper MARs.[18] By 1992, 95% of US hospitals were using the unit dose system, with 64% having a complete unit dose system and comprehensive intravenous admixture program-many with nearly all intravenous preparations being prepared in the pharmacy.[183] Over time these systems have been modified to a partial unit dose system – where the nurses select the unit doses to be administered.[39] Finally, patients at discharge in the USA are given prescriptions for "new medications" which the patient typically must fill on their own.

The UK, in comparison, chose to focus on changing the process of documentation to reduce errors rates and developed a document, still in common use, known as the Drug Chart, which acts a combined physician order and MAR. Doctors prescribe directly onto the drug chart, which nurses then use to record administration. In order to ensure that the drug charts stay on the ward with the patients at all times, ward pharmacy services were introduced with pharmacists visiting the wards on a once or twice daily basis to check drug charts and supply any items not held as floor stock. Hospitals aimed to have at least 80% of doses available from floor stock. Pharmacists initiated patient specific supply by transcribing orders onto pharmacy held stationery, which was then taken to pharmacy, and used to supply non-unit doses packaged drugs for 7 to 14 days, i.e. bottles or packets of medicine rather than sets of individualised doses. Pharmacies were not routinely open for 24 hours, because of the emphasis on floor stock. [22] This had the result that functions such as central intravenous admixtures are relatively infrequent in the UK, where nurses prepare many of the intravenous preparations. In the UK, patients leave hospital with a two-week supply of all their medications already dispensed. Not all these medications will be "new," and some will be the actual medication packets used in hospital. Increasingly with the era of medication reconciliation, some of this stock may even be part of the stock that the patient brought to the hospital at admission. This makes it easier for the patient to

get their medication, and decreases medication waste. (See Tables 1-3 and Figure 3 for further details)

3.32 Case Studies

See Figure 3 and Table 1-3

Table 1. Differences in Hospital Medication Systems – Prescribing

	Hospital: USA	**Hospital: UK**
Who	Doctor	Doctor
How	On electronic CPOE system with Decision support	On paper Drug Chart that is also the MAR.
Medication Administration Records	• Computerised MAR.	• Paper Drug Chart • Rewritten by doctor every 14 days / when full
Drug history assessment	• Taken by doctor at time of admission. Supported by computer records.	• Taken by doctor at time of admission. And supported by previous paper records
Reconciliation of hospital drug history with primary care record at admission and discharge	• Reconciliation just started to occur	• Pharmacist confirms drug history with patient against current medication supplies and where necessary contacts both PCP and community pharmacy to clarify queries • Assesses patient's own medicines for continued use on the ward.

Table 2. Differences in Hospital Medication Systems Pharmacist screen and Supply

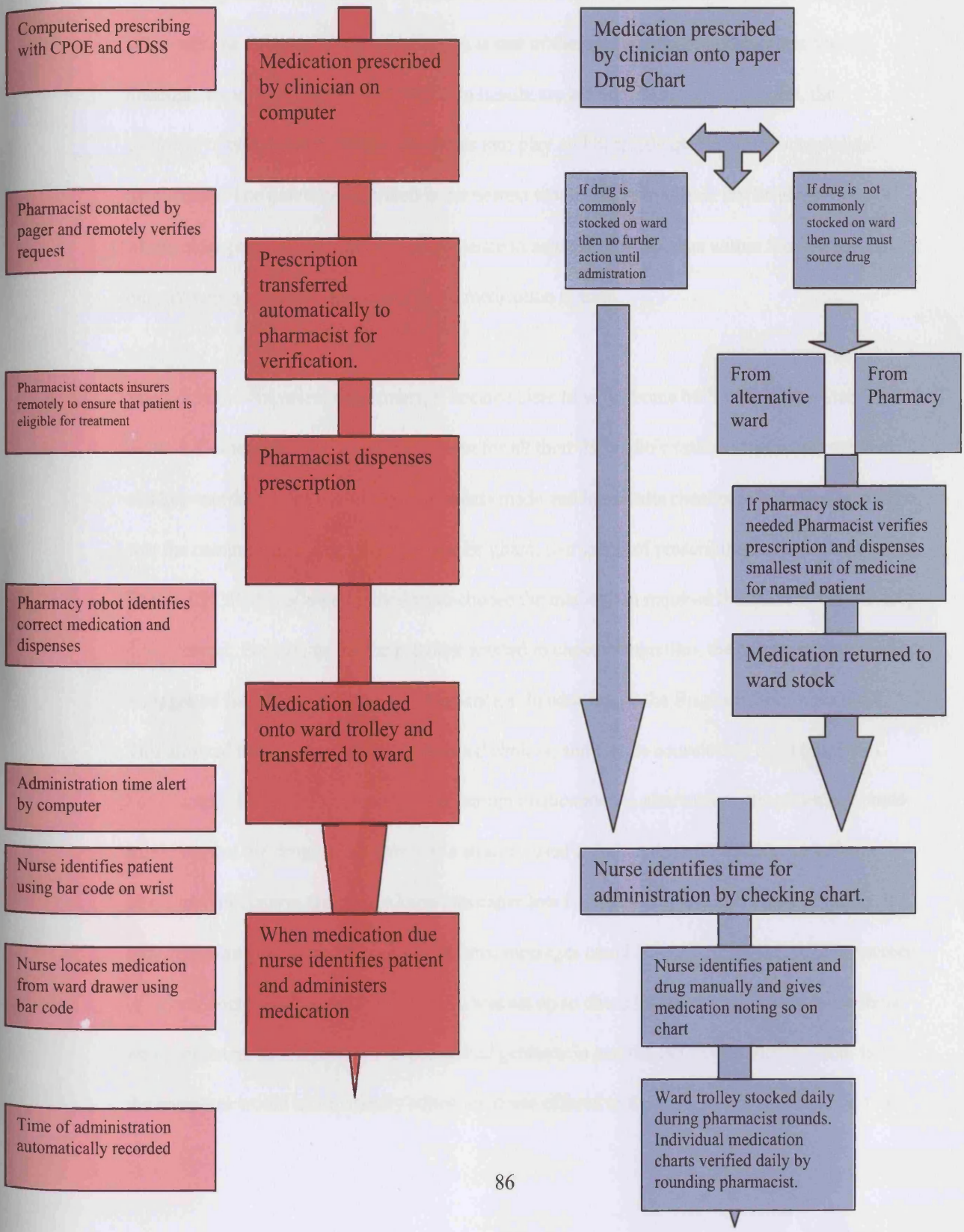
	Hospital: USA	**Hospital: UK**
Pharmacist screen/ Verification	• Hospital policy requires each new order to be checked and authorized by a pharmacist before a nurse can administer • Pharmacists carry tablet PCs and pagers which allow them to quickly verify orders • Pharmacy runs 24 hour 7 day prescription verification service	• Clinical pharmacist visit wards periodically (usually daily) to check and authorize prescription and to initiate supplies of medicines not held as ward stock. • Nurse can administer medication prior to pharmacist verification
Drug supply and storage on the wards	• Floor stocks of commonly used drugs held in automated ward cabinets. Patient profiles of cabinets updated when pharmacist verifies order – only then can nurse access patient profile for that order • Items not held as floor stock are dispensed for 24 hours in unit dose packs.	• Floor stock of commonly held drugs held in non-automated cupboards, lockable bedside cabinets and trolleys. • Items not held as floor stock are dispensed in 28 patient packs for storage on ward
Initiation of supply	• Electronic verification of order automatically • Either, updates patients profile in ward automated cabinet so that drug can be accessed • Or triggers generation of unit dose label in a dispensary for immediate dispensing	• 90% of doses are available from floor stock and can be accessed immediately after order written • If not on ward patient specific drugs will be ordered by the pharmacist on their next visit, which will occur between 0 and 24 hours from order being written or, a nurse will bring the drug chart to pharmacy to request supply.

Table 3. Differences in Hospital Medication System-Administration

	Hospital: USA	**Hospital: UK**
Timing of delivery	• Individual patient times • Nurses aware because drug changes on computer screen and alert shows	• Standard timed drug rounds four times a day • Nurse/ Patient must be aware/ check chart for changes
Who administers	• Patients named nurse	• Nurse doing drug round
Checks	• Single nurse administration for all drugs except narcotics and cytotoxic chemotherapy	• Single nurse administration for all drugs except narcotics and cytotoxic chemotherapy
Identification	• Nurse identifies patient from name band and matches with MAR via barcode	• Nurse identifies patient from name band and matches with drug chart visually
Documentation	• Automatically registers on computer	• Nurse signs drug chart • If not given reason stated • PRN meds time/ signature/ amount noted

Figure 3. A comparison of the US and UK in patient medication system

Pink= USA Blue=UK



3.321 The Brigham and Women's Hospital- The Future?

At the Brigham, as described the medication process was followed from start to finish, interviewing staff along the way to ensure that a thorough understanding of the system was achieved. The Brigham along with the VA is one of the most automated hospitals in the US although not uniquely so, as the benefits to healthcare are becoming more apparent, the competitive nature of US healthcare comes into play and hospitals quickly follow successful innovations. The pathway described is the newest that exists even within the Brigham Hospital where older paper MAR's are still in existence in some wards, whereas within the VA this is the only system- i.e. a completely automated medication system.

Starting in the outpatient department, it became clear how the home built computer system worked. Doctors used the computer system for all their daily clinic tasks. Notes were recorded and key-worded on the system, appointments made and lab results checked. Of particular interest was the computerised prescribing. At the Brigham, two levels of prescribing were in place. Firstly, CPOE, this allowed providers to choose the medication required from an easy to use drop down format. For example if the provider wanted to choose ampicillin, the computer would offer a suggested list of doses, routes and frequencies. In addition, at the Brigham there was CDSS. This allowed the clinician to make informed choices, some were consciously done others not. For example, by diverting prescribers of certain medications to alternatives, the pharmacy could subtly control the drugs used. This was a strategy used to help reduce C. difficile rates, by directing clinicians to antibiotics known to cause less Pseudomembraneous Colitis. Equally, if a new drug was discovered to have side effects, messages could be enabled to flash onto the screen to inform doctors. More subtly the system was set up to check lab results before the prescribing was completed, so if a patient was prescribed gentamicin and the lab results showed renal failure, the computer would automatically adjust the doses offered to the clinician, to those safe in renal

failure. The computer was also able to spot interactions that the clinician might miss. In particular, it was apparent that the clinical interface was user friendly, and yet behind this façade was incredibly complex computing power integrating information unseen by the healthcare providers. More than this, it was apparent that the meticulous planning that had gone into creating the system was leading to immense real time benefit for clinicians. The system helped their practice, because it was designed with them in mind. Discussions later revealed that not only did clinicians develop the original system but also that updates were clinician led. For example, oncologists wanted to develop a program for oncology prescribing in response to a tragic medication error, which led to a death. A group was set up of clinicians and technicians and the system created which is now in widespread use. The Brigham has taken this still further, by teaching post-graduate courses on medical informatics, to ensure that clinicians are trained to speak the language of IT specialists and enable systems to be developed that meet real clinical need.

After the prescription is written a paper copy is given to the patient and a computerised copy sent to the hospital pharmacy, in case the patient should choose to have the drug dispensed in the hospitals own pharmacy. The wards have a very similar system in place, here the information is automatically send to the pharmacy, for verification and dispensing.

The pharmacy therefore has two domains inpatient and outpatient. Tours by the Chief Pharmacist and a Research Pharmacist enabled an understanding of how these processes combine in practice. Technology is at the core of both areas. For example, outpatients were issued with pagers so that they did not need to sit in the pharmacy waiting for their scripts. Wherever the prescription was sourced from the information was then fed into the pharmacy robot. The pharmacy robot is a complex combination of computer power and storage system. Drawers full

of bar-coded medications are stored ready to be dispensed when required. Once a prescription is transferred to the system the robot is able to translate the information using bar codes and extracts the correct medication, ready for verification and delivery to the ward or patient. Bar codes are becoming an increasingly common phenomenon in medical life. Pharmaceutical companies use bar codes to identify packets of medicines but few use bar codes for individual doses. The US system requires that each dose be dispensed separately for inpatients and so to accommodate this, the hospital has a separate room where each pill is separated from the box and bar-coded.

During the dispensing system, pharmacists use the internet to contact the myriad of health care insurers to assess that the patient is eligible to receive that particular medication. Once the medication has been authorised by the insurers, dispensed and verified, the prescription is either handed to the patient, for an outpatient prescription or transferred to the ward for an inpatient prescription. Outpatients are recalled to collect their medications by the paging system, and after the pharmacist checks their identity and receives any outstanding co-pay, the medications are given to the patient. The inpatient doses are put into the ward storage cupboard. Each drug in a separate bar-coded drawer. The whole cupboard once stocked with the needs of the individual ward patients is returned to the ward by the pharmacy technician.

On the ward, when it was time for a patient to receive a dose the nurse was alerted via the computer screen. The nurse then took the storage cupboard to the patient. The patient was identified using the bar code on the patient's wristband, and a hand held scanning device. Once the unit was sure that the patient was the correct patient, the drawer with the medication to be given opened. The nurse then scanned the medication and the dose could then be given. Correct

dose, correct patient. In addition, the exact time the medicine was given was recorded automatically.

These systems therefore required 24-hour pharmacy presence and close contact to the pharmacists who therefore carry pagers or clamshell computers with remote access, to enable swift verification, because no order can be processed without their authorisation.

The Veterans Administration hospital worked on a very similar way, although they did not use the pagers in the pharmacy. The exact system used was different, as they too have developed their own in house. In addition, unlike the Brigham, the data including medication records was available throughout the VA system because one computer system is used. This reduces problems when patients see clinicians in different settings. Thus, a patient seen in LA one day could be seen in San Francisco the next and the clinician has access to a complete record. The same system also allows benchmarking between institutions and even individual clinicians, and is used to drive quality improvement. For example, rates of influenza vaccination prescription can be monitored against standards.

3.322 The UK

The description below is an amalgamation of visits, working experience in two hospitals in the UK, a District General Hospital and a Teaching Hospital and input from two UK based pharmacists. In the UK, in the inpatient setting, as explained in Section 3.2, medications are prescribed by the doctor or nurse prescriber on a medication chart. (See Annex 2 for an example). The doctor writes the drug, the dose, the timing and the route. The nurse then checks the chart. If the drug is a common drug such as an antibiotic, the drug will be stored on the ward in a drug trolley or if it is a drug that the patient is already on, the stock may be held in a locked

cabinet by the bedside. Increasingly patients are encouraged to bring their current drugs with them to hospital and these drugs are used in the hospital to avoid confusion and reduce costs. Therefore, only if the drug is unusual or the trolley stores are exhausted is the chart sent to the pharmacy. If the drug is available on the ward, the nurse will check the drug, often with a colleague, and then administer the drug to the patient at the correct time. This is then manually noted on the drug chart. The nurse's signature and the time of the dose are recorded. To ensure that the correct patient is given the dose the nurse checks the prescription against the patient's name badge. The pharmacist visits the ward on a daily basis during the week, to ensure that the ward trolley / cabinets are adequately stocked and to check through each chart to ensure that there are no errors. The pharmacist signs by each drug so that all know that chart has been reviewed. If errors are found these are discussed with, the relevant staff and amendments made.

If the drug were not available on the ward then the nurse would send the chart to the pharmacy. Here a pharmacist checks the chart (although not necessarily the pharmacist nominally attached to the ward, and therefore not necessarily one with specialist knowledge of that area.) The chart is signed if all is correct and the medication sent to the ward with the patients name on it. Ward stock are not individually named. The nurse then administers the drug as before. At night, if the drug is not on the ward the nurses may try to source the drug from other wards or from an emergency drug cupboard, to which the night sister has the key. If the drug is not found in these places and is needed urgently, then usually an on-call pharmacist will come into the hospital, often from home and dispense the drug. Unlike the US, system pharmacists are not therefore compulsorily resident on call in all hospitals. As with the US system special care is needed when prescribing, dispensing and administering certain drugs such as chemotherapy agents and often-special systems are in place for these drugs.

In some hospitals such as the Hammersmith there has been the adoption of the pharmacy robot to aid the process of dispensing, however the overall schema remains as detailed. So that once the drug is located and dispensed by the pharmacy robot the drug still returns to the ward to the drug trolley. Porters carry the drugs to the ward.

3.4 The advances made in the USA

Both the USA and the UK have much to learn from the others' medication systems, in particular with respect to how information technology can assist in improving patient safety. The USA and UK have, to date, adopted technology to different degrees into their medication systems, partly due to the underlying differences in these processes.

Within the USA, research has identified the importance of automation of the prescribing stage. Many US studies have focused in particular on the role of computerised physician order entry systems and decision support software, (CPOE and CDSS). Bates et al demonstrated that CPOE in combination with increased pharmacist participation on the ward reduced non-intercepted serious medication errors by 55%.[4] Connecting for Health has as one of its medium term goals introduction of CPOE, but few hospitals currently have electronic prescribing. However, unlike the USA where introducing computerised prescribing has had such substantial impact on errors the introduction in the UK may produce more modest reductions in errors. This is because when the paper MAR was in existence prior to the adoption of CPOE there was the need for repeated transcribing from the doctor to the nurse medication chart. In the UK, there is less transcription as the nurses and doctors and pharmacists use the same chart- the drug chart. However, as this is a paper record there is a finite amount of space, even in those charts, which have been converted

to multiple pages. (See Annex 2 for example). This means there is an element of transcribing often by a junior doctor, often in hurried situations. Furthermore, the change to the computerised model does eliminate another source of error, poor or illegible handwriting; so whilst the gains may be less they should still occur. To date there have only been isolated implementations of CPOE in the UK. Connecting for Health is yet to reach this stage of the implementation. However, where it has been tried there have been reductions in MEs. A rate of 6.7% pre introduction and 4.8% post introduction, re-enforcing the above reasoning. [184]

A further study by Bates et al examing the introduction of CDSS in a time series analysis showed that non-intercepted serious medication errors fell by over 86% when baseline was compared with the final time period. During the four time periods increasingly complex decision support became available.[150] CDSS has been shown to improve medication error rates but studies have been insufficiently powered to identify the effect on ADEs. [152] This may well be the mechanism by which the most benefit is seen in the UK. Firstly, UK hospitals use formulary based approaches to the exact drugs prescribed. CDSS will allow the pharmacy more control over the everyday prescription of medications. For example if X statin was on the formulary then only X statin would be permitted to be prescribed unless cleared by the pharmacy. Equally with hospital acquired infection rates rocketing in the UK- there are now over 5000 cases p.a. of MRSA bacteraemia compared to less than 1000 in 1995 [227] and evidence suggesting antibiotic choice affects incidence of such diseases such as Clostridium difficile; [185]controlling the types of antibiotics may have a profound impact.

The uptake evidence in the USA is also a lesson to the UK. Even within the USA uptake by hospitals is occurring slowly. The AHSP 2004 survey found that 4.2% of hospitals were using a CPOE system, with larger hospitals more likely to do so, although many other hospitals plan to implement soon. Decision support was present in 73.6% of these hospitals.[186;187] Whilst the UK has yet to start this implementation, the goal is for all healthcare providers both in hospitals and primary care to have access to such computerized support; this will be funded and overseen by government through Connecting for Health. Early trials are occurring at the Charing Cross where the ServeRx system is in place, this is made up of three elements: electronic prescribing, ward based automated dispensing and electronic drug trolleys. To date the number of prescribing errors has been found to be reduced from 3.8% to 2% and errors at the administration stage fell from 7 to 4.3%; implying that national adoption of such systems would have considerable impact on error rates. [160] The fact that systems are to be adopted nationally in the UK may well cause faster progress than the USA where individual institutions or systems must make their own decisions and investments and therefore lessons from the UK might be of benefit to the US if the systems exist to enable the communication. The recent creation of Office of the National Coordinator for Information Technology (ONCHIT) could be seen to be an attempt to follow a more British approach.[188]

CPOE reduces prescription errors and transcription errors; in addition it can facilitate improvements in dispensing and administration.[4] Research has shown benefits for a variety of other computer-based tools at the verification and dispensing stage. Robots have been designed to permit automated dispensing. These systems require that medication is bar-coded, which allows the robot to identify requested medicines from a store, and present these to the pharmacist / assistant. The IOM report also identified this automation as a good preventative step.[9] About

8% of hospitals in the USA use robotic dispensing systems; again uptake is related to hospital size. [186] Within the UK hospitals are starting to use robotic systems such as the Charing Cross and Addenbrooke's. At the Charing Cross after installation of a Swisslog Pack Picker automated dispensing machine clear benefits were seen. The rate of dispensing errors fell from 2.7% to 0.9%, time taken to pick items was reduced, stock control increased, as did storage capacity (by 23%), however there was no impact on time taken for labelling and assembly of prescriptions or turnaround time for discharge prescriptions. [160] It may be that the process is simpler in the UK than in the US. This is because whereas in the US individual doses are needed to be bar-coded to fulfil the unit dose model in the UK packets will simply need to be coded, and this is often done by the manufacturers whereas unit dose coding is not. This will be cost beneficial to the UK as in hospital bar coding could be avoided. The UK following other nations also means that much of the efforts to encourage standardization of bar-code systems will have been initiated already.

Bar-coding and computerized medication administration records have also been used on the wards, although only limited evidence is available about the impact of this to date. Bedside bar coding is just starting to be used with 1.5% of hospitals currently employing this technology.[186] Another technology is automated dispensing devices. To date there is only one trial of this in the UK, at Charing Cross. [160] With these, medications are stored in cabinets that are managed by computers. Nurses either scan or type in patient details and are given access to patient medications.[157] Not only do these aid administration and reduce errors, but they also help to automate supply to the ward.[187]Within the UK there has already been considerable interest in automation of pharmacy processes, but save for pilot studies, like that mentioned, utilization of bar coding during administration has yet to become standard practice. Again, as the UK does not demand each patient to have their own individualized mediations the automation of the drug trolley may be easier. However as there is starting to be a trend toward using patient's own

medications in the hospital it may be that the UK system is slipping closer to the US, and so the actually systems used in the US, may be of more relevance to the UK in the future.

At the administration stage, infusion pumps have been developed with integrated computers, which allow selection of pre-programmed options for individual drugs so that the nurse can be warned if they attempt to deliver too high a dose, and also allows tracking of high doses and overrides. However, the first large trial of these pumps found that an early version did not reduce the error rate, although it did allow identification of a large number of clinically important errors that could not otherwise have been detected. [161] In the UK equivalent pumps are beginning to be used for particular regimes such as patient controlled analgesia, although prevalence figures are not available, and they are currently not being used broadly. This may be one area in which direct importation of technology is possible because the two systems are similar here. However, unlike in the US where intravenous admixtures tend to be made up in the pharmacy many are made up in the ward in the UK and so the similarities are not absolute.

Technology has been used at the monitoring stage. Clinicians require complex and up to date patient information to aid decisions, but accessing this information, particularly in a timely manner can be difficult. Poon et al looked at current practice and found that only 41% of doctors were satisfied with the current report result management.[162] and Tate et al have developed systems to improve physician warning of potentially life-threatening laboratory results.[163] To date this is not yet occurring in the UK, partly because paging systems are not as automated as the USA – web based paging is not the norm in the UK. In the US it is possible to page a doctor within a hospital through the internet. This means that it is easier to link result systems to the paging system than in the UK. This is a key example where direct transfer would lead to no

benefit, but adapting the system or moderating the UK system first would allow a successful technology to be applied to the UK.

To summarize at each step of the medication pathway information technology is starting to play a role particularly in the US. Many of these technologies have been shown to improve patient safety. However, they are not directly applicable to the UK, unless the differences in the system are acknowledged and addressed prior to implementation. The value of understanding the two systems and communicating the differences is therefore evident.

3.5 Lessons Learned

See Figure 4.

Figure 4. Shared learning about Information Technology and Medication Safety

What can the US can learn from the UK

- Interoperability
    - The UK is developing a UK wide system, which will be completely accessible from any NHS medical provider within the UK.
- National Patient Safety Agency
    - Oversees research and policy to create one body with responsibility for safety
- Drug Chart
    - The integration of prescribing and administration facilitates care

What the UK can learn from the USA

- Introduction of CPOE and CDSS
    - High profile successes and failures have provided ample opportunities for learning.
        - Early multidisciplinary involvement in the development and implementation of IT is crucial.
        - The system must be easier and quicker to use than previous systems.
        - The system must be specific to the needs of that institution/ department.
- To innovate

  New technologies are being developed for all stages of the medication and these rely on understanding the problems and developing novel solutions.

The UK can learn much from successful and unsuccessful introduction of information technology in the USA. With respect to CPOE, Poon et al surveyed hospital management at hospital within the USA and found that three areas were important to successful implementation. Firstly, overcoming physician resistance; hospitals that succeeded had strong leadership, identified and utilized physician champions, recognized and addressed workflow related issues and listened to the feedback of house staff. Secondly, using outside influences and charting the benefits of CPOE helped overcome concerns that the investment required was too large. With respect to choosing the correct product, Poon et al suggest that this can be done if the vendor is fully committed to the hospital and is willing to adapt the product for the individual situation.[189] A recent series of newspaper articles in the UK, highlight the concerns with the Connecting for Health, both by the public, some reports quote that more than 80% of the public are concerned with privacy of information issues and the doctors themselves, today, only 17% of doctors admit to enthusiasm for the program down from 47% four years ago. These concerns cover worries about how the new system will work in practice, worries about protecting patients' confidentiality; but also the immense cost.[190;191] If Poon el at are correct them implementation is already in difficulty unless something is done to win this war of opinion.[189] Poon et al make a third point, concerning the importance of systems designed to the specific needs of institutions. With a national program, even one split into regions there is a risk of this important point being ignored in the rush to ensure introduction.

Implementation failures also provide important lessons. Cedars-Sinai hospital in California was forced to suspend implementation of this technology, due to the unpopularity of the system. [192;193] In an earlier effort, the University of Virginia Medical Centre experienced an extremely difficult implementation, which was only finally successful after hospital staffs' concerns—

mostly about how long it took to perform key functions were addressed. In particular, it was the formation of senior management committees that met regularly to review and act on feedback from the implementation, which ultimately ensured the success of this project. [166;194] In retrospect, it has been acknowledged that the planning stage prior to implementation was a key weakness. In particular, there was insufficient involvement of the key staff groups who would ultimately be required to use the system.[194;166]Again with a national system and a background of increasing mistrust of the new programs the risk of this is high. Connecting for Health is seeking to address the inadequate involvement of clinicians now, but this is may be too little too late.

The UK can also learn from previous attempts at trans-Atlantic translations. Limited attempts at introducing CPOE to the UK have not always been successful for a variety of reasons, including the differences in the formularies.[39] During the late 80's doctors became enthused by the idea of computerisation of healthcare, spurred on in part, by US models. The NHS Executive responded to demand by developing the HISS pilots. One of the earliest of which was at Greenwich General Hospital. The pilots were in the main, provided with technology solutions by US companies, eager for a foothold in a new market. This early enthusiasm was not without cost though, and a National Audit Commission Report, showed that the pilots had been mired in procurement problems and delays. Ultimately, this led to the reduced financial benefit expected from such schemes; worse still the rush of other hospitals to get on board led to a hotchpotch patchwork of IT provision around the country- with no connectivity and repeated similar delays and problems. Whilst not specifically involving medications this computerisation project could be construed as a precursor to Connecting for Health, and it seems that where HISS failed this was because the US companies merely transposed systems between the US and UK. Greenwich has one of the most computerised hospitals to date, many feel that this was because as the first HISS pilot huge

amounts of effort were put into making the system fit the need; something that was lost in subsequent cash strapped, and time pressured projects; ironically one of the most successful companies at creating this tailoring was a young UK company- iSOFT. [226]

During the 1990's a number of pilots of CPOE linked to automated drug cabinets were started. Almond et al introduced a CPOE system with an automated drug cabinet to one ward of a hospital in the UK. Although the implementation was successful, feedback from the staff was negative. The new system was found to be more time-consuming for doctors, nurses and ancillary workers. The problem was sufficiently serious for doctors to express a desire to return to the older paper system. [167]

It should be noted that translation of ideas is not restricted to the UK and USA. Many of the new automated systems being introduced into the UK come from the Germany as their medication systems are more similar. Similarly, CPOE systems come from Australia, Israel and Singapore.

Furthermore, it should also be noted that translation is not a one-way street, as alluded to earlier; the UK has many attributes that the US could learn from (See Figure 4).

In particular, having a nationalized system of healthcare means that adoption, if well planned, may be faster than the US and more coordinated, so all institutions will be able to link data together through a "spine" unlike in the US where even the most integrated systems cannot communicate with institutions outside of their partnerships. Secondly having the NPSA and other national bodies may make the whole patient safety agenda more successful. [142]

3.6 Conclusion

Initial attention on patient safety in the 1970's led to the US and the UK developing different systems to deliver medicines within the hospital setting. Now, again there is a focus on patient safety this time with the hope that technology may provide at least some answers. The US is trailblazing, in part because of the massive investments and in part because the nature of the healthcare system- a series of disconnected institutions encourages experimentation. As stressed throughout this thesis communication is crucial to both preventing and resolving patient safety concerns. Part of this must therefore be a dialogue between those who experiment and those who later implement. This dialogue cannot occur though without understanding the fundamental differences between the systems that are trying to be fixed.

This chapter has outlined the different systems in the US and in the UK. It has examined the lines of experimentation that the US has undertaken which have been shown to be successful in reducing medication related errors and it has attempted given the knowledge of the two systems to identify how these innovations could work and be adapted in the UK. Further more an examination of the limited examples written up in the literature of successful implementations and failures of adoption helps to guide the future for the UK. "Knowledge is Power" is found inscribed on the walls of the Library of Congress, but application of knowledge, based on true understanding, derived from complex communications is key.

Chapter 4: Information Provision and Medication Safety

4.1 Introduction

4.11 Introduction

Having considered the lessons the UK can learn from the US and vice versa this chapter turns to generating new knowledge that could be a source of important transferable information in the future if the lessons of the previous chapter are heeded. This chapter attempts to answer the fundamental concern of this thesis. What is the role that advice- the communication of information, plays in the generation of medication errors within the ambulatory setting? This question could be asked and attempted to be answered, because I was involved in the POP study undertaken at Brigham and Women's Hospital in Boston, Massachusetts as described earlier. There, the research underway was the most ambitious study to date, examing errors in the ambulatory or outpatient paediatric setting.

As described in the methods section- Section 2.3 The POP study was a three-phase study. Phase 1 was underway when I arrived in Boston and so I was not present for the initial work on the design of the study. Therefore, my analysis is a secondary analysis of data collected from this Phase. Phase 1 was an assessment of the current epidemiology of errors in this setting. Phase 2 was a repeat of Phase 1 but after the introduction of computerised prescribing in half of the participating sites. Phase 3 is currently just started and is a further assessment, but this time after the introduction of computerised weight based prescribing.

4.12 Why is the ambulatory setting important?

The ambulatory setting is where most care is received by the vast majority of people. [195] Studies have shown that there is also significant morbidity associated with medication use outside of the hospital. Gandhi et al performed a prospective cohort study of adult patients in the outpatient

setting and found that 25% of adults experienced an adverse drug event, of which 11% were preventable.[3] In a similar prospective study in the paediatric ambulatory setting, Kaushal et al demonstrated rates of 3% for preventable adverse drug events. Of the preventable adverse events, 69% occurred at the administration stage. [5]

It is also increasingly apparent that these errors may be prevented by improved communication of information between healthcare providers and patients or their families. [123] Understanding how the content and delivery of medication advice impacts on medication safety will facilitate the development of interventions. We hypothesized that effective and efficient communication of advice would reduce the prevalence of medication administration errors. The specific aims of this study were to analyze current advice provision by doctors and pharmacists, to parents and children regarding prescribed medications, and to perform a multivariable analysis to examine whether advice provision reduced reported medication administration error rates.

4.2 Methods

(Please see Chapter 2, section 2.3 for a detailed description of the methodology)

4.21 Definitions

The terms were defined as noted in the methods section, based on the work of Bates et al. In particular, errors were divided into ME s, Near Misses and ADEs. [11] They were also categorized as preventable, non-preventable or ameliorable.[11] Of particular note in this study, the generic term medication administration error is used to describe medication errors, near misses and ADEs occurring at the administration stage of medication use.

4.22 Study Sites

As explained in more detail in Chapter 2, Section 2.32; Data were collected from 6 practices within the Boston area, which represented a wide range of socioeconomic and ethnic diversity. The 6 office practices or offices chosen were paired, so that there were 3 pairs, thus in Phase 2 one from each pair would act as a control and one would be computerised.

4.23 Study Timing

The data for this study were collected between July 2002 and April 2003, however, there was a rolling data collection process so that data was not collected from more than 2 sites at anyone time (See Chapter 2.33 for additional information). Institutional review board (ethics) approval was obtained.

4.24 Providers

Prior to my arrival a data collection exercise had occurred. This consisted of a survey to all the healthcare professional taking part in the study. (See Annex 1 for Dataforms).Among the providers evaluated, 66 (50%) were physicians still in training, 53 (40%) were physicians who had completed their training and 13 (10%) were nurse practitioners. Among those who had completed their training, the average was 11.7 years post training. Overall, 89 (67%) of the providers were female and the mean age was 39.8. [5]

4.25 Study Patients

As with the previous sections, more details on methodology may be found in Chapter 2 –this section is outlined further in section 2.36. All patients under 21 who were prescribed a

medication at an office during the study period were eligible for inclusion in the study. Exclusion criteria were repeat prescriptions; if the treatment was for a sexually transmitted diseases and if the patients language did was not one of the languages for which interpreters were available, for logistic reasons. Patients were able to opt out at various stages of the study- see Figure 2.

4.26 Study Protocol

This study was a secondary of analysis of data collected for phase one of a multi-center study examining the role of computerization in reducing errors in the ambulatory setting. Patient inclusion, triggered by creation of a prescription, led to a duplicate copy being sent to the study nurses. This in turn triggered a series of telephone interviews with the patient's parents, and a review of the medical notes by the study nurses. Once this key data had been gathered the nurses then assessed if errors has occurred. If errors were found these were presented to an expert panel for further classification.

The data was then transferred from paper form to an Access database by a dedicated company. However, in the information transfer data was often mis-entered. In addition, the variation in questionnaires used during the study period meant that data cleaning was needed before analysis could begin.

4.27 Statistical Analysis

Detailed in Chapter 2.38. Data has been recorded and displayed in a descriptive manner, further more a univariate analysis, comparing patients with administration errors to those with no administration errors was then performed. From these analyses, all variables of clinical

significance were included in a multivariable analysis to determine the unique contribution of each factor in predicting administration errors. The main outcome of interest was a binary response indicating the presence or absence of any medication administration error, with the most important predictors as the type and place of advice. As described in Chapter 2.38 the data was examined to see if provision of information on medication indication, side effect and written information in either the pharmacy or the office affected the likelihood of an administration error. The model adjusted for patient attributes parental characteristics and provider characteristics.

4.3 Results

The majority of the 1685 children included in the study were under 12 (Table 4), and white children made up just under half of the study population (49%), followed by Hispanics (21%) and African Americans (15%).

Table 4 Descriptive statistics for demographic data on children and their caregivers (Percentage in parentheses)

	Frequency
Age	
Less than 5 years	896 (53.1)
5-12 years	633 (37.5)
More than 12 years	160 (9.5)
Ethnicity of Child	
White	815 (49.3)
Non-White	838 (50.7)
Sex of Child	
Female	850 (50.5)
Male	835 (49.5)
Education Of Parent	
College Education or Higher	1148 (69.4)
Less than College	506 (30.6)
Household Income	
Less than $10,000	199 (15.6)
$10,000 to $50,000	412 (32.3)
More than $50,000	665 (52.1)

Over two thirds of parents had a college degree or higher (70%) and more than half of the households had an annual household income of over $50,000, although 16% had an annual household income of less than $10,000. (Groupings were decided after discussion with statistician and team working on POP, because of the various versions of forms in use See methods in previous section).

Results from the survey indicated that healthcare providers based in office practices provided information on the medication indication 91% of the time. Less information on side effects (28 %) and even less written information (14%) were provided. In pharmacies, 19% of prescriptions were accompanied by advice on their indication, 9% with information on side effects and 82% with written information. Of over-the-counter medications, 61% were accompanied by advice on indication. This advice could have been from either the office or the pharmacy. Written information was provided 13% of the time for these medications (Table 5)

Table 5 Information Provision –Frequency of prescriptions accompanied by advice (Percentages in parentheses)

	Office	Pharmacy	Office or Pharmacy for Over The Counter Medications
Information on Medication Indication	1917 (90.9)	255 (19.2)	406 (60.6)
Information on Side Effects	570 (28.2)	139 (9.0)	Not available
Provision of Written Information	284 (14.0)	1653 (82.0)	86 (12.9)

In both the office and the pharmacy, the most common reason that parents did not receive information on medication indication was that they chose not to (85% of the time in the office, and 74% of the time in the pharmacy.) In contrast, written information was not given to parents

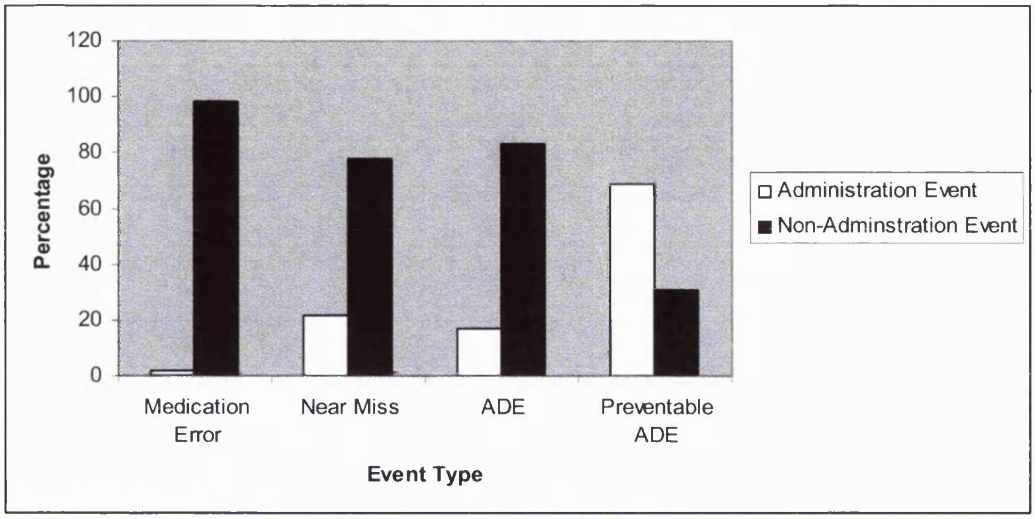
primarily because it was not offered. Of those, not receiving written advice in the office 74% gave this as the reason; in the pharmacy, it was 69%. Similarly, 57% of the time when advice on side effects was not reaching parents, the reason stated was that it was not offered. (Table 6)

Table 6 Reasons for Lack of Information Provision – per prescription
(Percentages in parentheses)

	Office		Pharmacy	
	Parental Choice	Not Provided	Parental Choice	Not Provided
Information on Medication Indication	102 (85)	18 (15)	907 (74.3)	314 (25.7)
Information on Side Effects	520 (43.0)	689 (57.0)	Not available	Not available
Provision of Written Information	398 (25.7)	1149 (74.3)	78 (31.3)	171 (68.7)

Evaluation of the relative percentage of administration versus non-administration errors by type of error (Figure 5) revealed that 1.7% of medication errors and 22% of the near misses occurred at the administration stage. Examples of this were the failure to fill a prescription for an antibiotic and worsening of symptoms, pulmicort given incorrectly for asthma management resulting in an emergency room visit and premature discontinuation of nystatin for treatment of thrush and return of symptoms.

Figure 5. Relative percentage of errors by stage – administration vs. non-administration (ME – medication errors, NM near misses and ADE adverse drug events)



Univariate analyses demonstrated that no factor was a significant predictor of administration errors (versus no administration error) except the number of medications. Taking more than one medication increased the risk of a medication administration error, with odds ratio =1.60 (95% CI: 1.15-2.23). Information provision by both the pharmacy and the office seemed to have no effect on the rates of administration errors compared to non-administration errors. However, the data were relatively sparse for some of these comparisons (Table 7).

Table 7. Univariate analysis of predictors of medication administration errors.

	Administration Errors	Odds Ratio	**P-Value**
Patient characteristics			
Age			
<5 years	88 (9.8)	1.48 (0.77, 2.83)	0.24
5-12 years	59 (9.3)	1.39 (0.71, 2.72)	0.33
>12 years *	11 (6.9)		
Ethnicity			
African American	26 (10.2)	1.19 (0.74, 1.90)	0.48
Hispanic	34 (9.9)	1.15 (0.75, 1.77)	0.52
Other	21 (8.8)	1.01 (0.61, 1.68)	0.97
White*	71 (8.7)		
Sex			
Female	73 (8.6)	0.84 (0.60, 1.17)	0.32
Male*	84 (10.1)		
English Language Spoken			
Poorly	17 (8.7)	0.93 (0.55,1.58)	0.90
Well*	137 (9.3)		
Presence of Chronic Condition			
Yes	53 (10.6)	1.26 (0.88, 1.78)	0.23
No *	101 (8.7)		
Parental Characteristics			
Supervision			
Other	12 (6.2)	0.60 (0.32,1.10)	0.12
Parental/Legal Guardian*	142 (10.0)		
Income			
< $10,000	21 (10.6)	1.21 (0.72,2.05)	0.47
$10,000-$50,000	41 (9.9)	1.14 (0.75,1.73)	0.55
$>50,000*	59 (8.9)		
Education			
Less than college educated	49 (9.7)	1.08 (0.74,1.54)	0.71
College Educated*	104 (9.1)		
Provider Characteristics			
Continuity of Care			
Care with PCP< 1 year	100 (8.7)	0.81 (0.57, 1.14)	0.24
Care with PCP>1 year*	57 (10.6)		
Medication Related Characteristics			
Number of Medications			
2or>	69 (12.2)	1.60 (1.15, 2.23)	0.008
1*	88 (8.0)		
Advice			
Office			
Information not on Medical Indication	12 (8.5)	0.98 (0.53, 1.82)	1.00
Information on Medical Indication-Y*	129 (8.6)		
Information not on SE	98 (8.5)	1.01 (0.68, 1.50)	1.00
Information on SE- Y*	37 (8.4)		
No provision of written information	118 (8.4)	1.01 (0.59, 1.71)	1.00
Provision of written information*	17 (8.4)		

Pharmacy			
Information on Medical Indication –N	82 (9.9)	1.61 (0.88, 2.95)	0.14
Information on Medical Indication-Y*	13 (6.4)		
Information on SE-N	86 (9.4)	1.17 (0.57, 2.4)	0.86
Information on SE- Y*	9 (8.1)		
Provision of written information-N	22 (7.8)	0.90 (0.56, 1.45)	0.72
Provision of written information-Y*	113 (8.6)		

* Reference group
# Fisher's Test used in place of Chi-square

The multivariable analyses controlled for age, ethnicity, sex, language proficiency, presence of a chronic condition, income, education, continuity of care, and number of medications. After adjusting for these factors, the analyses showed that as in the univariate analysis form and location of advice did not reduce medication administration errors relative to non-admistration errors. Taking more than one medication increased the likelihood of a medication administration error compared to no administration error, with an adjusted odds ratio=1.68 (95% CI: 1.15-2.46). Furthermore in this analysis, age less than 5 years was also a significant predictor of an increased risk of a medication administration error, odds ratio=2.35 (95%CI: 1.05-5.28) (Table 8)

Table 8. Multivariable logistic regression analysis of medication administration errors.

Variable	Multivariate Predictors	
	Odds Ratio	**P-Value**
Patient characteristics		
Age		
<5 years	2.35 (1.05, 5.28)	0.04
5-12 years	1.70 (0.74, 3.91)	0.21
>12 years*		
Ethnicity		
Hispanic	1.27 (0.72, 2.24)	0.41
African American	1.07 (0.63, 1.80)	0.81
Other	0.88 (0.49, 1.57)	0.66
White*		
English Language Spoken		
Poorly	0.63 (0.29, 1.35)	0.24
Well*		
Presence of Chronic Condition		
Yes	1.25 (0.84, 1.87)	0.28
No*		
Parental Characteristics		
Education		
Less than college educated	0.98 (0.63, 1.52)	0.91
College Educated*		
Provider Characteristics		
Continuity of Care		
Care with PCP< 1 year	0.75 (0.51, 1.09)	0.13
Care with PCP>1 year*		
Medication Related Characteristics		
Number of Medications		
2or>	1.68 (1.15, 2.46)	0.008
1*		
Advice		
Office		
Information on Medical Indication-N	0.99 (0.51, 1.94)	0.97
Information on Medical Indication-Y*		
Information on SE-N	1.03 (0.67, 1.58)	0.89
Information on SE- Y*		
Information as written information-N	1.17 (0.64, 2.11)	0.61
Provision of written information-Y*		
Pharmacy		
Information on Medical Indication-N	NA	
Information on Medical Indication-Y*		
Information on SE-N	NA	
Information on SE- Y*		
Provision of written information –N	0.96 (0.59, 1.56)	0.87
Provision of written information-Y*		

NA= not available due to number of missing data

4.4 Discussion

Most Americans receive their healthcare in the ambulatory setting. Green et al estimate that 113 of every 1000 people (including adults and children) visit a primary care physician each month; among these, 8 are hospitalized. [195] Data from the USA presented by Chevarley et al identified that 73.8% of children under 18 visited a doctor in an outpatient or clinic setting in the previous 12 months (excluding the emergency room). [196] Medication use is considerable among adults, with 81% taking at least 1 medication per month, and 50% taking a prescribed medication. [197] Chevarley et al estimated that 54.8% of paediatric patients seen in the ambulatory setting received a prescription.[196] In the UK 200 million prescriptions were estimate to have been written for children and adolescents in 2002. [198]

The potential exists to reduce the frequency of paediatric medication errors, particularly at the administration stage, especially as drugs are largely given by non-healthcare professionals. One contributing factor to these errors may be inadequate information provision. Parents (and other caregivers, such as legal guardians or grandparents) need adequate knowledge to administer medication safely, and administration in children is complex.

Evidence from paediatric practice supports the hypothesis that improved information provision can improve adherence and outcome. [123] Information transfer necessitates effective communication between health care providers and parents. Research on the factors that contribute to successful communication has generally focused on the doctor-patient relationship.[199-202] Doctors are the source of the majority of medication information.[92] However, patients trust doctors only slightly more than pharmacists to provide information about prescription drugs, (76% as compared to 70%).[140] Pharmacists are particularly good at providing information on medication use, associated risks, benefits, side effects,[203] and over the counter

medications.[198] These are areas that physicians often fail to explore effectively with the patients, frequently due to time constraints and competing priorities.[92] However, research on the topic of communication has often utilized end points such as patient satisfaction[201;204] rather than more safety orientated outcome measures such as error rates. Good communication between the doctor and the patient does appear to improve health outcomes, and probably reduces medical malpractice claim rates.[126]

Some research has examined the method of advice given and who delivers the advice, although relatively little of it has been done in paediatrics. In particular, written advice has been shown to be useful in decisions on pain relief and postpartum contraception. [205;206] To be effective, written advice must be provided at an appropriate literacy level. [100; 102;105] Videos, cartoons and multimedia-based tools have also been demonstrated to be effective aids. [110-112]

As demonstrated, there is a complex relationship between advice provision and administration errors in the ambulatory paediatric setting. This study showed insufficient advice was provided, especially about medication side effects, and that little written material was given by office practices. Parents do not receive this advice, not from choice but from lack of provision. Giving advice to parents would seem worthwhile because they are the most widespread supervisors of administration in the home environment, although the efficacy of delivering routine written advice in the office setting has received relatively little evaluation. When advice was given, and even when other factors are adjusted for, this advice was not associated with lower medication administration error rates compared to no administration error. However, patients less than 5 years of age and those taking more than one medication had an increased risk of suffering from a medication administration error.

Previous studies have examined the effect of communication on medication adherence, [207] but not looked directly at medication safety. Instead, they have focused on patient satisfaction, adherence, and recall of provided information and health outcomes. The prevalence of administration errors compared to non-administration errors is interesting. While few other studies to date have evaluated the ambulatory paediatric setting, the high level of preventable administration ADEs is surprising, given that the administration stage is just one of many steps in the medication process. An inpatient paediatric study found that 5% of near misses occurred at the administration stage, [17] as compared to 22% in this study. Moreover, 69% of the ADEs, which were preventable, occurred at the administration stage. It is possible that there are more ADEs at the home administration stage than near misses because when a serious medication error is made at the end of the medication process, there is very little chance for interception, and therefore it becomes actual harm to a patient rather than potential harm that is intercepted.

The results demonstrate the paucity of advice given. In the office, little information is provided on side effects or in written form, similarly in the pharmacy there is little advice on indication or side effects. However, written information provision was higher in pharmacies, perhaps due to the presence of leaflets associated with medications. Of particular note is that parents report failed information availability was due to inadequate provision not because offered advice was rejected. This suggests that delivering additional written advice might be welcomed and could potentially reduce the frequency of medication administration errors. Gandhi et al in a similar study of adverse medication related errors in the adult ambulatory setting emphasizes the need for such advice, however she considered predictors of the number of adverse drug events rather than the relative rates of errors.[3]

The univariate and multivariable analyses showed that there was no relationship between giving advice and the relative error rate. This is contrary to some other work; for example, researches have found that patients were less likely to experience an adverse drug event when they were warned about the potential adverse consequences of a drug.[208] Advice provision may be broken into two sections, content and delivery. It might be that current advice provision is not only inadequate but also has inappropriate content (i.e. that the functional health literacy of the patients was lower than the provided information). Functional health literacy (FHL) describes both the ability to understand verbally communicated health related information and information communicated in the written form. [99] Functional health literacy has been found to be surprisingly low, which is one potential explanation for our results. In one an American survey, 42% of patients could not understand relatively simple verbal instructions such as "to take medication on an empty stomach."[100] Furthermore the beneficial effect of written material depends heavily on the literacy level at which it is written; often this is too high for the average American literary level of 8th grade.[102;105] More evaluation about how to best deliver advice is needed and this must account for functional level of literacy. Furthermore, although 70% of parents had a college education or higher, data show that there is a poor correlation between stage of schooling and literacy. [102] Instead, literacy appears to be best addressed by specific tests such as the Test of Functional Health Literacy in Adults (TOFHLA) [103]

The second element of advice communication is delivery. Studies have looked at the effect of delivery on medication adherence. Medication administration errors contribute significantly to medication adherence. In adults, poor information transfer has been found to correlate with increased use of alternative cancer therapies.[209] Therefore, how the information was provided may have been part of the reason why in our study reported advice provision did not equate to a reduction in reported administration related medication incidents.

How should medication advice be provided? First, it must be given at a functional health level that is correct for the majority of home caregivers, i.e. no more complex than 8th grade level. [102] Second, if novel methods such as the Internet are to be used the programs must be simple and also at the correct FHL. RAND assessed that 100% of studied websites written in English were at 9th grade or higher and six out of seven Spanish language sites presented information at, high school level or higher. [107] Additionally difficulties with gaining access to the required information on-line are underestimated. [109] Methods have been developed that combat problems with verbal or written materials, such as novel methods of presenting data. [110-112]

This study did however show that age less than five years and use of more than one medication were correlated with increased medication administration error rates. This is similar to inpatient findings where young age [58;59] and increased medication use have been shown to be associated with increased risk of absolute errors. [17] It may be that parents are more likely to make errors if there are more opportunities to do so, perhaps because it is harder to clearly remember how to give each medication. Young age may predict risk because caring for these children is complex and time consuming and so administration of medications is more fraught. Alternatively, it may be that in these children, care is divided between more people and so the medication provision is less of a routine.

Because this study was limited by the method of data collection reporting bias may have been present. Since the survey approach was used, we were reliant on participants' memories of advice provision, which may not have been accurate. In addition, reporting bias may have been present, because parents may have been concerned to admit that mistakes in medication administration had occurred. Furthermore, neither copies of written advice or examples of conversations were captured from either the office or the pharmacy; therefore, it is difficult to

assess how these communications occurred. Previous studies have highlighted the importance of the nature of the interactions, both verbal and non-verbal, between patients (or parents) and healthcare providers. [207] To fully understand and improve the administration related error rates, real-time assessment of these complex interactions would be required.

In conclusion, relatively low levels of provision of information about medication administration to parents were identified, even though administration errors were associated with a large proportion of the preventable ADE's. Furthermore, provision of advice was not associated with a lower administration error rate. The high frequency of harm related to administration errors suggests that new strategies for delivering advice need to be developed and tested. The literature suggests that for these strategies to be effective, the information given must be appropriate for the functional health literacy of the home-caregivers and must be delivered in an effective manner. The multivariable analysis further suggests that particular attention should be paid when prescribing for young children (less than 5) and multiple medications.

Therefore, these data suggest that there is not evidence to support the claim that communication could improve patient safety in this setting. However, the detail collected because of this being a secondary analysis may explain these results. Further investigation, is therefore required to try to answer the question of the role of communication in the doctor-patient /parent relationship and the link with errors.

Chapter 5: Paediatric Medication Safety and the Media: What Does the Public See?

5.1 Introduction

The media play a pivotal role in forming public opinion by presenting news and information to the public that shapes their views. In addition, the degree of coverage of news stories reflects the public's interests. [175;210; 178; 211] Newspapers represent a key part of the media, and it is relatively straightforward to assess what information has been presented over a defined period compared to other media such as television and radio.

The public is justifiably concerned about medical safety. In a Kaiser Family Foundation survey in 2000, 47% of respondents reported that they were "very concerned" about an error resulting in injury happening to them or their families, when receiving health care in general. [140] When a child dies or is injured unnecessarily, it is especially heart wrenching. Adverse drug events occur in 2.3-6% of all paediatric inpatient admissions. [13;17] In ambulatory paediatrics, 16% of patients experienced an adverse drug event.[5]

Providers and especially the public, often blame individuals when an accident occurs. In a study comparing the views of the public and physicians Blendon et al found that the public were more likely to believe that "the party" responsible for the error (i.e. the care provider) should be sued for malpractice than physicians surveyed. Of physicians, 4% thought surgeons should be sued, whereas 30% of the public supported this ($p<0.001$). The public also endorsed suggestions that the care provider should be fined by a government agency, have their licenses suspended, and involved institutions such as hospitals should risk loss of accreditation.[212] This conflicts with increasing evidence suggesting that improved safety is most likely to be achieved in non-punitive cultures in which mistakes are seen as opportunities for improvement.[16] The importance of safety culture has been demonstrated in the aviation industry.[213;138] News editors commission stories and reporters develop stories that are topical (in the public eye), and will interest readers,[175;214]

so it is not surprising that child deaths or injuries receive a great deal of coverage.[215] These articles may be influential, affecting not only the public but also policymakers when the topic ignites sufficient public outcry.[175] These articles can either motivate hospitals to improve or negatively influence hospitals or providers to cover up future events. [211]

This study attempts to understand how the public is presented with information about paediatric medication safety. The aims were to: 1) quantify the amount of newspaper reporting of paediatric medication safety issues and compare international rates, 2) identify how the issue is framed to the public, and 3) elucidate the key themes within the articles.

5.2 Methods

5.21 Introduction

The concept for this study is derived from work from researchers examining public perception to the tobacco industry. [176] This methodology was modified for this study. The tobacco press is considerably larger than that covering medication safety and so adaptations were needed. (See Chapter 2.41 for more details).

5.22 Sample

Articles from newspapers were chosen and identified using an online database – Lexis Nexis for logistic reasons as outlined in Chapter 2. Articles were identified from 1994 to 2004 All newspaper articles from the USA, Canada, UK, Australia and Ireland that contained the keywords "paediatric," "infant," "child," or "adolescent" in combination with "medication," "prescribing," "dispensing, or "drug" and either "error" or "mistake" were identified.

5.23 Coding Variables

For more detail on methods please see Chapter 2.4 The country of origin, date of publication, newspaper, article type (news article, editorial or letters) were noted. The articles were categorised by event type and article slant; event type classified the actual story reported into four categories, negative, positive, mixed and neutral. The article slant is the skew of the report written about. To account for varying country size, the total number of articles for each country was divided by the country population. The articles were also coded using a more qualitative approach. First, articles were coded according to the four main themes (or combinations of themes): patient incident, research, policy or other. To assess overall classification reliability, a second independent researcher re-assessed a random sample of 30 of the articles. A PubMed search using the same keywords allowed an approximation of the amount of published research on paediatric medication safety, and thereby allow a comparison of the trends in the newspapers with the trends in research.

More detailed evaluation of the content of articles was then carried out. This allowed an assessment of the extent to which the media framed articles within the context of a culture of safety. In particular, whether the media presented the public with the three key tenets of a culture of safety was examined. First, to what extent did the news articles portray adverse events as systems failures? Second, did the cases described in the news articles illustrate best practices for providers for dealing with adverse events? It is acknowledged that after an adverse event occurs, there should be an apology to the family or patient, a thorough investigation of why the event occurred; and institution of polices and procedures to prevent repeat occurrences. This is directly linked with the final concept examined- to what extent was the concept of shared learning prominent within articles?

5.24 Analysis

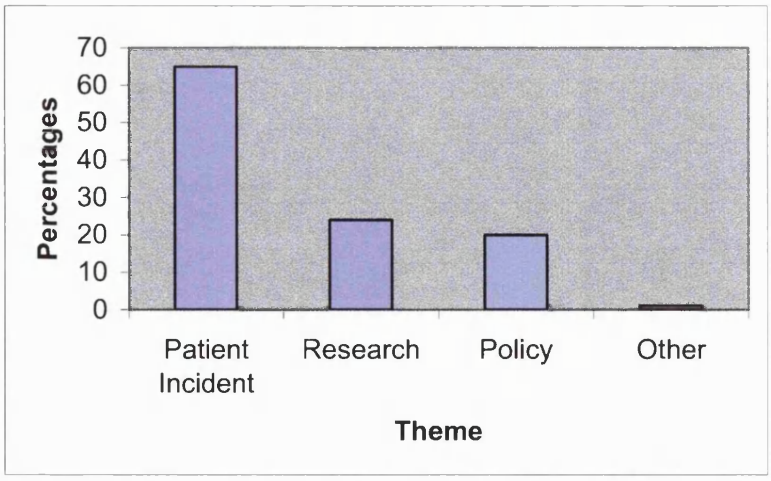
The numeric data on the event type and article slant is presented in tabular form. The distribution of articles by theme, temporal relationships and distribution by nationality are presented graphically. The data from PubMed is also presented in graphic form. The qualitative data are presented a content analysis.

5.3 Results

5.31 Descriptive

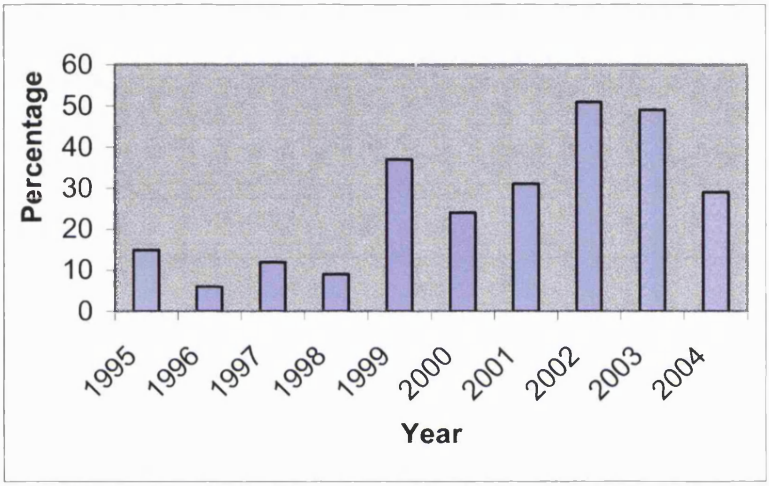
Altogether, 263 articles were identified from a range of newspapers both tabloid and broadsheet. Analysis was not performed according to this definition because this is not a differentiation common in some of the countries examined, e.g. Canada. Among these, 59% covered patient incidents alone, and an additional 6% covered patient incidents in addition to other themes, thus 65% of articles published discussed patient incidents. In addition, 12% of articles covered policy, with a further 8% covering policy and other themes. Research was covered in 19% of articles alone, and 6% in combination with other themes (Figure 6).

Figure 6. Distribution of Articles by Theme



Over the ten-year period examined, there has been a considerable increase in the frequency of articles published on paediatric medication safety (Figure 7). For example, 15 articles were published in 1995, while 49 articles were published in 2003, which had the highest frequency. The USA and Canada both show temporal distributions similar to the overall rate. While the numbers are small, the UK had its highest frequency in 1999 with fewer per year published since.

Figure 7. Temporal Relationship by Total Number of Articles



The countries with the highest absolute numbers of articles were the USA, which had 93, followed closely by Canada with 87 and the UK with 74. If these figures are adjusted for country population, Canada has the highest rate, followed by the UK, with the USA in fifth position (Figure 8). Since the overwhelming majority of articles are about patient incidents, these account for most of the overall trend (Figure 9). Of note, though, in 2001, 7 articles covering paediatric medication safety policy were published, compared to only 2 articles in 2000 (Figure 10). There was a similar increase in articles on the theme of paediatric medication research from 8 in 2000 to 12 in 2001 (Figure 11). A Medline search shown in (Figure 12) demonstrates that the trend shown in articles about research mirrors the tendency shown in published research.

Figure 8. Distribution by Country adjusted for Population. Population Data from National Census Data. Canadian, British, Irish, Australian from 2001, American from 2000.

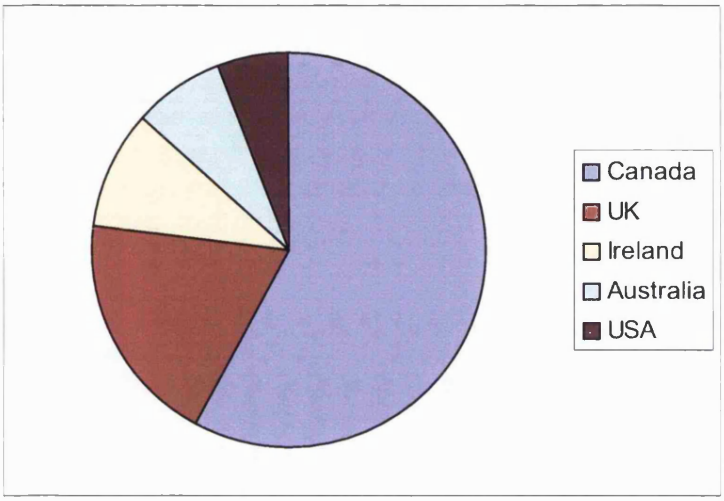


Figure 9. Temporal Relationship by Patient Incidents

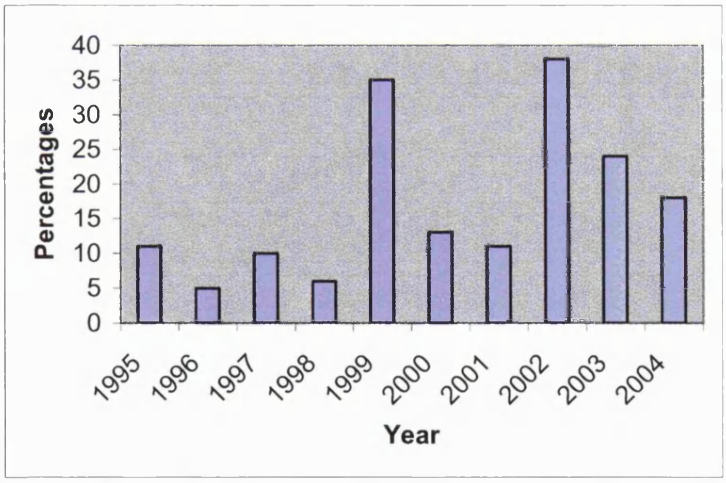


Figure 10. Temporal Relationship by Policy Theme

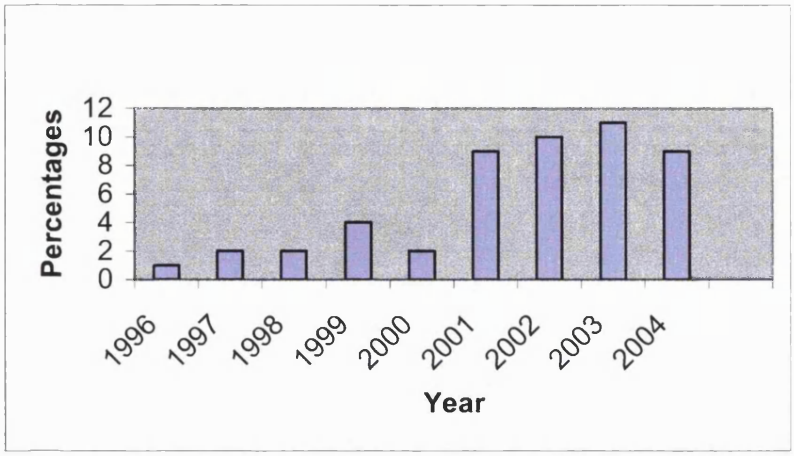


Figure 11. Temporal Relationship by Research Theme

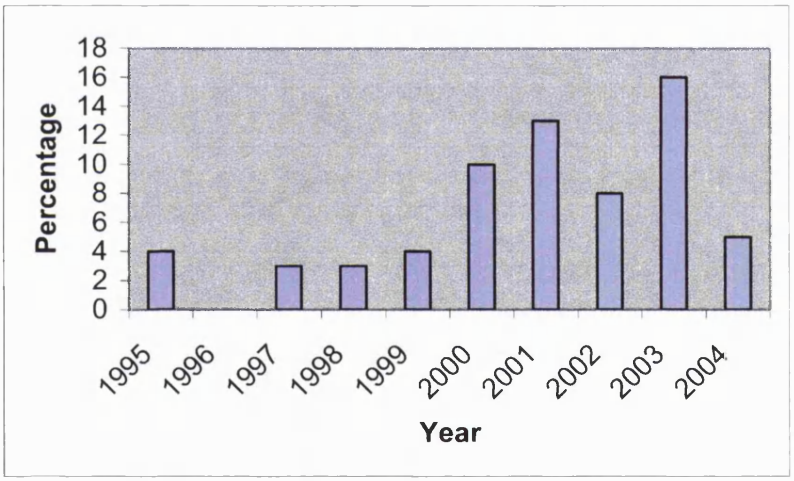
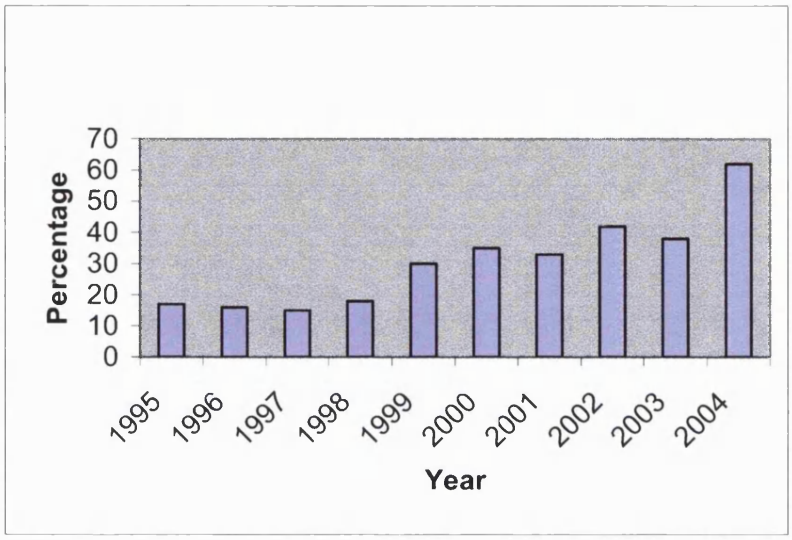


Figure 12. Number of Articles From PubMed by Year



Most articles were news articles (92%). However, 3% of articles were features or letters and 2% of articles were opinion pieces. In all, 72% of the articles covered events, which were negative for patient safety. This is unsurprising given the previous comment that 65% of articles covered patient incidents. Indeed, 86% of the articles covering a negative event covered patient incidents.

The slant in the majority of articles was neutral (71%). Of the events judged to be negative for patient safety, 75% were covered in a neutral way, and only 19% were reported in an unduly negative manner. Of the articles covering a negative event, 4% had a positive orientation (Tables 9 and 10). The kappa score between the independent reviewer and the main assessment was 0.55 for event type, while it was 0.33 for article slant and 0.54 for theme.

Table 9. Event Type

	Event Type					
Theme		Mixed	Negative	Neutral	Positive	Total
	Patient Incident	1(0)	151(57)	1(0)	1(0)	3(1)
	Research	3(1)	20(8)	19(7)	7(3)	49(19)
	Policy	4(2)	5(2)	10(4)	13(5)	32(12)
	Patient Incident and Policy	2(1)	6(2)	1(0)	1(0)	10(4)
	Policy and Research	0	2(1)	4(2)	2(1)	8(3)
	Patient Incident and Research	0	5(2)	0	0	5(2)
	Patient Incident and Policy and Research	1(0)	1(0)	0	0	2(1)
	Other	0	0	2(1)	1(0)	3(1)
	Total	11(4)	190(72)	37(14)	25(10)	263(100)

Table 10. Article Slant

	Article Slant					
Theme		Mixed	Negative	Neutral	Positive	Total
	Patient Incident	2(1)	34(13)	114(43)	4(2)	154(59)
	Research	2(1)	2(1)	35(13)	10(4)	49(19)
	Policy	0	2(1)	17(6)	13(5)	32(12)
	Patient Incident and Policy	1(0)	0	7(3)	2(1)	10(4)
	Policy and Research	0	0	6(2)	2(1)	8(3)
	Patient Incident and Research	0	1(0)	4(2)	0	5(2)
	Patient Incident and Policy and Research	0	0	1(0)	1(0)	2(1)
	Other	0	0	2(1)	1(0)	3(1)
	Total	5(2)	39(15)	186(71)	33(13)	263(100)

Among the events that were neutral for patient safety, 92% were presented to the public in a neutral manner, while 8% were positively skewed. Overall, 10% of events were positive for patient safety and of these 84% were presented in a positive light. (Tables 9 and 10)

5.32 Qualitative Analysis

This chapter is an attempt to identify examples of safety issues covered in the ways that safety experts view most accidents, could be found; in particular that multiple defects can be found when most accidents are evaluated, and that improving safety requires changing systems.[8] A number of anecdotes illustrated that this is indeed the case. For example, Claire Lewis was an 11-year-old girl, undergoing surgery for a benign brain tumour, who died at MacMaster University Medical Centre, in part from inappropriate use of desmopressin (DDAVP). The Chief of Staff-Dr Andrew McCallum, at this hospital, was quoted as follows: "We didn't find a single person or a single event that led to this. We found a series of events and occurrences, slips, lapses, errors in judgment that led to this tragic outcome."[216] In another periodical- Maclean's he explains. "It's important to understand that saying we are moving from a culture of blame to one of understanding and learning doesn't mean everybody gets off."[85] This coverage highlights the understandable difficulty that parents have in accepting accidents. "I guess what the health-care industry needs to ask itself is, how does the family of, say, an 11-year-old child killed by physicians feel about the death being regarded a learning experience for physicians, nurses and the hospital?" asked Claire Lewis' father.[85]

Four clear steps have been identified and accepted as best practice after an adverse event. These are timely apologies; thorough, honest investigation; institution of policy and practice change; and shared learning.[8] These are goals that parents, care providers, and the wider public appeared to share in newspaper articles on paediatric medication safety. An article describing the death in

1997, in B.C. Children's' Hospital, of a young girl from administration of intrathecal Vincristine, instead of intravenous administration, demonstrated that the care providers appeared to accept and enact this approach. The hospital president explained -"Our only options are to understand it and to do everything we can to reduce risks in the future."[80] Lisa Shore died at the Toronto Sick Kids Hospital, after being administered morphine, with insufficient monitoring. The coroner's jury in this case summed up that, hospitals must respond "quickly, accurately and openly." This example highlights how members of the public view the responsibility of care providers, and importantly how the public expects institutions to respond. [217]

The first step in dealing with an adverse event is to recognize the event, and to apologise to the patient and family. In doing so the healthcare providers need to recognize that there are two victims. The patient is clearly the primary victim, but the provider also often suffers substantially and has been dubbed the "second victim."[83] The media has recognized the second victim, in particular by focusing on the difficulty practioners face in apologizing. While apologizing is extremely important, it is very difficult, both because of the potential legal corollaries and because it is hard to find a way to apologize. The B.C. hospital president sums this up. "This is the most difficult thing I have ever had to tell a family: we failed, and as a result, your child died.... There is no way to adequately apologize for this failure."[80] However, news articles also identify examples of poor or absent apologies. For example, "...nobody wanted to talk to us. Nobody would acknowledge that anything was done in error." Explained Sharon Shore, the mother of Lisa Shore.[218]

Secondly, best practice demands thorough investigation of events. Often this occurs only because of prolonged parental campaigns, frequently involving the media.[218] The third and fourth steps are learning from the mistake and disseminating this knowledge. Time after time, media reports

stress that parents whose children have suffered adverse events want healthcare in general, and the organization in particular, to learn from their mistakes. This idea of shared learning is exemplified by the parents of the child who died in Vancouver, "We desire our daughter's memory should be honoured by the knowledge that some good will come from this tragedy."[80] News articles articulate that institutions are aware of the need for this approach. As Dr Phillip Herbert, a family physician and bioethicist at the Sunnybrook & Women's College Health Sciences Centre in Toronto, explained, "It sure would be nice to learn what a hospital in Saskatchewan is doing, and what a hospital in Halifax is doing," says Hebert, "So that people aren't required to reinvent the wheel at every institution."[85]

Stressing shared aims helps to impart to the public that providers and parents are able to share goals and work together to reduce adverse events. Previously there would have been more emphasis on identifying the providers at fault and then punishing them. This is not to say that there are not parents calling for accountability, sometimes very strongly, and sometimes still pointing fingers at individuals, and understandably, this is reported, as it is often very newsworthy. This is particularly true if the parents are forced into a position of crusading for information, and allegations of cover-ups start to fly, such as in the case of Lisa Shore. The Vancouver Province reports Lisa's mother "immediately demanded a police investigation, the dismissal of hospital staff involved in her daughter's care and a public inquiry."[219]

Reporting adverse event rates is a prerequisite of shared learning. Examples exist of misinterpretation of research by the media. For example, when an Australian hospital reported its data, the Herald Sun summarized, "The hospital's figures reveal dozens of the state's sickest children have fallen victim to potentially disastrous drug mix-ups."[220] In a similar vein, subtle criticism is aimed at the hospitals for requiring such research. The Daily Mail reports; "DOZENS

of seriously-ill babies and children are being put at risk every week because hospital doctors give them the wrong drug dosages, it is revealed today. Disturbing evidence uncovered by the Daily Mail has exposed a widespread problem, which could be solved by simple checking procedures. Ministers are so concerned they have commissioned a study which is expected to reveal the extent of the scandal."[221]

Whilst overall the media may be fair and frame the news within the context of a culture of safety, misinterpretation of research findings is not the only example of skew. This occurs against a background in which it may be difficult for the public to develop an overall sense of individual cases, due to the unavoidable piecemeal nature of reporting. In the case of Lisa Shore's parents' court battle, a reader would need to follow a story daily (or be lucky enough to read the report on the final day of court) to develop a clear picture of events. It should be noted that cases which lead to lengthy court battles not only provide more newsworthy opportunities for newspapers but also very powerful stories, thus perhaps unbalanced presentation can be explained. The opposite is also true. The media may even be actively excluded from cases where information, apologies and policy/ practical changes occur speedily, thus heavily prejudicing their coverage. In the B.C. case the hospital apologized, investigated and fully disclosed to the parents the causes of the incident, and enacted a series of changes to policy such as warning stickers and a training video (dedicated to the child's memory). The family's response to this was to request privacy. "While we understand that the hospital's error is newsworthy, it is our choice not to participate in your coverage," said the family. [80]

While the media cannot control some of the imbalance, some of the language used is dramatic. Ross Woolard died from complications of a phaeochromocytoma, diagnosed at post mortem. The article in the Daily Record reports, "Less than 24 hours later, he was dead after appalling

blunders by hospital staff who failed to diagnose a rare tumour. Not realizing it was totally the wrong thing to do, they pumped so much fluid into Ross that, ultimately, he drowned."[222] The headline alone may be sufficiently skewed to affect the public. "Doctor Zombie; with no training in the field, Andrew Holton misdiagnosed 618 children as epileptic then numbed their minds with drugs that made their lives a misery"[223]

Often, however, the media does go beyond the norm expected in a positive direction and attempts to educate the public on how to be advocates for their children and diminish adverse events, such as those due to inappropriate prescription of antibiotics in the presence of allergies.

5.4 Discussion

These results demonstrate that paediatric medication safety is of increasing interest to the media. Whilst this study focused on newspapers, there is evidence, that newspaper coverage is highly correlated with reporting of similar issues in both radio and television. [177] Over 65% of articles covered patient incidents, but as the body of research literature and policy has grown, this too is increasingly being covered. Perhaps surprisingly, of those events judged negative for patient safety more than 75% were covered in a neutral manner. The qualitative analysis did identify examples in which coverage was unduly sensational, but overall suggested that newspapers appear to be attempting to frame news articles in the light of a culture of safety.

Leape sets out the key elements to reducing adverse events, and suggests in particular that adopting a culture of safety is crucial for error reduction. [8] Nonetheless, work by the Kaiser Family Foundation and Blendon et al demonstrates that the public in general has not yet endorsed this concept.[212;140] Ryan describes three models by which the media may affect public

opinion. Firstly, according to the "hypodermic needle theory," – the media injects ideas directly into the public psyche. The "minimal effects model" suggests that the public play a limited role in modifying media ideas. Finally the "constructionist model" originally developed by William Gamson and Andre Modigliani suggests that the public actively decides what to accept from the media. Whichever theory is correct, it seems clear that the media play a major role in affecting public opinion.[175]

This study attempted to answer three questions. First, the extent of newspaper coverage of paediatric medication safety was assessed and it was found that paediatric medication safety is a topic of increasing interest to the media. The dip in 2004 may be due to the lag time in loading data onto Lexis Nexis. Over the last five years, the number of articles covering research and policy has increased considerably. This time period coincides with increased research and policy interest in patient safety since the publication of the Institute of Medicine's report on the topic; "To Err is Human".[9] As an example, in 2005 the Agency for Healthcare Research and Quality (AHRQ) will spend upwards of $84 million on safety research, a $ 4 million dollar increase on the previous year.[224]When raw figures are adjusted for country population, Canada has the most prolific coverage, followed by the UK, and USA. Relatively few studies estimating the prevalence of adverse drug events have been carried out worldwide, particularly looking at paediatrics.[17] Without national errors or adverse events data it is hard to explain this as due solely, to variations in adverse events. There are likely to be other factors such as type of newspapers that exist in each country, and national efforts to affect reductions in adverse outcomes. While attempts were made to produce per capita data, this is a crude estimate. More complex techniques are available but these do not work easily when the rarity of articles forces collection of data internationally. Furthermore, even the most complex techniques have yet to adapt for a world in which newspapers may be read online, thus making readership numbers

even harder to asses. Additionally this assessment of the effect of coverage is potentially an underestimate, because public opinion on paediatric medication safety is moulded by exposure to more general articles on patient safety, and by exposure to more than just newspapers.

Second, the framing of the topic to the public was examined. It was found that even when an event that was negative for patient safety was reported, 75% of these articles had a neutral slant. It could, though, be argued that since most of the articles deal with negative events such as child death additional negative skew is not necessary to interest the public.

The content analysis shows that the media is, overall, attempting to present cases in the light of a culture of patient safety and not blame and that occasionally papers even go further and provide detailed tips on how parents can be advocates for safety. This is almost beyond the norm expected of the media, who have a widely acknowledged duty to present the news, and with some arguing that it is not an important role to educate the public.[210;225]

These data suggest that the media may be helping to close the gap between the expert approach to reducing adverse events, through the culture of safety, and public opinion. This is an important message for care providers, and these data also suggest that the efforts to reduce adverse event rates should be publicized to the public, through the media.

The study has a number of limitations. One group relates to issues the Lexis Nexis database and search engine. Lexis Nexis is the largest newspaper database, but there are complex inclusion biases. Publishers are in control of the amount of articles given to Lexis Nexis and this varies widely, and for copyright reasons no articles written by freelance journalists are included. Little assessment has been made of the accuracy of alternative strategies such as use of news clipping

services. This chapter is also unable to express the number of articles published on paediatric medication safety as a proportion of the total number published. Equally it was difficult to find mechanisms to define the types of newspapers examined because classification is very much country dependent, e.g. tabloids are considered differently in the States, where so many newspapers are regional. Finally the narrow focus of the analysis, using just newspapers whilst necessary, did limit the scope of the work, and in an age of falling newspaper sales this may be pertinent. While attempts were made to overcome the subjective nature of assessing theme and content, by asking a second independent reviewer to analyze a subset, this is also a potential limitation of the study.

This study provides evidence that the topic of paediatric medication safety is of increasing interest to the public and the media. Overall, the information is provided in a fair manner by the media, in ways that should make it possible to build a culture of safety in healthcare. Health providers have a duty to maximize the potential benefits of this by contributing to research, striving to encompass the culture of safety into everyday practice, teaching this key message to junior staff and educating the public on how to interpret media commentaries, in a similar fashion to the instructions given on medical website information. From this research the media seem to be moving in the same direction as researchers, policy makers, and health care providers, in a direction believed necessary to improve patient safety. This chapter is a first step in understanding how the media views paediatric medication safety and presents it to the public. It is a small look at a complex field of communicating information to the public which helps to form and shape attitudes. In a world where patients have increasing knowledge, understanding how these opinions are generated is key. But understanding how ideas are formulated is not enough to improve care. To do this requires adoption of innovations; however, this too is not without communication difficulties.

Chapter 6 Discussion

6.1 Introduction

Since Hippocrates first encapsulated the aims of medicine, healthcare providers and patients have understood the importance of patient safety. In the last 50 years this area, and in particular medication safety has been examined extensively. Extensive research since the 1960's has helped to define the problems faced, and research continues to explore solutions.[18;22-24]

6.2 Conclusions of thesis

This thesis has considered medication safety in general and looked specifically at areas of paediatric medication safety. This thesis has attempted to identify how important communication is to medication safety. I have also examined both the adult and paediatric literature, in part because whilst this thesis is concerned with paediatrics, this is a new area of research interest and so much can be learned from the adult data.

I have attempted to explore the importance of communication to medication safety by examing four areas. Firstly, I examined the patient safety literature. One of the first areas in which the importance of communication became apparent, was the very definitions of the terms used so freely in the research. The lack of clarity makes interpretation and understanding difficult. Secondly, different methodologies have been used over time to examine patient safety and in particular, medication safety and this means that comparison between studies can be difficult and time-consuming. Finally, the results of studies are expressed in a range of methods: number of errors per admissions, per discharges, per charts etc. adding to the confusion. Clear terms and methods are needed or at least clear communication of deviations from standard procedures to help readers particularly those without specialist knowledge, to interpret and benefit from this important research. This introductory chapter, which examines this area, then continues to look at how communication plays a role in both the generation and resolution of errors.

The second area that communication plays a role in is explored in chapter 3 of this thesis. This chapter grew from my time spent in the US and is an attempt to try to explore the differing medication systems of the USA and UK. This analysis attempts to identify these differences and use these to identify how IT can be implemented in the UK given these differences. In essence, it attempts to show the benefits of understanding and communicating knowledge at the broadest level, between countries.

The second area that communication is important is the doctor- patient (or in paediatrics parent) interaction. Chapter 4 is a study, which aimed to examine for the first time the role that communicating advice plays in the generation of a specific type of error, those that occur in the homes of patients. The findings of this unique study are that advice does not seem at present to affect directly the generation of errors, although the study had many limitations outlined in the chapter.

Chapter 5 looked at how communication plays a role in a broader aspect of the medication safety debate. This chapter sought to understand how the public received information from one source- newspapers. This quantative study found that the majority of information provided to the public was presented fairly, and covered a range of themes including research findings. Furthermore, qualitative analysis showed that the framing of stories in the media was starting to mirror the approach posited by patient safety campaigners-, which looks at errors as system not individual failures.

I believe that this thesis develops the importance that communication has in both the study of medication safety in paediatrics, the development of such errors, the resolution of such errors, and the translation of solutions from their developmental home to the wider world and the

exploration of this topic to the public. I believe that I have demonstrated how communication plays a role in each of these areas and it is my hope that work such as this will help to fulfil Hippocrates great aim "First do no harm".

6.3 Future Work

Chapter 1 has highlit the problems with terminology and part of future efforts must be to clarify both the terms used, the methods used to study this area the wording used to express outcomes. The taxonomy underdevelopment by the WHO and other work by the Patient Safety Alliance might help this problem. In Chapter 3 I have attempted to learn lessons from one country and impose these on another, fully understanding the differences between the two countries methods of working. This is just a first step, there are many variations on the case studies that I have examined, many innovations in place that are not documented in the formal research literature and much could be learned from further case study type investigations in both countries of innovations and their relevance worldwide.

Chapter 4 highlights the need for more work looking at mechanism to improve information transfer to the public so that they understand how to administer medication. Part of this research is the need to continue to use hard outcomes such as medication error rates rather than proxy measures. Chapter 5 examined how the media convey information. I examined one small area of patient safety using one medium; it may be that further important information is gleaned from a wider examination using other media such as TV or the internet.

6.4 Summary

To conclude medication safety is a topic of increasing importance, which will undoubtedly become ever more important as more effective drugs are developed and the population ages. A key theme touching all strands presented is the important role that communication plays in the generation, resolution and prevention of medical errors.

Annex 1

DATAFORM 1

Prescription Screening Form

1. Study ID Number: ___ ___-___ ___ ___ ___

2. Reviewer ID Number: ___ ___

3. Provider ID Number: ___ ___-___ ___ ___

4. Number of prescriptions from index visit ___

5. Date of prescription(s) ___ ___/___ ___/ ___ ___

	Prescription 1	**Prescription 2**	**Prescription 3**
6. Name of drug	_____	_____	_____
7. Category of drug *(from table on next page)*	___ If other, specify _____ ___	___ If other, specify _____ ___	___ If other, specify _____ ___

1. Analgesic (narcotic)	25. Local Anesthetic
2. Analgesic (non-narcotic, non-NSAID)	26. Muscle relaxants
2.01 Acetaminophen	27. Nasal Sprays
2.02 Other	28. NSAID
3. Antianemia	28.01 Ibupfrofen
4. Antibiotic	28.02 Other
4.01 Cephalosporins	29. Oral contraceptive
4.02 Clindamycin	30. Sedative, hypnotic
4.03 Macrolides	31. Steroids (inhaled)
4.04 Misc. antibiotics	32. Steroids (oral)
4.05 Ophthalamic preps	33. Steroids (topical)
4.06 Otic Preps	34. Stimulants
4.07 Penicillin or derivative	35. Thyroid agents
4.08 Quinolones	36. Vaccines
4.09 Sulfa	37. Vitamins
4.10 Tetracycline	38. Other
4.11 Topical	39. Antimalarial
4.12 Other	40. Contraceptive (injectable)
4.13 Nitrofuran antimicrobial	41. Contraceptive (patch)
5. Anticoagulant	42. Dermatologicals
6. Anticonvulsant	43. Emollients
7. Antidepressant	44. Epinephrine
8. Antifungals (oral)	45. Immunologicals, topical
9. Antifungals (topical)	46. Iron
10. Antihelmintics	47. Normal Saline
11. Antihistamine (all forms)	48. Scabicide
12. Antihypertensive	49. Topical anesthetic
13. Antineoplastic	50. Antianxiety
14. Antipsychotic	51. Beta Blocker
15. Antituberculosis	52. Estrogen, topical
16. Antitussive	53. Cerumenolytic
17. Antiviral (all forms)	54. Emetic
18. Bronchodilator (inhaled)	55. Hemostatic
26. Bronchodilator (oral)	56. Mast cell stabilizer
27. Decongestant	57. Antiarrythmic
28. Diabetes (oral agents)	58. Anticholinergic
29. GI Meds	59. Antiemetic
22.01 Antiflatulent	60. Keratolytic
22.02 H2 blocker	90. Equipment
22.03 Proton pump inhibitor	91. Formula
22.04 Probiotic	92. Immunization
22.05 Antacid	93. Lab or x-ray
22.06 Laxative	94. Medication given in clinic
23. Insulin	
24. Leukotriene Receptor Antagonists	

	Prescription 1 **Name** _____	**Prescription 2** **Name** _____	**Prescription 3** **Name** _____
8. Dose	1. Specified *(indicate below)* 2. Not specified 3. Not applicable 4. Illegible	1. Specified *(indicate below)* 2. Not specified 3. Not applicable 4. Illegible	1. Specified *(indicate below)* 2. Not specified 3. Not applicable 4. Illegible
	_____	_____	_____
9. Route *(complete specify field for response 8 only)*	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	1. PO 2. Topical 3. Subcutaneous 4. Rectal 5. Otic 6. Eye 7. Inhalation 8. Other, specify 9. Not specified 10. Nasally 11. As directed 12. Illegible		
11. Frequency *(complete specify field for response 7 or 8 only)*	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	Once per day Twice per day Three times per day Four times per day Once per week As needed As needed, every ___ _____; specify Other, specify Not specified As directed Illegible		

	Prescription 1 **Name** _____	**Prescription 2** **Name** _____	**Prescription 3** **Name** _____
12. Amount of medicine provided *(write in what was provided, for example 20 tablets or 1 inhaler)*	1. Specified *(indicate below)* 2. Not specified 3. Illegible	1. Specified *(indicate below)* 2. Not specified 3. Illegible	1. Specified *(indicate below)* 2. Not specified 3. Illegible
	_____	_____	_____
13. Strength of medicine *(for example mg/ml)*	1. Specified *(indicate below)* 2. Not specified 3. Not applicable 4. Illegible	1. Specified *(indicate below)* 2. Not specified 3. Not applicable 4. Illegible	1. Specified *(indicate below)* 2. Not specified 3. Not applicable 4. Illegible
	_____/___or ___%	_____/_____ or ___%	_____/___ or ___%
14. Duration of therapy	_____	_____	_____
	1. Short course <1 month) 2. Long term (>1 months) 3. Not specified 4. PRN 5. Not applicable 6. Known long term; duration not indicated 7. Other, specify 8. As directed 9. Illegible		
15. Was there an error present?	_____ _____	_____ _____	_____ _____
	1. None *(Skip to question 17)* 2. Medication error (little or no potential for harm) *(Go on to question 16)* 3. Potential adverse drug event (PADE) *(Go on to question 16)* 4. Both medication error and PADE *(Go on to question 16)*		

	Prescription 1 **Name** _____	**Prescription 2** **Name** _____	**Prescription 3** **Name** _____
16. Classification of each error *(multiples may apply)*	_____ _____ _____ _____ _____ _____ Specify _____	_____ _____ _____ _____ _____ _____ Specify _____	_____ _____ _____ _____ _____ _____ Specify _____
	1. Illegible Order 1.01 MD signature illegible 1.02 Patient name illegible 1.03 Med name illegible 1.04 Illegible route 1.05 Illegible frequency 1.06 Illegible length of treatment 1.07 Illegible amount to be dispensed 1.08 Entire prescription illegible 1.09 Illegible dose or dose units 1.10 Illegible strength or strength units 1.11 Illegible date 1.12 Illegible weight or weight 1.13 Illegible directions for use 2. Dose error 2.01 Overdose 2.02 Underdose 2.03 Dose omitted (from order/when dispensed) 2.04 Dose units omitted 2.05 Dose form incorrect 2.06 Extra dose(s) 2.07 Missed dose(s) (not given/taken) 3. Route error 3.01 Route omitted 3.02 Route incorrect 4. Frequency error 4.01 Frequency omitted 4.02 Frequency incorrect	5. Length of Treatment Error 5.01 Length of treatment omitted 5.02 Length of treatment incorrect 6. Directions Error 6.01 Directions for use omitted 6.02 Directions for use incorrect 6.03 Directions for use incomplete 7. Strength Error 7.01 Strength omitted 7.02 Strength incorrect 7.03 Strength incomplete 7.04 Strength without units 8. Amount to be dispensed error 8.01 Amount to be dispensed omitted 8.02 Amount to be dispensed incorrect 8.03 Amount to be dispensed without units 9. PRN without indication 10. Weight Error 10.01 Weight omitted 10.02 Weight wrong 10.03 Weight units missing 11. Date Error 11.01 Date omitted 11.02 Date incorrect 12. Inappropriate use of abbreviation 13. Other, specify: _____ _____	
17. Brief summary of situation	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

DATAFORM 2A Version 4.0

10 Day Follow-up: Telephone Interview Form

Collect these data at T plus 10 days

RN Review (initials) _____ Date ____/____/____

1. Study ID Number: ____ ____-____ ____ ____ ____
2. Interviewer ID Number (Your initials): ____ ____
3. Date of Index Visit: ____ ____/____ ____/____ ____
4. Date of Telephone Interview: ____ ____/____ ____/____ ____

Start here: **May I speak with the parent or legal guardian of** _____

[Child's Name]

If the parent or legal guardian is NOT available, then ask for the best time to reach that person during the next day.

Hello, my name is _____ **and I'm calling on behalf of** _____.
[Your Name] **[Clinic Name]**

Your doctor/health care provider is participating in a research study to improve the way medicine is prescribed in paediatricians' offices. You should have received a letter in the mail about this study. We are interviewing parents and legal guardians of children who have recently been prescribed a medicine by their paediatrician. The interview takes approximately 20 minutes and all the information you provide is completely confidential. Participation is entirely voluntary and you may skip any questions that you do not feel comfortable answering.

5. Would you like to participate? _____
   1. No *(Go on to Q6)*
   2. Yes *(Skip to Q7)*

6. Would you take a few moments to tell us why _____
   1. Not interested
   2. Concerned about confidentiality
   3. Not enough time
   4. Refuses to answer
   5. Other, specify: _____

Thank you very much for your time.

ASK ONLY IF CHILD 12 OR OVER TODAY... We would like to speak directly to your child if he/she currently takes medicine on his/her own.

7. Is your child able to participate in the interview? *(Complete dataform 2B at the end of the interview)*	____	1. No 2. Yes 3. Under 12 years of age

These questions are asked of parent/guardian or the primary caregiver

8. What is your relationship to the child?	_____	1. Parent/Legal Guardian 2. Grandparent/Other Relative 3. Babysitter/Nanny
9. Who supervises your child when medicine is administered? *(Choose all that apply)*	_____ _____ _____	1. No one 2. Parent/Legal Guardian 3. Grandparent/Other Relative 4. Friend/Neighbor 5. Day care provider 6. Babysitter/Nanny 7. School nurse 8. Sibling
10. How is your child doing now, compared to the time of his/her visit on ___/___/___?	_____	1. Much worse 2. A little worse 3. About the same 4. A little better 5. Much better
11. In general how would you rate you child's health at the present time?	_____	1. Poor 2. Fair 3. Good 4. Very good 5. Excellent
12. Does your child have a chronic or long-term health condition (a condition lasting longer than 3 months)?	_____	1. No 2. Yes, specify _____ _____

The next set of questions will ask you specifically about the prescriptions your child received when you saw Dr. _____ on ____/____/____. I will read your response choices whenever possible.

On this date, your child received prescriptions for:

13.	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
14. Sometimes it is difficult to go to the pharmacy. Were you able to fill your prescription?	_____	_____	_____
	1. No *(Go on to Q15)* 2. Yes *(Skip to Q17)*		
15. If no, why not? *(Go on to question 16, then Skip to Q40-Q45, then Q59-Q75)*	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	1. No time, too busy 2. Couldn't get to the pharmacy 3. Still have some of old medicine left 4. Couldn't afford medicine 5. Insurance does not cover medicine 6. Feeling better, I didn't think they needed medicine 7. Feeling better, Dr. prescribed just in case 8. Didn't think it was the right medicine 9. Other: Specify		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
16. If you were not able to fill the prescription, what did you do instead? (*Skip to Q40-Q45, then Q59-Q75)*	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	1. Got a different prescription, specify: 2. Got better without medicine 3. Gave another medicine had at home already, specify 4. Used an over the counter medicine instead, specify 5. Used an alternative medicine instead 6. Other, specify		
17. Besides the prescriptions your child received at this visit, do they take any additional prescription medications?	_____	_____	_____
	1. No *(Go on to Q18)* 2. Yes *(Complete Prescription Medication Supplement and go on to Q18)*		

The next set of questions asks you about ALL the PRESCRIPTION medicine your child is currently taking. This includes the medications your child received at this specific visit as well as any other prescription medications that they are taking. I am going to have you read me some things off the labels of the bottles so I will hold while you retrieve all the prescription medicine containers.

Questions 18 to 39 concern only the medications the patient received at the target visit.
Use Chart Supplement form for additional prescription medications.
If they have the medicine containers--**Please read directly from the medicine containers.**

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
18. Do you still have the medicine containers from this visit?	____	____	____
	1. No *(Skip to Q29)* 2. Yes *(Go on to Q20)* 3. Yes, not available *(Skip to Q29)*		
19. Drug Class *(to be filled in by RN)*	____	____	____
20. Is this a new prescription or a refill?	____	____	____
	1. New prescription 2. Refill 3. Don't know/remember		
21. Please read the strength of the medicine.	____	____	____
22. Dose: Please read the dosage.	____	____	____
23. Frequency: Please read how often the medicine is supposed to be taken.	____ specify: _____	____ specify: _____	____ specify: _____
	1. 1 time a day 2. 2 times a day 3. 3 times a day 4. As needed, specify frequency 5. Other, specify		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
24. Route: Please read the route by which the medicine should be taken.	_____ specify: _____	_____ specify: _____	_____ specify: _____
	1. PO 2. Topical 3. Subcutaneous 4. Rectal 5. Otic 6. Eye 7. Inhalation 8. Other, specify 9. Not specified 10. Nasally 11. As directed		
25. Duration: How long should the medicine be taken for?	_____	_____	_____
26. Duration Units	_____ specify: _____	_____ specify: _____	_____ specify: _____
	1. Days 2. Weeks 3. Months 4. As needed 5. Other, specify		
27. Please read the total amount of medicine in the container.	_____	_____	_____

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
28. What does your child take this medicine for?	_____ specify: _____	_____ specify: _____	_____ specify: _____
	1. Know, specify 2. Don't know		
29. If any of the medicines were liquid, what type of measuring device did you use?	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	1. Not a liquid 2. Kitchen teaspoon 3. Kitchen tablespoon 4. Measuring spoon (used for recipes) 5. Measuring device provided with this medicine (measuring cup, tube, syringe) 6. Measuring devise provided with another medicine 7. Lid of the bottle 8. None 9. Other: Specify		

Now I will ask you about information you received when you were given the prescription

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
30. When you received the prescription at the office and the medication at the pharmacy, did anyone tell you what the medicine was for? *(Choose all that apply)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	1. No *(Go on to Q31)* 2. Yes, my primary care provider *(Skip to Q32)* 3. Yes, another doctor/provider *(Skip to Q32)* 4. Yes, the nurse in the office *(Skip to Q32)* 5. Yes, the pharmacist in the pharmacy *(Skip to Q32)* 6. Yes, I received printed information about the medicine at the office or pharmacy *(Skip to Q32)* 7. Don't know/remember *(Skip to Q32)*		
31. If no, why not	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	1. Was not offered to me 2. Have received this medicine before and did not need further instruction 3. Didn't want any 4. I did not have enough time 5. Other: Specify 6. I did not accompany my child to the office 7. I did not pick up the medicine at the pharmacy		
32. Did anyone tell you about possible side effects?	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	1. No *(Go on to Q33)* 2. Yes, my primary care provider *(Skip to Q34)* 3. Yes, another doctor/provider *(Skip to Q34)* 4. Yes, the nurse in the office *(Skip to Q34)* 5. Yes, the pharmacist in the pharmacy *(Skip to Q34)* 6. Yes, I received printed information about the medicine at the office or pharmacy *(Skip to Q34)* 7. Don't know/remember *(Skip to Q34)*		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
33. If no, why not	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	1. Was not offered to me 2. Have received this medicine before and did not need further instruction 3. Didn't want any 4. I did not have enough time 5. Other: Specify 6. I did not accompany my child to the office 7. I did not pick up the medicine at the pharmacy		
34. Did your pharmacist have any questions regarding your prescription that he had to ask you or your health care provider about?	____	____	____
	1. No *(Skip to Q36)* 2. Yes—I was able to clarify it *(Go on to Q35)* 3. Yes—the pharmacist had to call the health care provider *(Go on to Q35)* 4. Don't know/remember *(Skip to Q36)*		
35. What was the question about? *(Choose all that apply)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	1. Name of medicine 2. Dose 3. Route 4. Frequency 5. Directions for use 6. Number/amount to be dispensed 7. Strength 8. Drug to drug interactions 9. Allergies 10. Weight 11. Age/Date of Birth 12. Don't know/remember 13. Other: Specify		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
36. To your knowledge, were there any differences between what your child's health care provider prescribed and the medicine you got from the pharmacist?	____	____	____
	1. No *(Skip to Q38)* 2. Yes *(Go on to Q37)* 3. Don't know/remember *(Skip to Q38)*		
37. What was the difference? *(List up to three choices)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	1. Name of medicine 2. Dose 3. Route 4. Frequency 5. Directions for use 6. Number/amount to be dispensed 7. Strength 8. Drug to drug interactions 9. Allergies 10. I received a medication intended for another pt. 11. The name of the patient on the medicine was not my child 12. Don't know/remember 13. Other: Specify		
38. Is your child still taking the medicine?	____	____	____
	1. No *(Go on to Q39)* 2. Yes *(Skip to Q40)* 3. Don't know/remember *(Skip to Q40)*		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
39. If no, why not? *(List up to three choices)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	1. Completed therapy 2. Health care provider changed course of therapy 3. Ran out of medicine 4. Medicine not available from the pharmacy 5. I felt that my child did not need the medicine 6. Side effect of the medicine 7. Child refused medicine 8. Never took medicine		

40. Is your child allergic to any medicines? _____ 1. No *(Skip to Q42)*
2. Yes *(Go on to Q41)*

41. Indicate medicine and type of reaction:

A. Medication	**B. Type of Reaction**

42. Since the health care provider's visit, has your child had any side effects from any medicine(s) or symptoms made worse by the any medicine(s)? _____

1. No *(Skip to Q46)*
2. Yes *(Go onto Q43)*
3. Don't know/remember *(Skip to Q46)*

43. What side effects has your child experienced? *Fill in the chart below.*

A Side Effect Description	B Side Effect Code *See table below for codes*	C How long ago did this symptom start? 1=<1 day 2= 1-3 days 3= 4-7 days 4= 8-28 days 5= 1-3 months 6= > 3 months	D How long did this symptom last? 1=< 1 day 2= 1 day 3= 2 days 4= 3-4 days 5= 5-7 days 6= 8-14 days 7= 15-28 days 8= 1-3 months 9= > 3 months 10=ongoing	E Do you think this symptom is related to a medicine? *Choose all that apply* 1= Target rx (specify) 2= Other rx (specify) 3= DK 4=not related to medicine *(skip to H)*	F Is your child still taking the medicine? 1= No 2= Yes, all the time 3= Yes, PRN	G Does/did this symptom occur with every dose? 1= No 2= Yes 3= DK	H How soon after taking the medicine did these symptoms occur? 1=<1 day 2= 1-3 days 3= 4-7 days 4= >7 days 5=before the medicine	I Since the symptom began, have /did you discuss(ed) it with a health care provider? 1=No 2=Yes, MD 3=Yes, RN 4=Yes, NP 5=Yes, PA 6=Yes, other person in office 7=Yes, pharmacist 8= Yes, other, specify **If YES, skip toK** ***If NO, go on to J***	J If the health care provider was not contacted, why not? 1= Could not get in touch with provider 2= Did not think it was important 3= Sx went away too quickly 4= Medicine was completed 5= Was told to expect this 6= Other **Skip to M**	K Was anything done in response? 1= No 2= Yes *If YES, go on to L* *If NO, skip to M*	L What was done? 1= Continue with med 2= Treatment with another med 3=Med changed/ stopped 4= Changed dose of med 5= Other (specify) *Go on to M*	M Did this symptom require an additional visit to a medical facility or contact with a health care provider? *Choose all that apply* 1=No 2=Clinic visit 3= Emergency room visit 4=Hospitalization 5= Email 6=Phone call 7=Other (specify)

Codes for column B:

1. Fever	6. GI: Pain	11. Resp: Wheeze	16. CNS: Hyperactivity	21. Derm: Skin rash or itch
2. Hydration	7. GI: Nausea/Vomitting	12. Resp: Cyanosis	17. CNS: Headache	22. Derm: Swelling mouth/throat/tongue
3. GI: Eating	8. GU: Frequency	13. CNS: Fatigue/Dowsy	18. CNS: Fussiness	23. Cardiac: Palpitations, tachycardia
4. GI: Diarrhea	9. GU: Pain	14. CNS: Difficulty sleeping	19. CNS: Altered status	24. Other: Specify_____
5. GI: Constipation	10. Resp: SOB	15. CNS: Confusion	20. CNS: Seizure	25. Other: Specify_____

We would like to contact the health care provider about these symptoms. If you do not give us permission, we will not contact the health care provider regarding these symptoms. If there is anything you are worried about, please contact the health care provider.

44. Would it be OK for us to contact your health care provider about these symptoms _____ 1. No 2. Yes

45. How many times in total did you contact the health care provider or has your child been seen by a health care provider about the above symptoms?

a. How many... _____ Clinic visits?
b. How many... _____ Emergency room visits?
c. How many... _____ Hospitalizations?
d. How many... _____ Emails?
e. How many... _____ Phone calls?
f. How many... _____ Other, specify _____?

Most children miss medicine doses at one time or another. It is hard to take medicines exactly as the health care provider said, especially with children. We understand how difficult it is to give children all their medicines. These questions are about the medicines your child was prescribed at the last visit.

46. In the last week, how many doses do you think your child has missed? _____
1. None *(Skip to Q49)*
2. One or Two *(Go to Q47)*
3. Three or Four *(Go to Q47)*
4. Five or Six *(Go to Q47)*
5. More than Six *(Go to Q47)*

47. Which medicine did you child miss and why?

A. Name of Medication Missed	**B. Medication Class** *(Completed by RN)*	**C. Why was the medicine missed** ***(Use codes below)***	
		Code	**Specify**
a.			
b.			
c.			

Codes for column C

1. Forgot to take the medicine
2. Ran out of medicine
3. Medicine not available (misplaced or not with the patient at time of dose)
4. Felt that the medicine was not needed
5. Side effect of the medicine
6. Refused
7. Spit out
8. Vomited
9. Asleep
10. Other, specify _____

48. What do you usually do if he/she misses a dose of medicine?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. What do you do if a dose is missed? 1= Double the next dose 2= Give as soon as I remember 3= Skip the dose 4= Other: Specify 5= Don't double up	
		Code	**Specify**
a.			
b.			
c.			

49. Who told you what to do if you missed a dose? *(Choose all that apply and Go on to Q50)*

_____ _____ _____

1. Primary care provider or Another doctor/provider
2. The nurse in the office
3. Pharmacist in the pharmacy
4. Printout from pharmacy or doctor's office
5. Other, specify: _____
6. Don't know/remember
7. Nobody *(Skip to Q51)*

50. What did they tell you to do?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. What did they tell you to do? 1= Double the next dose 2= Give as soon as I remember 3= Skip the dose 4= Other: Specify 5= Don't double up 6= Refer to printout	
		Code	**Specify**
a.			
b.			
c.			

51. In the last week, how many extra doses do you think he/she has been given/taken

_____

1. None *(Skip to Q53)*
2. One or Two *(Go to Q52)*
3. Three or Four *(Go to Q52)*
4. Five of Six *(Go to Q52)*
5. More than Six *(Go to Q52)*

52. Which medicine did you child receive extra doses of and why?

A. Name of Medication	B. Medication Class *(Completed by RN)*	C. Why was extra medicine given *(Use codes below)*	
		Code	**Specify**
a.			
b.			
c.			

Codes for column C

1. Tried to catch up on missed doses
2. Thought is was better to take more or that the child needed more
3. Forgot the medicine was already taken/given
4. Gave what was left in the bottle
5. Caregiver miscommunication
6. Other, specify: _____

53. Does/Did your child need to take medicine while in school or day care?

_____ 1. No *(Skip to Q56)*
2. Yes *(Go on to Q54)*

54. Did your child miss any doses that where due in school or day care?

_____ 1. No *(Skip to Q56)*
2. Yes *(Go on to Q55)*
3. Don't know *(Skip to Q56)*

55. Which medicine did you child miss and why?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. Why was the medicine missed *(Use codes below)*	
		Code	**Specify**
a.			
b.			
c.			

Codes for column C

1. Forgot to go the nurse
2. Nurse forgot to have child come to office
3. No nurse was available to give the medicine
4. Did not have enough medicine
5. Did not have a note to administer medicine
6. Forgot to send medicine to school
7. Did not want to send medicine to school
8. Don't know/remember
9. Other, specify _____

56. Does your child take any over the counter medicines (including fever or pain medicine, such as tylenol, motrin, or advil; cough and cold medicine; vitamins; dietary supplements; and herbal supplements or teas)

_____ 1. No *(Skip to Q59)*
2. Yes *(Go on to Q57)*
3. Don't know/remember *(Skip to Q59)*

57. Please tell me all the non-prescription medicine your child is currently taking.

A. Medication Name	*B. Drug Class (to be completed by RN)*	C. How frequently does your child take this medicine? 1=daily 2=weekly 3=monthly 4=as needed 5= daily when sick 6= as needed when sick	D. What does your child take this medicine for? 1=Know: Specify 2=Don't know		E. Has your child had any problems with this medicine? 1=Yes: Specify 2=Don't know 3=No	
			Code	Specify	Code	Specify
1.						
2.						
3.						
4.						

58. Did anyone in the office or pharmacy recommend or tell you how to use any of these medicines? *(Choose all that apply)* _____ _____ _____

1. No
2. Primary care provider or Another doctor/provider,
3. The nurse in the office
4. Pharmacist in the pharmacy
5. Other, specify: _____
6. Don't know/remember

We're almost done, I would just like to ask you a few demographic questions. Let me once again remind you that the information you provide is completely confidential. You can decide not to answer any question that makes you uncomfortable. I will read you response choices whenever possible.

59. How well do you think you speak English? _____

1. Very well
2. Well
3. Poorly
4. Not at all
5. Refused

60. What language do you speak with your paediatrician? *Q62)*

_____ 1. English *(Skip to*

2. Spanish *(Go on to Q61)*
3. Portuguese, including Portuguese Creole *(Go on to Q61)*
4. Cambodian (Khmer) *(Go on to Q61)*
5. French *(Go on to Q61)*

6. Other: _____ *(Go on to Q61)*
7. Refused

61. Was an interpreter used during your visit? _____
1. No interpreter used
2. Professional interpreter provided by the clinic
3. Professional interpreter I brought with me.
4. Child for whom the script was written
5. Other child
Specify age of child: ____
6. Other relative, specify: _____
7. Friend
8. Other, specify: _____
9. Refused

62. What language do you speak at home? _____ _____
1. English
2. Spanish
3. Portuguese, including Portuguese Creole
4. Cambodian (Khmer)
5. French
6. Other, specify: _____
7. Refused

63. What other languages do you speak? *(Choose all that apply)* _____ _____
1. English
2. Spanish
3. Portuguese, including Portuguese Creole
4. Cambodian (Khmer)
5. French
6. Other, specify: _____
7. None
8. Refused

64. What is the highest level of education you have completed? _____
1. 8th grade or less
2. Did not finish high school
3. High school graduate or GED
4. Some college or technical school
5. College graduate (Bachelor's degree)
6. Some post-graduate education
7. Post-graduate degree
8. Other, specify: _____

9. Technical program (completed)
10. Associates Degree (completed)
11. Refused

65. Which of the following describes your child's race? *(Choose all that apply)* ____ ____ ____
1. White
2. Black or African-American
3. American Indian or Alaska Native
4. Hispanic
5. Asian
6. Native Hawaiian or other Pacific Islander
7. Other race, specify _____
8. Refused

66. How many adults live in your household? ____

67. How many children live in your household? ____

68. What kind of insurance do you have? *(Indicate the name of the insurance)* _____

69. Do you have a co-pay for prescriptions? ____
1. No *(Skip to Q71)*
2. Yes *(Go on to Q70)*
3. Refused

70. How much do you pay? $ ____

71. Do you have a co-pay for office visits? ____
1. No *(Skip to 73)*
2. Yes *(Go on to Q72)*
3. Refused

72. How much do you pay? $ ____

I would like to ask one final question about your average household total yearly income.

73. Is your average yearly income ____
1. Under $30,000 *(Go on to Q74)*
2. Over $30,000 *(Skip to Q75)*
3. Refused *(End of interview)*
4. Don't know *(End of interview)*

74. Is that... ____
1. Under $10,000 *(End)*
2. $10,000 to $20,000 *(End)*
3. Over $20,000 *(End)*
4. Don't know *(End)*
5. Refused *(End)*

75. Is that...

_____ 1. Under $40,000 *(End)*
2. $40,000 to $50,000 *(End)*
3. $50,000 to $80,000 *(End)*
4. Over $80,000 *(End)*
5. Don't know *(End)*
6. Refused *(End)*

That completes our survey. I would like to thank you again for your time, effort, and patience. Your participation in the Paediatric Outpatient Prescribing Study is greatly appreciated. We will contact you again, by phone, in 6 weeks. What is a good time of day to call? _____

Thanks again! Have nice day! ☺

DATAFORM 2A Version 5.0

10 Day Follow-up: Telephone Interview Form

Collect these data at T plus 10 days

RN Review (initials) _____ Date ____ / ____ / ____

2. Study ID Number: ____ ____-____ ____ ____ ____

3. Interviewer ID Number (Your initials): ____ ____

5. Date of Index Visit: ____ ____ / ____ ____ / ____ ____

6. Date of Telephone Interview: ____ ____ / ____ ____ / ____ ____

Start here: **May I speak with the parent or legal guardian of _____**

[Child's Name]

If the parent or legal guardian is NOT available, then ask for the best time to reach that person during the next day.

Hello, my name is _____ and I'm calling on behalf of _____.
[Your Name] [Clinic Name]
Your doctor/health care provider is participating in a research study to improve the way medicine is prescribed in paediatricians' offices. You should have received a letter in the mail about this study. We are interviewing parents and legal guardians of children who have recently been prescribed a medicine by their paediatrician. The interview takes approximately 20 minutes and all the information you provide is completely confidential. Participation is entirely voluntary and you may skip any questions that you do not feel comfortable answering.

5. Would you like to participate? _____
   1. No *(Go on to Q6)*
   2. Yes *(Skip to Q7)*

6. Would you take a few moments to tell us why _____
   1. Not interested
   6. Concerned about confidentiality
   7. Not enough time
   8. Refuses to answer
   9. Other, specify: _____

Thank you very much for your time.

ASK ONLY IF CHILD 12 OR OVER TODAY... We would like to speak directly to your child if he/she currently takes medicine on his/her own.

7. Is your child able to participate in the interview? *(Complete dataform 2B at the end of the interview)*	____	1. No 2. Yes 3. Under 12 years of age

These questions are asked of parent/guardian or the primary caregiver

9. What is your relationship to the child?	_____	1. Parent/Legal Guardian 9. Grandparent/Other Relative 10. Babysitter/Nanny 11. Mother 12. Father 13. Legal Guardian-Female 14. Legal Guardian- Male 15. Grandmother 16. Grandfather 17. Patient 18. Other: Specify_____
9. Who supervises your child when medicine is administered? *(Choose all that apply)*	_____ _____ _____	1. No one 2. Parent/Legal Guardian 3. Grandparent/Other Relative 4. Friend/Neighbor 5. Day care provider 6. Babysitter/Nanny 7. School nurse 8. Sibling
10. How is your child doing now, compared to the time of his/her visit on ___/___/___?	_____	1. Much worse 2. A little worse 6. About the same 7. A little better 8. Much better
11. In general how would you rate you child's health at the present time?	_____	1. Poor 2. Fair 6. Good 7. Very good 8. Excellent

12. Does your child have a chronic or long-term health condition (a condition lasting longer than 3 months)?

_____ 1. No
2. Yes, specify _____
_____

The next set of questions will ask you specifically about the prescriptions your child received when you saw Dr. _____ on ____/____/____. I will read your response choices whenever possible.

On this date, your child received prescriptions for:

13.	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
14. Sometimes it is difficult to go to the pharmacy. Were you able to fill your child's presciption?	_____	_____	_____
	3. No *(Go on to Q15)* 4. Yes *(Skip to Q17)*		
15. If no, why not? *(Go on to question 16, then Skip to Q40-Q45, then Q59-Q75)*	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	10. No time, too busy 11. Couldn't get to the pharmacy 12. Still have some of old medicine left 13. Couldn't afford medicine 14. Insurance does not cover medicine 15. Feeling better, I didn't think they needed medicine 16. Feeling better, Dr. prescribed just in case 17. Didn't think it was the right medicine 18. Other: Specify		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
16. If you were not able to fill the prescription, what did you do instead? *(Skip to Q40-Q45, then Q59-Q75)*	____ Specify: _____	____ Specify: _____	____ Specify: _____
	1. Got a different prescription, specify: 2. Got better without medicine 3. Gave another medicine had at home already, specify 4. Used an over the counter medicine instead, specify 5. Used an alternative medicine instead 6. Other, specify		
17. Besides the prescriptions your child received at this visit, do they take any additional prescription medications?	____	____	____
	3. No *(Go on to Q18)* 4. Yes *(Complete Prescription Medication Supplement and go on to Q18)*		

The next set of questions asks you about ALL the PRESCRIPTION medicine your child is currently taking. This includes the medications your child received at this specific visit as well as any other prescription medications that they are taking. I am going to have you read me some things off the labels of the bottles so I will hold while you retrieve all the prescription medicine containers.

Questions 18 to 39 concern only the medications the patient received at the target visit.
Use Chart Supplement form for additional prescription medications.
If they have the medicine containers--**Please read directly from the medicine containers.**

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
18. Do you still have the medicine containers from this visit?	____	____	____
	4. No *(Skip to Q29)* 5. Yes *(Go on to Q20)* 6. Yes, not available *(Skip to Q29)*		
19. Drug Class *(to be filled in by RN)*	____	____	____
20. Is this a new prescription or a refill?	____	____	____
	4. New prescription 5. Refill 6. Don't know/remember		
21. Please read the strength of the medicine.	____	____	____
22. Dose: Please read the dosage.	____	____	____
23. Frequency: Please read how often the medicine is supposed to be taken.	____ specify: _____	____ specify: _____	____ specify: _____
	6. 1 time a day 7. 2 times a day 8. 3 times a day 9. As needed, specify frequency 10. Other, specify		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
24. Route: Please read the route by which the medicine should be taken.	_____ specify: _____	_____ specify: _____	_____ specify: _____
	12. PO 13. Topical 14. Subcutaneous 15. Rectal 16. Otic 17. Eye 18. Inhalation 19. Other, specify 20. Not specified 21. Nasally 22. As directed		
25. Duration: How long should the medicine be taken for?	_____	_____	_____
26. Duration Units	_____ specify: _____	_____ specify: _____	_____ specify: _____
	6. Days 7. Weeks 8. Months 9. As needed 10. Other, specify		
27. Please read the total amount of medicine in the container.	_____	_____	_____

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
28. What does your child take this medicine for?	_____ specify: _____	_____ specify: _____	_____ specify: _____
	3. Know, specify 4. Don't know		
36. If any of the medicines were liquid, what type of measuring device did you use?	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	10. Not a liquid 11. Kitchen teaspoon 12. Kitchen tablespoon 13. Measuring spoon (used for recipes) 14. Measuring device provided with this medicine (measuring cup, tube, syringe) 15. Measuring devise provided with another medicine 16. Lid of the bottle 17. None 18. Other: Specify		

Now I will ask you about information you received when you were given the prescription

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
37. When you received the prescription at the office and the medication at the pharmacy, did anyone tell you what the medicine was for? *(Choose all that apply)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	8. No *(Go on to Q31)* 9. Yes, my primary care provider *(Skip to Q32)* 10. Yes, another doctor/provider (*Skip to Q32)* 11. Yes, the nurse in the office *(Skip to Q32)* 12. Yes, the pharmacist in the pharmacy *(Skip to Q32)* 13. Yes, I received printed information about the medicine at the office or pharmacy *(Skip to Q32)* 14. Don't know/remember *(Skip to Q32)*		
38. If no, why not	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	8. Was not offered to me 9. Have received this medicine before and did not need further instruction 10. Didn't want any 11. I did not have enough time 12. Other: Specify 13. I did not accompany my child to the office 14. I did not pick up the medicine at the pharmacy		
39. Did anyone tell you about possible side effects?	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____

	8. No *(Go on to Q33)* 9. Yes, my primary care provider *(Skip to Q34)* 10. Yes, another doctor/provider *(Skip to Q34)* 11. Yes, the nurse in the office *(Skip to Q34)* 12. Yes, the pharmacist in the pharmacy *(Skip to Q34)* 13. Yes, I received printed information about the medicine at the office or pharmacy *(Skip to Q34)* 14. Don't know/remember *(Skip to Q34)*		
	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
40. If no, why not	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	8. Was not offered to me 9. Have received this medicine before and did not need further instruction 10. Didn't want any 11. I did not have enough time 12. Other: Specify 13. I did not accompany my child to the office 14. I did not pick up the medicine at the pharmacy		
41. Did your pharmacist have any questions regarding your prescription that he had to ask you or your health care provider about?	____	____	____
	5. No *(Skip to Q36)* 6. Yes—I was able to clarify it *(Go on to Q35)* 7. Yes—the pharmacist had to call the health care provider *(Go on to Q35)* 8. Don't know/remember *(Skip to Q36)*		
42. What was the question about? *(Choose all that apply)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____

	14. Name of medicine 15. Dose 16. Route 17. Frequency 18. Directions for use 19. Number/amount to be dispensed 20. Strength 21. Drug to drug interactions 22. Allergies 23. Weight 24. Age/Date of Birth 25. Don't know/remember 26. Other: Specify

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
40. To your knowledge, were there any differences between what your child's health care provider prescribed and the medicine you got from the pharmacist?	____	____	____
	4. No *(Skip to Q38)* 5. Yes *(Go on to Q37)* 6. Don't know/remember *(Skip to Q38)*		
41. What was the difference? *(List up to three choices)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	14. Name of medicine 15. Dose 16. Route 17. Frequency 18. Directions for use 19. Number/amount to be dispensed 20. Strength 21. Drug to drug interactions 22. Allergies 23. I received a medication intended for another pt. 24. The name of the patient on the medicine was not my child 25. Don't know/remember 26. Other: Specify		
42. Is your child still taking the medicine?	____	____	____
	4. No *(Go on to Q39)* 5. Yes *(Skip to Q40)* 6. Don't know/remember *(Skip to Q40)*		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
43. If no, why not? *(List up to three choices)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	9. Completed therapy 10. Health care provider changed course of therapy 11. Ran out of medicine 12. Medicine not available from the pharmacy 13. I felt that my child did not need the medicine 14. Side effect of the medicine 15. Child refused medicine 16. Never took medicine		

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40. Is your child allergic to any medicines? _____ 1. No *(Skip to Q42)*
2. Yes *(Go on to Q41)*

41. Indicate medicine and type of reaction:

A. Medication	B. Type of Reaction

42. Since the health care provider's visit, has your child had any side effects from any medicine(s) or symptoms made worse by the any medicine(s)?

_____ 1. No *(Skip to Q46)*
2. Yes *(Go onto Q43)*
3. Don't know/remember *(Skip to Q46)*

43. What side effects has your child experienced? *Fill in the chart below.*

A Side Effect Description	B Side Effect Code *See table below for codes*	C How long ago did this symptom start? 1=<1 day 2= 1-3 days 3= 4-7 days 4= 8-28 days 5= 1-3 months 6= > 3 months	D How long did this symptom last? 1=< 1 day 2= 1 day 3= 2 days 4= 3-4 days 5= 5-7 days 6= 8-14 days 7= 15-28 days 8= 1-3 months 9= > 3 months 10=ongoing	E Do you think this symptom is related to a medicine? *Choose all that apply* 1= Target rx (specify) 2= Other rx (specify) 3= DK 4=not related to medicine *(skip to H)*	F Is your child still taking the medicine? 1= No 2= Yes, all the time 3= Yes, PRN	G Does/did this symptom occur with every dose? 1= No 2= Yes 3= DK	H How soon after taking the medicine did these symptoms occur? 1=<1 day 2= 1-3 days 3= 4-7 days 4= >7 days 5=before the medicine	I Since the symptom began, have /did you discuss(ed) it with a health care provider? 1=No 2=Yes, MD 3=Yes, RN 4=Yes, NP 5=Yes, PA 6=Yes, other person in office 7=Yes, pharmacist 8= Yes, other, specify **If YES, skip toK** *If NO, go on to J*	J If the health care provider was not contacted, why not? 1= Could not get in touch with provider 2= Did not think it was important 3= Sx went away too quickly 4= Medicine was completed 5= Was told to expect this 6= Other **Skip to M**	K Was anything done in response? 1= No 2= Yes *If YES, go on to L* *If NO, skip to M*	L What was done? 1= Continue with med 2= Treatment with another med 3=Med changed/ stopped 4= Changed dose of med 5= Other (specify) *Go on to M*	M Did this symptom require an additional visit to a medical facility or contact with a health care provider? *Choose all that apply* 1=No 2=Clinic visit 3= Emergency room visit 4=Hospitalization 5= Email 6=Phone call 7=Other (specify)

Codes for column B:

1. Fever	6. GI: Pain	11. Resp: Wheeze	16. CNS: Hyperactivity	21. Derm: Skin rash or itch
2. Hydration	7. GI: Nausea/Vomitting	12. Resp: Cyanosis	17. CNS: Headache	22. Derm: Swelling mouth/throat/tongue
3. GI: Eating	8. GU: Frequency	13. CNS: Fatigue/Dowsy	18. CNS: Fussiness	23. Cardiac: Palpitations, tachycardia
4. GI: Diarrhea	9. GU: Pain	14. CNS: Difficulty sleeping	19. CNS: Altered status	24. Other: Specify_____
5. GI: Constipation	10. Resp: SOB	15. CNS: Confusion	20. CNS: Seizure	25. Other: Specify_____

We would like to contact the health care provider about these symptoms. If you do not give us permission, we will not contact the health care provider regarding these symptoms. If there is anything you are worried about, please contact the health care provider.

44. Would it be OK for us to contact your health care provider about these symptoms _____ 1. No 2. Yes

45. How many times in total did you contact the health care provider or has your child been seen by a health care provider about the above symptoms?

a. How many... _____ Clinic visits?
b. How many... _____ Emergency room visits?
c. How many... _____ Hospitalizations?
d. How many... _____ Emails?
e. How many... _____ Phone calls?
f. How many... _____ Other, specify _____?

Most children miss medicine doses at one time or another. It is hard to take medicines exactly as the health care provider said, especially with children. We understand how difficult it is to give children all their medicines. These questions are about the medicines your child was prescribed at the last visit.

46. In the last week, how many doses do you think your child has missed? _____
1. None *(Skip to Q49)*
2. One or Two *(Go to Q47)*
3. Three or Four *(Go to Q47)*
4. Five or Six *(Go to Q47)*
5. More than Six *(Go to Q47)*

47. Which medicine did you child miss and why?

A. Name of Medication Missed	**B. Medication Class** *(Completed by RN)*	**C. Why was the medicine missed** ***(Use codes below)***	
		Code	**Specify**
a.			
b.			
c.			

Codes for column C

1. Forgot to take the medicine
11. Ran out of medicine
12. Medicine not available (misplaced or not with the patient at time of dose)
13. Felt that the medicine was not needed
14. Side effect of the medicine
15. Refused
16. Spit out
17. Vomited
18. Asleep
19. Other, specify _____

48. What do you usually do if he/she misses a dose of medicine?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. What do you do if a dose is missed? 1= Double the next dose 2= Give as soon as I remember 3= Skip the dose 4= Other: Specify 5= Don't double up	
		Code	**Specify**
a.			
b.			
c.			

49. Who told you what to do if you missed a dose? *(Choose all that apply and Go on to Q50)*

_____ _____ _____

1. Primary care provider or Another doctor/provider
2. The nurse in the office
3. Pharmacist in the pharmacy
4. Printout from pharmacy or doctor's office
5. Other, specify: _____
6. Don't know/remember
7. Nobody *(Skip to Q51)*

50. What did they tell you to do?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. What did they tell you to do? 1= Double the next dose 2= Give as soon as I remember 3= Skip the dose 4= Other: Specify 5= Don't double up 6= Refer to printout	
		Code	**Specify**
a.			
b.			
c.			

51. In the last week, how many extra doses do you think he/she has been given/taken

_____

1. None *(Skip to Q53)*
2. One or Two *(Go to Q52)*
3. Three or Four *(Go to Q52)*
6. Five of Six *(Go to Q52)*
7. More than Six *(Go to Q52)*

52. Which medicine did you child receive extra doses of and why?

A. Name of Medication	B. Medication Class *(Completed by RN)*	C. Why was extra medicine given *(Use codes below)*	
		Code	Specify
a.			
b.			
c.			

Codes for column C

1. Tried to catch up on missed doses
7. Thought is was better to take more or that the child needed more
8. Forgot the medicine was already taken/given
9. Gave what was left in the bottle
10. Caregiver miscommunication
11. Other, specify: _____

53. Does/Did your child need to take medicine while in school or day care?
_____ 1. No *(Skip to Q56)*
2. Yes *(Go on to Q54)*

54. Did your child miss any doses that where due in school or day care?
_____ 1. No *(Skip to Q56)*
2. Yes *(Go on to Q55)*
3. Don't know *(Skip to Q56)*

55. Which medicine did you child miss and why?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. Why was the medicine missed *(Use codes below)*	
		Code	Specify
a.			
b.			
c.			

Codes for column C

10. Forgot to go the nurse
11. Nurse forgot to have child come to office
12. No nurse was available to give the medicine
13. Did not have enough medicine
14. Did not have a note to administer medicine
15. Forgot to send medicine to school
16. Did not want to send medicine to school
17. Don't know/remember
18. Other, specify _____

56. Does your child take any over the counter medicines (including fever or pain medicine, such as tylenol, motrin, or advil; cough and cold medicine; vitamins; dietary supplements; and herbal supplements or teas)
_____ 1. No *(Skip to Q59)*
2. Yes *(Go on to Q57)*
3. Don't know/remember *(Skip to Q59)*

57. Please tell me all the non-prescription medicine your child is currently taking.

A. Medication Name	***B. Drug Class (to be completed by RN)***	**C. How frequently does your child take this medicine?** **1=daily** **2=weekly** **3=monthly** **4=as needed** **5= daily when sick** **6= as needed when sick**	**D. What does your child take this medicine for?** **1=Know: Specify** **2=Don't know**		**E. Has your child had any problems with this medicine?** **1=Yes: Specify** **2=Don't know** **3=No**	
			Code	Specify	Code	Specify
1.						
2.						
3.						
4.						

58. Did anyone in the office or pharmacy recommend or tell you how to use any of these medicines? *(Choose all that apply)* ____ ____ ____

1. No
2. Primary care provider or Another doctor/provider,
3. The nurse in the office
7. Pharmacist in the pharmacy
8. Other, specify: _____
9. Don't know/remember

We're almost done, I would just like to ask you a few demographic questions. Let me once again remind you that the information you provide is completely confidential. You can decide not to answer any question that makes you uncomfortable. I will read you response choices whenever possible.

59. How well do you think you speak English? ____

1. Very well
12. Well
13. Poorly
14. Not at all
15. Refused

60. What language do you speak with your paediatrician? *Q62)* ____

1. English *(Skip to*

8. Spanish *(Go on to Q61)*
9. Portuguese, including Portuguese Creole *(Go on to Q61)*
10. Cambodian (Khmer) *(Go on to Q61)*
11. French *(Go on to Q61)*

12. Other: _____ *(Go on to Q61)*
13. Refused

61. Was an interpreter used during your visit? _____
1. No interpreter used
10. Professional interpreter provided by the clinic
11. Professional interpreter I brought with me.
12. Child for whom the script was written
13. Other child
Specify age of child: ____
14. Other relative, specify: _____
15. Friend
16. Other, specify: _____
17. Refused

62. What language do you speak at home? _____ _____
1. English
2. Spanish
8. Portuguese, including Portuguese Creole
9. Cambodian (Khmer)
10. French
11. Other, specify: _____
12. Refused

63. What other languages do you speak? *(Choose all that apply)* _____ _____
1. English
2. Spanish
9. Portuguese, including Portuguese Creole
10. Cambodian (Khmer)
11. French
12. Other, specify: _____
13. None
14. Refused

64. What is the highest level of education you have completed? _____
1. 8th grade or less
2. Did not finish high school
3. High school graduate or GED
6. Some college or technical school
7. College graduate (Bachelor's degree)
16. Some post-graduate education
17. Post-graduate degree
18. Other, specify: _____

19. Technical program (completed)
20. Associates Degree (completed)
21. Refused

65. Which of the following describes your child's race? *(Choose all that apply)* _____ _____ _____
1. White
2. Black or African-American
3. American Indian or Alaska Native
4. Hispanic
9. Asian
10. Native Hawaiian or other Pacific Islander
11. Other race, specify _____
12. Refused

66. How many adults live in your household? _____

67. How many children live in your household? _____

68. What kind of insurance do you have? *(Indicate the name of the insurance)* _____

69. Do you have a co-pay for prescriptions? _____
1. No *(Skip to Q71)*
2. Yes *(Go on to Q70)*
3. Refused

70. How much do you pay? $_____

71. Do you have a co-pay for office visits? _____
1. No *(Skip to 73)*
2. Yes *(Go on to Q72)*
3. Refused

72. How much do you pay? $_____

We have two final questions to ask you. The first question is about your average household total yearly income.

73. Is your average yearly income _____
1. Under $30,000 *(Go on to Q74)*
5. Over $30,000 *(Skip to Q75)*
6. Refused *(Skip to Q76)*
7. Don't know *(Skip to Q76)*

74. Is that... _____
1. Under $10,000 *(Skip to Q76)*
6. $10,000 to $20,000 *(Skip to Q76)*
7. Over $20,000 *(Skip to Q76)*

8. Don't know *(Skip to Q76)*
9. Refused *(Skip to Q76)*

75. Is that... _____
1. Under $40,000 *(Go on to Q76)*
7. $40,000 to $50,000 *(Go on to Q76)*
8. $50,000 to $80,000 *(Go on to Q76)*
9. Over $80,000 *(Go on to Q76)*
10. Don't know *(Go on to Q76)*
11. Refused *(Go on to Q76)*

76. What is your age? _____
1. 20 or less *(End of interview)*
2. 21-25 *(End)*
3. 26-30 *(End)*
4. 31-35 *(End)*
5. 36-40 *(End)*
6. 41-45 *(End)*
7. 46-50 *(End)*
8. 51-55 *(End)*
9. 56-60 *(End)*
10. >61 *(End)*
11. Decline to answer *(End)*

That completes our survey. I would like to thank you again for your time, effort, and patience. Your participation in the Paediatric Outpatient Prescribing Study is greatly appreciated. We will contact you again, by phone, in 6 weeks. What is a good time of day to call? _____

Thanks again! Have nice day! ☺

DATAFORM 2A Version 6.0

10 Day Follow-up: Telephone Interview Form

Collect these data at T plus 10 days

RN Review (initials)_____ Date_____/_____/_____

3. Study ID Number: ____ ____-____ ____ ____ ____

4. Interviewer ID Number (Your initials): ____ ____

7. Date of Index Visit: ____ ____ / ____ ____ / ____ ____

8. Date of Telephone Interview: ____ ____ / ____ ____ / ____ ____

Start here: May I speak with the parent or legal guardian of _____

[Child's Name]

If the parent or legal guardian is NOT available, then ask for the best time to reach that person during the next day.

Hello, my name is _____ and I'm calling on behalf of _____.
[Your Name] [Clinic Name]

Your doctor/health care provider is participating in a research study to improve the way medicine is prescribed in paediatricians' offices. You should have received a letter in the mail about this study. We are interviewing parents and legal guardians of children who have recently been prescribed a medicine by their paediatrician. The interview takes approximately 20 minutes and all the information you provide is completely confidential. Participation is entirely voluntary and you may skip any questions that you do not feel comfortable answering.

5. Would you like to participate? _____
   1. No *(Go on to Q6)*
   2. Yes *(Skip to Q7)*

6. Would you take a few moments to tell us why _____
   1. Not interested
   10. Concerned about confidentiality
   11. Not enough time
   12. Refuses to answer
   13. Other, specify: _____

Thank you very much for your time.

ASK ONLY IF CHILD 12 OR OVER TODAY... We would like to speak directly to your child if he/she currently takes medicine on his/her own.

7. Is your child able to participate in the interview? *(Complete dataform 2B at the end of the interview)*	____	1. No 2. Yes 3. Under 12 years of age

These questions are asked of parent/guardian or the primary caregiver

10. What is your relationship to the child?	_____	1. Parent/Legal Guardian 19. Grandparent/Other Relative 20. Babysitter/Nanny 21. Mother 22. Father 23. Legal Guardian-Female 24. Legal Guardian- Male 25. Grandmother 26. Grandfather 27. Patient 28. Other: Specify_____
9. Who supervises your child when medicine is administered? *(Choose all that apply)*	_____ _____ _____	1. No one 2. Parent/Legal Guardian 3. Grandparent/Other Relative 9. Friend/Neighbor 10. Day care provider 11. Babysitter/Nanny 12. School nurse 13. Sibling
10. How is your child doing now, compared to the time of his/her visit on ___/___/___?	_____	1. Much worse 2. A little worse 9. About the same 10. A little better 11. Much better
11. In general how would you rate you child's health at the present time?	_____	1. Poor 2. Fair 9. Good 10. Very good 11. Excellent
12. Does your child have a chronic or long-term health condition (a condition lasting longer than 3 months)?	_____	1. No 2. Yes, specify _____ _____

The next set of questions will ask you specifically about the prescriptions your child received when you saw Dr. _____ on ____/____/____. I will read your response choices whenever possible.

On this date, your child received prescriptions for:

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
13.			
14. Sometimes it is difficult to go to the pharmacy. Were you able to fill your child's presciption?	_____	_____	_____
	5. No *(Go on to Q15)* 6. Yes *(Skip to Q17)*		
15. If no, why not? *(Go on to question 16, then Skip to Q40-Q45, then Q59-Q75)*	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	19. No time, too busy 20. Couldn't get to the pharmacy 21. Still have some of old medicine left 22. Couldn't afford medicine 23. Insurance does not cover medicine 24. Feeling better, I didn't think they needed medicine 25. Feeling better, Dr. prescribed just in case 26. Didn't think it was the right medicine 27. Other: Specify		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
16. If you were not able to fill the prescription, what did you do instead? *(Skip to Q40-Q45, then Q59-Q75)*	____ Specify: _____	____ Specify: _____	____ Specify: _____
	1. Got a different prescription, specify: 2. Got better without medicine 3. Gave another medicine had at home already, specify 4. Used an over the counter medicine instead, specify 5. Used an alternative medicine instead 6. Other, specify		
17. Besides the prescriptions your child received at this visit, do they take any additional prescription medications?	____	____	____
	5. No *(Go on to Q18)* 6. Yes *(Complete Prescription Medication Supplement and go on to Q18)*		

The next set of questions asks you about ALL the PRESCRIPTION medicine your child is currently taking. This includes the medications your child received at this specific visit as well as any other prescription medications that they are taking. I am going to have you read me some things off the labels of the bottles so I will hold while you retrieve all the prescription medicine containers.

Questions 18 to 39 concern only the medications the patient received at the target visit.
Use Chart Supplement form for additional prescription medications.
If they have the medicine containers--**Please read directly from the medicine containers.**

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
18. Do you still have the medicine containers from this visit?	_____	_____	_____
	7. No *(Skip to Q29)* 8. Yes *(Go on to Q20)* 9. Yes, not available *(Skip to Q29)*		
19. Drug Class *(to be filled in by RN)*	_____	_____	_____
20. Is this a new prescription or a refill?	_____	_____	_____
	7. New prescription 8. Refill 9. Don't know/remember		
21. Please read the strength of the medicine.	_____	_____	_____
22. Dose: Please read the dosage.	_____	_____	_____
23. Frequency: Please read how often the medicine is supposed to be taken.	_____ specify: _____	_____ specify: _____	_____ specify: _____
	11. 1 time a day 12. 2 times a day 13. 3 times a day 14. As needed, specify frequency 15. Other, specify		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
24. Route: Please read the route by which the medicine should be taken.	_____ specify: _____	_____ specify: _____	_____ specify: _____
	23. PO 24. Topical 25. Subcutaneous 26. Rectal 27. Otic 28. Eye 29. Inhalation 30. Other, specify 31. Not specified 32. Nasally 33. As directed		
25. Duration: How long should the medicine be taken for?	_____	_____	_____
26. Duration Units	_____ specify: _____	_____ specify: _____	_____ specify: _____
	11. Days 12. Weeks 13. Months 14. As needed 15. Other, specify		
27. Please read the total amount of medicine in the container.	_____	_____	_____

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
28. What does your child take this medicine for?	_____ specify: _____	_____ specify: _____	_____ specify: _____
	5. Know, specify 6. Don't know		
43. If any of the medicines were liquid, what type of measuring device did you use?	_____ Specify: _____	_____ Specify: _____	_____ Specify: _____
	19. Not a liquid 20. Kitchen teaspoon 21. Kitchen tablespoon 22. Measuring spoon (used for recipes) 23. Measuring device provided with this medicine (measuring cup, tube, syringe) 24. Measuring devise provided with another medicine 25. Lid of the bottle 26. None 27. Other: Specify		

Now I will ask you about information you received when you were given the prescription

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
44. When you received the prescription at the office and the medication at the pharmacy, did anyone tell you what the medicine was for? *(Choose all that apply)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	15. No *(Go on to Q31)* 16. Yes, my primary care provider *(Skip to Q32)* 17. Yes, another doctor/provider (*Skip to Q32)* 18. Yes, the nurse in the office *(Skip to Q32)* 19. Yes, the pharmacist in the pharmacy *(Skip to Q32)* 20. Yes, I received printed information about the medicine at the office or pharmacy *(Skip to Q32)* 21. Don't know/remember *(Skip to Q32)*		
45. If no, why not	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	15. Was not offered to me 16. Have received this medicine before and did not need further instruction 17. Didn't want any 18. I did not have enough time 19. Other: Specify 20. I did not accompany my child to the office 21. I did not pick up the medicine at the pharmacy		
46. Did anyone tell you about possible side effects?	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____

	15. No *(Go on to Q33)* 16. Yes, my primary care provider *(Skip to Q34)* 17. Yes, another doctor/provider (*Skip to Q34)* 18. Yes, the nurse in the office *(Skip to Q34)* 19. Yes, the pharmacist in the pharmacy *(Skip to Q34)* 20. Yes, I received printed information about the medicine at the office or pharmacy *(Skip to Q34)* 21. Don't know/remember *(Skip to Q34)*		
	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
47. If no, why not	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	15. Was not offered to me 16. Have received this medicine before and did not need further instruction 17. Didn't want any 18. I did not have enough time 19. Other: Specify 20. I did not accompany my child to the office 21. I did not pick up the medicine at the pharmacy		
48. Did your pharmacist have any questions regarding your prescription that he had to ask you or your health care provider about?	____	____	____
	9. No *(Skip to Q36)* 10. Yes—I was able to clarify it *(Go on to Q35)* 11. Yes—the pharmacist had to call the health care provider *(Go on to Q35)* 12. Don't know/remember *(Skip to Q36)*		
49. What was the question about? *(Choose all that apply)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____

	27. Name of medicine 28. Dose 29. Route 30. Frequency 31. Directions for use 32. Number/amount to be dispensed 33. Strength 34. Drug to drug interactions 35. Allergies 36. Weight 37. Age/Date of Birth 38. Don't know/remember 39. Other: Specify

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
44. To your knowledge, were there any differences between what your child's health care provider prescribed and the medicine you got from the pharmacist?	____	____	____
	7. No *(Skip to Q38)* 8. Yes *(Go on to Q37)* 9. Don't know/remember *(Skip to Q38)*		
45. What was the difference? *(List up to three choices)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	27. Name of medicine 28. Dose 29. Route 30. Frequency 31. Directions for use 32. Number/amount to be dispensed 33. Strength 34. Drug to drug interactions 35. Allergies 36. I received a medication intended for another pt. 37. The name of the patient on the medicine was not my child 38. Don't know/remember 39. Other: Specify		
46. Is your child still taking the medicine?	____	____	____
	7. No *(Go on to Q39)* 8. Yes *(Skip to Q40)* 9. Don't know/remember *(Skip to Q40)*		

	Prescription 1 Medication Name _____	Prescription 2 Medication Name _____	Prescription 3 Medication Name _____
47. If no, why not? *(List up to three choices)*	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____	___ ___ ___ Specify: _____
	17. Completed therapy 18. Health care provider changed course of therapy 19. Ran out of medicine 20. Medicine not available from the pharmacy 21. I felt that my child did not need the medicine 22. Side effect of the medicine 23. Child refused medicine 24. Never took medicine		

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40. Is your child allergic to any medicines? _____ 1. No *(Skip to Q42)*
2. Yes *(Go on to Q41)*

41. Indicate medicine and type of reaction:

A. Medication	**B. Type of Reaction**

42. Since the health care provider's visit, has your child had any side effects from any medicine(s) or symptoms made worse by the any medicine(s)?

_____ 1. No *(Skip to Q46)*
2. Yes *(Go onto Q43)*
3. Don't know/remember *(Skip to Q46)*

43. What side effects has your child experienced? *Fill in the chart below.*

A Side Effect Description	B Side Effect Code *See table below for codes*	C How long ago did this symptom start? 1=<1 day 2= 1-3 days 3= 4-7 days 4= 8-28 days 5= 1-3 months 6= > 3 months	D How long did this symptom last? 1=< 1 day 2= 1 day 3= 2 days 4= 3-4 days 5= 5-7 days 6= 8-14 days 7= 15-28 days 8= 1-3 months 9= > 3 months 10=ongoing	E Do you think this symptom is related to a medicine? *Choose all that apply* 1= Target rx (specify) 2= Other rx (specify) 3= DK 4=not related to medicine *(skip to H)*	F Is your child still taking the medicine? 1= No 2= Yes, all the time 3= Yes, PRN	G Does/did this symptom occur with every dose? 1= No 2= Yes 3= DK	H How soon after taking the medicine did these symptoms occur? 1=<1 day 2= 1-3 days 3= 4-7 days 4= >7 days 5=before the medicine	I Since the symptom began, have /did you discuss(ed) it with a health care provider? 1=No 2=Yes, MD 3=Yes, RN 4=Yes, NP 5=Yes, PA 6=Yes, other person in office 7=Yes, pharmacist 8= Yes, other, specify **If YES,** **skip toK** *If NO, go on to J*	J If the health care provider was not contacted, why not? 1= Could not get in touch with provider 2= Did not think it was important 3= Sx went away too quickly 4= Medicine was completed 5= Was told to expect this 6= Other **Skip to M**	K Was anything done in response? 1= No 2= Yes *If YES, go on to L* *If NO, skip to M*	L What was done? 1= Continue with med 2= Treatment with another med 3=Med changed/ stopped 4= Changed dose of med 5= Other (specify) *Go on to M*	M Did this symptom require an additional visit to a medical facility or contact with a health care provider? *Choose all that apply* 1=No 2=Clinic visit 3= Emergency room visit 4=Hospitalization 5= Email 6=Phone call 7=Other (specify)

Codes for column B:

1. Fever	6. GI: Pain	11. Resp: Wheeze	16. CNS: Hyperactivity	21. Derm: Skin rash or itch
2. Hydration	7. GI: Nausea/Vomitting	12. Resp: Cyanosis	17. CNS: Headache	22. Derm: Swelling mouth/throat/tongue
3. GI: Eating	8. GU: Frequency	13. CNS: Fatigue/Dowsy	18. CNS: Fussiness	23. Cardiac: Palpitations, tachycardia
4. GI: Diarrhea	9. GU: Pain	14. CNS: Difficulty sleeping	19. CNS: Altered status	24. Other: Specify_____
5. GI: Constipation	10. Resp: SOB	15. CNS: Confusion	20. CNS: Seizure	25. Other: Specify_____

We would like to contact the health care provider about these symptoms. If you do not give us permission, we will not contact the health care provider regarding these symptoms. If there is anything you are worried about, please contact the health care provider.

44. Would it be OK for us to contact your health care provider about these symptoms _____
    1. No
    2. Yes

45. How many times in total did you contact the health care provider or has your child been seen by a health care provider about the above symptoms?

    a. How many... _____ Clinic visits?
    b. How many... _____ Emergency room visits?
    c. How many... _____ Hospitalizations?
    d. How many... _____ Emails?
    e. How many... _____ Phone calls?
    f. How many... _____ Other, specify _____?

Most children miss medicine doses at one time or another. It is hard to take medicines exactly as the health care provider said, especially with children. We understand how difficult it is to give children all their medicines. These questions are about the medicines your child was prescribed at the last visit.

46. In the last week, how many doses do you think your child has missed? _____
    1. None *(Skip to Q49)*
    2. One or Two *(Go to Q47)*
    3. Three or Four *(Go to Q47)*
    4. Five or Six *(Go to Q47)*
    5. More than Six *(Go to Q47)*

47. Which medicine did you child miss and why?

A. Name of Medication Missed	**B. Medication Class** *(Completed by RN)*	**C. Why was the medicine missed** ***(Use codes below)***	
		Code	**Specify**
a.			
b.			
c.			

Codes for column C

1. Forgot to take the medicine
20. Ran out of medicine
21. Medicine not available (misplaced or not with the patient at time of dose)
22. Felt that the medicine was not needed
23. Side effect of the medicine
24. Refused
25. Spit out
26. Vomited
27. Asleep
28. Other, specify _____

48. What do you usually do if he/she misses a dose of medicine?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. What do you do if a dose is missed? 1= Double the next dose 2= Give as soon as I remember 3= Skip the dose 4= Other: Specify 5= Don't double up	
		Code	**Specify**
a.			
b.			
c.			

49. Who told you what to do if you missed a dose? *(Choose all that apply and Go on to Q50)*

_____ _____ _____

1. Primary care provider or Another doctor/provider
2. The nurse in the office
3. Pharmacist in the pharmacy
4. Printout from pharmacy or doctor's office
5. Other, specify: _____
6. Don't know/remember
7. Nobody *(Skip to Q51)*

50. What did they tell you to do?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. What did they tell you to do? 1= Double the next dose 2= Give as soon as I remember 3= Skip the dose 4= Other: Specify 5= Don't double up 6= Refer to printout	
		Code	**Specify**
a.			
b.			
c.			

51. In the last week, how many extra doses do you think he/she has been given/taken

_____

1. None *(Skip to Q53)*
2. One or Two *(Go to Q52)*
3. Three or Four *(Go to Q52)*
8. Five of Six *(Go to Q52)*
9. More than Six *(Go to Q52)*

52. Which medicine did you child receive extra doses of and why?

A. Name of Medication	B. Medication Class *(Completed by RN)*	C. Why was extra medicine given *(Use codes below)*	
		Code	Specify
a.			
b.			
c.			

Codes for column C

1. Tried to catch up on missed doses
12. Thought is was better to take more or that the child needed more
13. Forgot the medicine was already taken/given
14. Gave what was left in the bottle
15. Caregiver miscommunication
16. Other, specify: _____

53. Does/Did your child need to take medicine while in school or day care?
_____ 1. No *(Skip to Q56)*
2. Yes *(Go on to Q54)*

54. Did your child miss any doses that where due in school or day care?
_____ 1. No *(Skip to Q56)*
2. Yes *(Go on to Q55)*
3. Don't know *(Skip to Q56)*

55. Which medicine did you child miss and why?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. Why was the medicine missed *(Use codes below)*	
		Code	Specify
a.			
b.			
c.			

Codes for column C

19. Forgot to go the nurse
20. Nurse forgot to have child come to office
21. No nurse was available to give the medicine
22. Did not have enough medicine
23. Did not have a note to administer medicine
24. Forgot to send medicine to school
25. Did not want to send medicine to school
26. Don't know/remember
27. Other, specify _____

56. Does your child take any over the counter medicines (including fever or pain medicine, such as tylenol, motrin, or advil; cough and cold medicine; vitamins; dietary supplements; and herbal supplements or teas)
_____ 1. No *(Skip to Q59)*
2. Yes *(Go on to Q57)*
3. Don't know/remember *(Skip to Q59)*

57. Please tell me all the non-prescription medicine your child is currently taking.

A. Medication Name	*B. Drug Class (to be completed by RN)*	C. How frequently does your child take this medicine? 1=daily 2=weekly 3=monthly 4=as needed 5= daily when sick 6= as needed when sick	D. What does your child take this medicine for? 1=Know: Specify 2=Don't know		E. Has your child had any problems with this medicine? 1=Yes: Specify 2=Don't know 3=No	
			Code	Specify	Code	Specify
1.						
2.						
3.						
4.						

58. Did anyone in the office or pharmacy recommend or tell you how to use any of these medicines? *(Choose all that apply)* _____ _____ _____

1. No
2. Primary care provider or Another doctor/provider,
3. The nurse in the office
10. Pharmacist in the pharmacy
11. Other, specify: _____
12. Don't know/remember

We're almost done, I would just like to ask you a few demographic questions. Let me once again remind you that the information you provide is completely confidential. You can decide not to answer any question that makes you uncomfortable. I will read you response choices whenever possible.

59. How well do you think you speak English? _____

1. Very well
22. Well
23. Poorly
24. Not at all
25. Refused

60. What language do you speak with your paediatrician? *Q62)*

_____ 1. English *(Skip to*

14. Spanish *(Go on to Q61)*
15. Portuguese, including Portuguese Creole *(Go on to Q61)*
16. Cambodian (Khmer) *(Go on to Q61)*
17. French *(Go on to Q61)*
18. Other: _____ *(Go on to Q61)*
19. Refused

61. Was an interpreter used during your visit? _____

1. No interpreter used
18. Professional interpreter provided by the clinic
19. Professional interpreter I brought with me.
20. Child for whom the script was written
21. Other child
    Specify age of child: ____
22. Other relative, specify: _____
23. Friend
24. Other, specify: _____
25. Refused

62. What language do you speak at home? _____ _____

1. English
2. Spanish
13. Portuguese, including Portuguese Creole
14. Cambodian (Khmer)
15. French
16. Other, specify: _____
17. Refused

63. What other languages do you speak? *(Choose all that apply)* _____ _____

1. English
2. Spanish
15. Portuguese, including Portuguese Creole
16. Cambodian (Khmer)
17. French
18. Other, specify: _____
19. None
20. Refused

64. What is the highest level of education you have completed? _____

1. 8th grade or less
2. Did not finish high school
3. High school graduate or GED
8. Some college or technical school
9. College graduate (Bachelor's degree)
26. Some post-graduate education
27. Post-graduate degree
28. Other, specify: _____
29. Technical program (completed)
30. Associates Degree (completed)
31. Refused

65. Which of the following describes your child's race? *(Choose all that apply)*

_____ _____ _____

1. White
2. Black or African-American
3. American Indian or Alaska Native
4. Hispanic
13. Asian
14. Native Hawaiian or other Pacific Islander
15. Other race, specify _____
16. Refused

66. How many adults live in your household? _____

67. How many children live in your household? _____

68. What kind of insurance do you have? *(Indicate the name of the insurance)* _____

69. Do you have a co-pay for prescriptions? _____

1. No *(Skip to Q71)*
2. Yes *(Go on to Q70)*
3. Refused

70. How much do you pay? $ _____

71. Do you have a co-pay for office visits? _____

1. No *(Skip to 73)*
2. Yes *(Go on to Q72)*
3. Refused

72. How much do you pay? $ _____

The next question is about your average household total yearly income.

73. Is your average yearly income _____

1. Under $30,000 *(Go on to Q74)*
8. Over $30,000 *(Skip to Q75)*
9. Refused *(Skip to Q76)*
10. Don't know *(Skip to Q76)*

74. Is that... _____

1. Under $10,000 *(Skip to Q76)*
10. $10,000 to $20,000 *(Skip to Q76)*
11. Over $20,000 *(Skip to Q76)*
12. Don't know *(Skip to Q76)*
13. Refused *(Skip to Q76)*

75. Is that... _____
1. Under $40,000 *(Go on to Q76)*
12. $40,000 to $50,000 *(Go on to Q76)*
13. $50,000 to $80,000 *(Go on to Q76)*
14. Over $80,000 *(Go on to Q76)*
15. Don't know *(Go on to Q76)*
16. Refused *(Go on to Q76)*

76. What is your age? _____
1. 20 or less
2. 21-25
3. 26-30
4. 31-35
5. 36-40
6. 41-45
7. 46-50
8. 51-55
9. 56-60
10. >61
11. Decline to answer

77. In a typical week, does your child spend time in more than one household? _____
1. No
2. Yes
3. Refused

Our last question is about your opinion of the study.

78. What do you think of your child's paediatrician participation in the Paediatric Outpatient Prescribing Study? _____
1. Very positive *(End of interview)*
2. Mostly positive *(End)*
3. Neutral *(End)*
4. Mostly negative *(End)*
5. Very negative *(End)*

That completes our survey. I would like to thank you again for your time, effort, and patience. Your participation in the Paediatric Outpatient Prescribing Study is greatly appreciated. We will contact you again, by phone, in 6 weeks. What is a good time of day to call?

Thanks again! Have nice day

DATAFORM 2B

10 Day Follow-up: Patient Interview
(For patients over the age of 12 who self administer medication)

Collect these data at T plus 10 days

RN Review (initials) ___ ___ ___ Date ___ ___/ ___ ___ /___ ___

4. Study ID Number: ___ ___-___ ___ ___ ___

5. Interviewer ID Number: ___ ___

9. Date of Index Visit: ___ ___ / ___ ___ / ___ ___

10. Date of telephone Interview: ___ ___ / ___ ___ / ___ ___

Hello, my name is _____ and I'm calling on behalf of _____.
[Your Name] [Clinic Name]
Doctor _____ is participating in a study to improve the way medicine is prescribed
[Doctor's Name]
in doctors' offices. I have already spoken with your _____ and he/she said it was ok to talk to you. [mom/dad/guardian/etc.]

Is this a good time for you to talk?
If not- - - - When would be a good time for us to call you?

We are interviewing parents and teenagers who have recently been prescribed medicine by their doctors. I will ask you about the medicines you are taking, what you do if you miss a medicine and any over the counter (or non-prescription medicines) you take.

Let me reassure you that the information that you provide is completely confidential. Your participation is voluntary and you may skip any questions you do not want to answer.

The interview will take approximately 15 minutes.

5. Would you like to participate? _____
1. No *(Go on to Q6)*
2. Yes *(Skip to Q7)*

6. Would you take a few moments to tell us why? _____
1. Not interested
14. Concerned about confidentiality
15. Not enough time
16. Refuses to answer
17. Other: Specify, _____

Thank you very much for your time.

First, I'd like to ask some general questions about your health.

7. How are you feeling now, compared to the time of your visit on ___/___/___?

_____
1. Much worse
2. A little worse
12. About the same
13. A little better
14. Much better

8. In general how would you rate your health at the present time?

_____
1. Poor
2. Fair
12. Good
13. Very good
14. Excellent

9. Do you have a chronic or long-term health condition (a condition lasting longer than 3 months)?

_____
1. No
2. Yes

The next set of questions asks you about ALL the PRESCRIPTION medicine you are currently taking and why you are taking them.

10. How many prescription medicines do you take? _____

11. What is the...

A. Name of the medicine	***B. Drug Class (to be completed by RN)***	**C. What do you take this medicine for?** **1=Know 2=Don't know**	
		Code	Specify
1.			
2.			
3.			
4.			
5.			
6.			

Most people miss medicine doses at one time or another. It is hard to take medications exactly as the doctor said. We understand how difficult it is to remember to take all your medicine.

12. In the last week, how many doses do you think you have missed? Include all the medicines you are taking

_____

1. None *(Skip to Q14)*
2. One or Two *(Go on to Q13)*
3. Three or Four *(Go on to Q13)*
4. Five or Six *(Go on to Q13)*
5. More than Six *(Go on to Q13)*

13. Which medicine did you miss and why"

A. Name of Medication Missed	**B. Medication Class** *(Completed by RN)*	**C. Why was the medicine missed** ***(Use codes below)***	
		Code	**Specify**
a.			
b.			
c.			

Codes for column C

1. Forgot to take the medicine
29. Ran out of medicine
30. Medicine not available (misplaced or not with the patient at time of dose)
31. Felt that the medicine was not needed
32. Side effect of the medicine
33. Refused
34. Spit out
35. Vomited
36. Asleep
10. Other, specify _____

14. What do you usually do if you miss a dose of medication?

A. Name of Medication Missed	**B. Medication Class** *(Completed by RN)*	**C. What do you do if a dose is missed?** 1=Double the next dose 2=Take as soon as I remember 3=Skip the dose 4=Other: Specify 5=Don't double up 6=Don't know	
		Code	**Specify**
a.			
b.			
c.			

15. Who told you what to do if you missed a dose of medicine? *(Choose all that apply)*

_____ _____ _____

1. Primary care provider or Another doctor/provider
2. The nurse in the office
3. The pharmacist in the pharmacy
4. Printout from pharmacy or doctor's office
5. Other, specify: _____
6. Don't know/remember
7. Nobody *(Skip to Q18)*

16. What did they tell you to do?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. What did they tell you to do? 1=Double the next dose 2=Take as soon as I remember 3=Skip the dose 4=Other: Specify 5=Don't double up 6=Refer to printout 7=Don't know	
		Code	**Specify**
a.			
b.			
c.			
d.			

17. In the last week, how many extra doses have you taken?

_____
1. None *(Skip to Q19)*
2. One or Two *(Go to Q18)*
3. Three or Four *(Go to Q18)*
10. Five or Six *(Go to Q18)*
11. More than Six *(Go to Q18)*
12. Don't know *(Go on to Q18)*

18. Which medicine did you receive extra doses of and why?

A. Name of Medication	B. Medication Class *(Completed by RN)*	C. Why was extra medicine given *(Use codes below)*	
		Code	**Specify**
a.			
b.			
c.			

Codes for column C

1. Tried to catch up on missed doses
17. Thought is was better to take more or that the child needed more
18. Forgot the medicine was already taken/given
19. Gave what was left in the bottle
20. Caregiver miscommunication
21. Other, specify: _____

19. Do/Did you need to take medicine while you are in school?

_____
1. No *(Skip to Q22)*
2. Yes *(Go on to Q20)*

20. Did you miss any doses that were due while you were in school?

_____
1. No *(Skip to Q22)*
2. Yes *(Go on to Q21)*
6. Don't know *(Skip to Q22)*

21. Which medicine did you miss and why?

A. Name of Medication Missed	B. Medication Class *(Completed by RN)*	C. Why was the medicine missed *(Use codes below)*	
		Code	Specify

Codes for column C

28. Forgot to go the nurse
29. Nurse forgot to have child come to office
30. No nurse was available to give the medicine
31. Did not have enough medicine
32. Did not have a note to administer medicine
33. Forgot to take medicine to school
34. Did not want to take medicine to school
35. Don't know/remember
9. Other, specify _____

Now, I am going to ask you about any non-prescription or over the counter medicines which you currently use.

22. Do you take any over the counter medicines (including fever or pain medicine, such as tylenol, motrin, or advil; vitamins, dietary supplements; and herbal supplements or teas)? _____

1. No *(Skip to Q26)*
2. Yes *(Go on to Q23)*
3. Don't know/can't remember *(Skip to Q26)*

23. Please tell me all the over the counter medication you are currently taking.

A. Medication Name	*B. Drug Class (to be completed by RN)*	C. How frequently do you take this medication? 1=daily 2=weekly 3=monthly 4=as needed 5=daily when sick 6=as needed when sick	D. What do you take this medication for? 1=Know (specify) 2=Don't know		E. Have you had any problems with this medication? 1=Know (specify) 2=Don't know	
			Code	Specify	Code	Specify
1.						
2.						
3.						
4.						
5.						
6.						

24. Did anyone in the office or pharmacy recommend any _____ _____ _____

1. No
2. Primary care provider or

of these medicines to you or tell you how to use them? *(Choose all the apply)*

Another doctor/provider
3. The nurse in the office
4. Pharmacist in the pharmacy
5. Other, specify: _____
6. Don't know/remember

25. Did anyone in the office or pharmacy give you any written information on these medicines? *(Choose all the apply)* _____ _____ _____

1. No
2. Primary care provider or Another doctor/provider
3. The nurse in the office
4. Pharmacist in the pharmacy
5. Other, specify: _____
6. Don't know/remember

26. Did you experience any side effects from a medicine received at the last visit? _____

1. No *(End of Interview)*
2. Yes *(Go on to Q27)*

27. Do you work? _____

1. No *(Skip to Q32)*
2. Yes *(Go on to Q28)*

28. How many hours per week do you work? _____ hours/week

29. Did you miss work because you had side effects from a medicine received at the last visit? _____

1. No *(Skip to Q32)*
2. Yes *(Go on to 30)*
3. Don't know *(Skip to Q32)*

30. How many hours of work did you miss? _____ hours

31. Why did you miss work? *(Choose all that apply)* _____ _____ _____

1. I went to the doctor's or ED due to medication side effects
1. I was hospitalized due to medication side effects
2. I was too sick to go to work due to medication side effects
3. I was worried about my medication side effects
4. I missed sleep because of my medication side effects
5. Other, specify: _____

32. Did you have other expenses, such as babysitting, parking or travel due to medicine side effects? _____

1. No *(End of Interview)*
2, Yes *(Go on to Q33)*

33. How much extra did you spend?

Expense	Amount
a. Babysitting	$___ ___ ___
b. Parking	$___ ___ ___
c. Travel (public transportation fare)	$___ ___ ___
d. Bridge or highway tolls	$___ ___ ___
e. Travel (gas)	$___ ___ ___
f. Travel (mileage)	___ ___ ___
g. New Medication	
h. Other, specify: _____	$___ ___ ___

This is the end of the survey. Thank you for participating in the Paediatric Outpatient Prescribing Study. Have nice day! ☺

DATAFORM 3A

6 Week Follow-up: Telephone Interview Form

Collect these data at T + 6 weeks (45 days)
RN Review (initials): _____ Date ____/____/____

5. Study ID Number:
   ____ ____-____ ____ ____ ____

7. Interviewer ID Number:
   ____

11. Date of Follow-up Interview (mm/dd/yy) ____ ____/____ ____/
    ____ ____

Start here--**May I speak with the parent or legal guardian of _____?**

[Name of Child]

If the parent or legal guardian is NOT available, then ask for the best time to reach that person during the next day.

Hello, my name is _____ and I'm calling on behalf of _____.
[Your name]
[Name of Clinic]
I spoke with you 6 weeks ago about some prescriptions your child received on ___/___/___. We are now conducting the final interview for our research study aimed at improving the way medicines are prescribed. The interview will take approximately 10 minutes.

Is this a good time for you to talk?
If not- - - - When would be a good time for us to call you?

Let me remind and reassure you that the information that you provide is completely confidential. Your participation is entirely voluntary and you many skip any questions that you do not feel comfortable answering.

4. Would you like to participate? ____
   1. No *(Go on to Q5)*
   6. Yes *(Skip to Q6)*

5. Would you take a few moments to tell us why? _____ 1. Not interested

2. Concerned about confidentiality
3. Not enough time
4. Refuses to answer
5. Other: specify

Thank you very much for your time.

_____

At your child's visit on ___ ___/___ ___/___ ___, he/she received the following prescriptions:

	Prescription 1 **Medication name:** _____	**Prescription 2** **Medication name:** _____	**Prescription 3** **Medication name:** _____
6. Is he/she still taking this medicine?	_____	_____	_____
	1. No *(Go on to Q7)* 2. Yes *(Skip to Q8)*		
7. If no, why not?	_____	_____	_____
	1. Completed course 2. Provider changed therapy 3. Ran out of medicine, no more was prescribed 4. Medication not available from pharmacy 5. I felt that my child didn't need the medicine 6. Side effect of medication 7. Insurance would not cover the medicine 8. Medicine was too expensive 9. Never took medicine 10. Other _____		

There are a lot of common symptoms that patients experience. We want to better understand how often they occur.

8. Since we last contacted you on __ __ / __ __ / __ __ , has your child experienced any noticeable symptoms or side effects?

_____ 1. No *(Skip to Q15)*

2. Yes *(Go to Q9)*

3. Don't remember

(Skip to Q15)

9. What symptoms or side effects have they experienced? *Fill in chart below.*

A. Description of symptom	B. Symptom Code *(Use code table below)*	C. Related to medication?			D. Which medication is most responsible for the symptom?			
		N	Y	DK	Rx #1	Rx #2	Rx #3	Other medication (specify)

Symptom Code List:

1. Fever
2. Hydration
3. GI: Eating
4. GI: Diarrhea
5. GI: Constipation
6. GI: Pain
7. GI: Nausea, Vomiting
8. GU: Frequency
9. GU: Pain
10. Resp: SOB
11. Resp: Wheeze
12. Resp: Cyanosis
13. CNS: Fatigue, drowsiness, sleepy
14. CNS: Difficulty going to sleep or staying asleep
15. CNS: Confusion
16. CNS: Hyperactivity
17. CNS: Headache
18. CNS: Fussiness
19. CNS: Seizure
20. CNS: Altered status
21. Derm: Skin rash or itch
22. Derm: Swelling of the mouth, throat, tongue
23. Cardiac: Palpitations, tachycardia
24. Other: Specify _____
25. Other: Specify _____

For symptoms that are related to medications (maximum of 3 most severe), go on to Q10.
*If **none** of symptoms are related to medications, skip to Q16.*

	Symptom 1 _____	**Symptom 2** _____	**Symptom 3** _____
10. How long has your child had or did your child have these symptoms?	_____	_____	_____
	1. less than 1 day 2. 1 day 3. 2 days 4. 3-4 days 5. 5-7 days 6. 8-14 days 7. 15-28 days 8. 1-3 months 9. >3 months		
11. Have you discussed these problems with your child's health care provider or someone in the office?	_____	_____	_____
	1. No *(Go on to Q12)* 2. Yes *(Skip to Q13)*		
12. If no, why not? *(Skip to question 15)*	_____	_____	_____
	1. Could not get in touch with provider 2. Did not think it was important 3. Sx went away too quickly 4. Medicine was completed 5. Was told to expect this 6. Other		

	Symptom 1 _____	Symptom 2 _____	Symptom 3 _____
13. What was done in response to the problem/symptom?	_____ _____ _____	_____ _____ _____	_____ _____ _____
	1. Nothing 2. Treatment with an additional medication 3. Medication changed to another medication 4. Medication discontinued 5. Changed dose of medication 6. Changed frequency of medication 7. Changed route of medication 8. Other _____		
14. How many total times did you contact the health care provider's office or has your child been seen by a health care provider?	____ By phone (to any provider) ____ By clinic visit ____ By emergency room visit ____ By email (with any provider) ____ Hospitalizations ____ Other : Specify _____		

We would like to contact the health care provider about these symptoms with your permission. If there is anything you are worried about, please contact the health care provider.

15. Would it be OK for us to contact your child's health care provider, regarding these symptoms?

_____ 1. No
2. Yes

I just have a few more questions about your child's current health.

16. How is your child doing now, compared to the time of his/her visit on ___/___/___?

_____ 1. Much worse
2. A little worse
3. About the same
4. A little better
5. Much Better

17. In general how would you rate you child's health at the present time?

_____ 1. Poor
2. Fair
3. Good
4. Very good
5. Excellent

18. Does your child have a chronic or long-term health condition (a condition lasting longer than 3 months)? _____
    1. No
    2. Yes, specify _____

That completes our survey, as well as your participation in the Paediatric Outpatient Prescribing Study. I would like to thank you again for your time, effort, and patience. Your participation is greatly appreciated. If you have any questions, please feel free to contact us at any time

Give phone number if appropriate

Thanks again! Have nice day! ☺

DATAFORM 4

Chart Review Form

Collect at 4 months from study enrollment date (one month prior to T)

1. Study ID Number: ___ ___-___ ___ ___ ___

2. Reviewer ID Number: ___ ___

3 Provider ID Number (Script Writer): ___ ___-___ ___ ___

4 Provider ID Number (Primary Care Provider): ___ ___-___ ___ ___

5. Date of Index Visit: ___ ___/___ ___/___ ___

6. Date of Chart Review: ___ ___/___ ___/___ ___

7. Date of Birth (mm/dd/yy): ___ ___/___ ___/___ ___

8. Gender: ____
   1. Male
   2. Female

9. Duration of continuous care at clinic/facility: ____
   1. < 6 months
   2. 6 months to 1 year 11 months
   3. 2-5 years
   4. > 5 years

10. Number of outpatient visits to any provider at primary care clinic/facility 1 month prior to study visit until 2 months following the visit until 2 months following the visit (including index visit)? ____
    1. Zero
    2. One
    3. Two
    4. Three
    5. More than three

11. Of these visits to the clinic/facility in question 10, how many were to the primary care provider? ____
    1. Zero (no visits)
    2. One
    3. Two
    4. Three
    5. More than three times

12. Number of emergency department visits in the one month prior to the study visit until 2 months following the visit? ____
    1. Zero (no visits)
    2. One
    3. Two
    4. Three
    5. More than three times

13. Has patient ever been admitted overnight to a hospital?

____ 1. No *(Skip to Q15)*
2. Yes *(Go on to Q14)*
3. Not sure *(Skip to Q15)*

14. If yes, how many admissions to the hospital in the last year?

____ 1. Zero (no admissions)
2. One
3. Two
4. Three
5. More than three times

15. Has the patient ever been in the ICU/NICU

____ 1. No *(Skip to Q17)*
2. Yes*(Go on to Q16)*
3. Not Sure *(Skip to 17)*

16. If yes, how many times in the last year?

____ 1. Zero (no admissions)
2. One
3. Two
4. Three
5. More than three times

17. Indicate the specialists the patient sees:

____ 1. Allergist
____ 2. Cardiologist
____ 3. Dermatologist
____ 4. Endocrinologist
____ 5. ENT
____ 6. Gastroenterologist
____ 7. Hematologist
____ 8. Nephrologist
____ 9. Neurologist
____ 10. Oncologist
____ 11. Ophthamologist
____ 12. Orthopedist
____ 13. Psychiatrist
____ 14. Pulmonologist
____ 15. Urologist
____ 16. Other, specify: _____
____ 17. Developmentalist
____ 18. Occupational Therapist
____ 19. Paediatric Surgeon
____ 20. Physical Therapist
____ 21. Not seen by a specialist

18. What was this visit for? ____

1. Routine checkup
2. Urgent care for new or ongoing condition
3. Follow up care after new illness
4. Other, specify: _____
5. Not sure

19. Has the patient had any of these conditions? Circle each condition that applies:

1. Neurological

1.01 ADD/ADHD
1.02 Developmental delay; specify _____
1.03 Epilepsy/seizures
1.04 Migraine
1.05 Other Neurological, specify _____
1.06 Headaches, not migraines
1.07 Febrile seizures

2. HEENT

2.01 Otitis media, acute

(No need for PE tubes)

2.02 Otitis media, chronic: PE tubes placed
2.03 Thrush
2.04 Other HEENT, specify _____
2.05 Conjunctivitis
2.06 Serous otitis media
2.07 Strep throat
2.08 Pharyngitis, not strep
2.09 Tonsillectomy and/or adenoidectomy
2.10 Otitis externa
2.11 Stabismus
2.12 Stomatitis
2.13 Stye
2.14 Blocked tear duct/dacrostenosis

3.Cardiovascular

3.01 Congenital heart anomalies (any kind) specify, _____
3.02 Other Cardiovascular, specify, _____
3.03 Murmur

4. Circulatory

4.01 Anemia (any kind), specify, _____
4.02 Sickle cell disease
4.03 Sickle cell trait
4.04 Other Circulatory, specify, _____

5. Respiratory

5.01 Asthma/RAD
5.02 Bronchitis

5.03 Pneumonia 5 episodes or less

5.03 a > 5 episodes

5.04 Sinusitis 5 episodes or less
5.04 a > 5 episodes
5.05 URI
5.06 Other respiratory specify, _____
5.07 Bronchiolitis
5.08 Croup
5.09 BPD

6. GI

6.01Gastroenteritis
6.02 GE reflux
6.03 GI, other: specify, _____
6.04 Constipation
6.05 Hyperbilirubinemia

6.06 Encoporesis
6.07 Pinworms

7. **7.GU**

7.01 GU reflux
7.02 UTI (Specify organism)
7.03 Other GU, specify, _____
7.04 Labial adhesions
7.05 Circumcision
7.06 Phimosis
7.07 Balanitis
7.08 Umbilical hernia
7.09 Hydrocele
7.10 Hernia
7.11 Pyelonephritis
7.12 Enuresis
7.13 Vaginitis

8.Musculoskeletal

8.01 Cerebral Palsy
8.02 Other musculoskeletal, specify, _____
8.03 Fracture
8.04 Sprain
8.05 Polydactyl
8.06 Tibial torsion
8.07 Hip dysplasia
8.08 Toxic synovitis

9. Psych

9.01 Anorexia Nervosa
9.02 Anxiety
9.03 Bulemia
9.04 Depression
9.05 Other psych, specify, _____

10. Skin

10.01 Ezcema/atopic dermatitis
10.02 Diaper rash
10.03 Ringworm
10.04 Other skin, specify,_____
10.05 Impetigo
10.06 Cellulitis
10.07 Contact dermatitis
10.08 Scabies
10.09 Warts
10.10 Acne
10.11 Molluscum contagiosum
10.12 Seborrhea
10.13 Hemangioma
10.14 Nevus

11. Other/Multisystem

11.01 Chicken pox

11.02 Coxsackie (hand , foot, and mouth)
11.03 Congential anolmalies, specify
11.04 Cystic fibrosis
11.05 Diabetes
11.06 Failure to thrive
11.07 Febrile seizure
11.08 Genetic disorder, specify
11.09 Hay fever/seasonal/other allergy
11.10 HIV/AIDS
11.11 Leukaemia/Lymphoma, specify
11.12 Malignancy,specify
11.13 Prematurity
11.14 Viral Syndrome
11.15 Other, Specify_____
11.16 Obesity
11.17 Peanut Allergy or other allergy requiring EpiPen
11.18 Sepsis
11.19 Umbilical Hernia

12. None
13. Well Child Check

20. Patient's diagnosis for visit on date of study enrollment _____ _____ _____ _____
(Choose diagnosis code(s) from list in Q19)

21. Patient medication list at end of index visit from note and/or medication list and/or other source (including prescriptions from that visit):

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

22. Category of medications *(Multiples permitted, skip to Q23 if no medications)*

4. Analgesic (narcotic)
5. Analgesic (non-narcotic, non-NSAID)
   2.01 Acetaminophen
   2.02 Other
6. Antianemia
5. Antibiotic
   4.01 Cephalosporins
   4.02 Clindamycin
   4.03 Macrolides
   4.04 Misc. antibiotics
   4.05 Ophthalamic preps
   4.06 Otic Preps
   4.07 Penicillin or derivative
   4.08 Quinolones
   4.09 Sulfa
   4.10 Tetracycline
   4.11 Topical
   4.12 Other
   4.13 Nitrofuran antimicrobial
5. Anticoagulant
19. Anticonvulsant
20. Antidepressant
21. Antifungals (oral)
22. Antifungals (topical)
23. Antihelmintics
24. Antihistamine (all forms)
25. Antihypertensive
26. Antineoplastic
27. Antipsychotic
28. Antituberculosis
29. Antitussive
30. Antiviral (all forms)
31. Bronchodilator (inhaled)
30. Bronchodilator (oral)
31. Decongestant
32. Diabetes (oral agents)
33. GI Meds
   22.01 Antiflatulent
   22.02 H2 blocker
   22.03 Proton pump inhibitor
   22.04 Probiotic
   22.05 Antacid
   22.06 Laxative Insulin
34. Insulin
35. Leukotriene Receptor Antagonist
36. Local Anesthetic
37. Muscle relaxants
38. Nasal Sprays
39. NSAID
   28.01 Ibupfrofen
   29.02 Other
   28.03 Cox-2 inhibitor
40. Oral contraceptive
41. Sedative, hypnotic
42. Steroids (inhaled)
43. Steroids (oral)
44. Steroids (topical)
45. Stimulants
46. Thyroid agents
47. Vaccines
48. Vitamins
49. Other
50. Antimalarial
51. Contraceptive (injectable)
52. Contraceptive (patch)
53. Dermatologicals
43. Emollients
44. Epinephrine
45. Immunologicals, topical
46. Iron
47. Normal Saline
56. Scabicide
57. Topical anesthetic
58. Antianxiety
59. Beta Blocker
60. Estrogen, topical
61. Cerumenolytic
62. Emetic
63. Hemostatic
56. Mast cell stabilizer
57. Antiarrythmic
58. Anticholinergic
59. Antiemetic
60. Keratolytic

23. Allergy history documented? _____

1. No, allergy history not documented *(Skip to Q25)*
2. Yes, allergy history documented and allergies are present *(Go on to Q24)*
3. Yes, allergy history documented and there are NKDA *(Skip to Q25)*

24. If yes, complete the table below

Medication	Reaction See below for codes		Date	Where documented 1. Allergy list 2. Face of chart 3. Note from target visit 4. Note from previous visit 5. Problem list 6. Other	
	Code	Specify		Code	Specify
1.					
2.					
3.					
4.					
5.					
6.					

Reaction Codes

1. Anaphylaxis	6. Hypotension	11. Drowsiness	16.Ears
2. Angioodema	7. Itching	12. Unknown	17. Nose
3. Dystonia	8. Mental Status change	13.Other___	18. Throat
4. GI Upset	9. Rash, other than hives	14. Not specified	19. Reproductive
5. Hives	10. Shortness of Breath	15. Eyes	20. Musculoskeltal

25. Since the index visit, is there any evidence that the patient had an adverse drug event?

____1. No *(STOP)*
2. Yes *(Go on to 26)*

26. If yes, how many documented adverse drug events in the medical record?

____ 1. One
2. Two
3. Three
4. More than three

27. Describe each adverse drug event (ADE):

ADE #	Medication Name	Dose	Route	Frequency/ Duration	Adverse Event/Reaction
ADE #1					
ADE #2					

DATAFORM 5

Medication Error Identification and Classification Form

1. Study ID Number: ___ ___-___ ___ ___ ___

2. Case Number: ___ ___ ___

3. Reviewer ID Number: ___ ___

4. Stage of error discovery
   ____ 1. Dataform 1: Prescription Screening Form
   ____ 2. Dataform 2A/2B: 10-day Follow-Up Form
   ____ 3. Dataform 3A: 6 Week Follow-Up Form
   ____ 4. Dataform 4: Chart Review Form

5. Brief description (e.g. inappropriate dose): _____

6. Target prescription *(One that had been reviewed)*
   ____ 1. No Provider #: ___ ___-___ ___ ___
   (Go on to question 7)
   2. Yes: Prescription # _____ *(from dataform 1)* from page _____ *(If yes, skip to Q11)*

7. Name of drug _____

8. Dose and frequency of drug _____

9. Route of Drug ____
   1. PO
   2. Topical
   3. Subcutaneous
   4. Rectal
   5. Otic
   6. Eye
   7. Inhalation
   8. Other, specify: _____
   9. Not specified
   10. Nasally
   11. As directed

10. Category of drug: ____

1. Analgesic (narcotic)
2. Analgesic (non-narcotic, non NSAID)
   - 2.01 Acetaminophen
   - 2.02 Other
3. Antianemia
4. Antibiotic
   - 4.01 Cephalosporin
   - 4.02 Clindamycin
   - 4.03 Macrolides
   - 4.04 Misc. antibiotics
   - 4.05 Ophthalamic preps.
   - 4.06 Otic preps.
   - 4.07 Penicillin or derivative
   - 4.08 Quinolones
   - 4.09 Sulfa
   - 4.10 Tetracyclines
   - 4.11 Topical
   - 4.12 Other
   - 4.13 Nitrofuran antimicrobial

Anticoagulant
Anticonvulsant
Antidepressant
Antifungal (oral)
Antifungal (topical)
Antihelmintics
Antihistamine (all forms)
Antihypertensive
Antineoplastic
Antipsychotic
Antituberculosis
Antitussive
Antiviral (all forms)
Bronchodilator (inhaled)
Bronchodilator (oral)Decongestant
Diabetes (Oral agents)
GI meds
- 22.01 Antiflatulent
- 22.02 H2 blocker
- 22.03 Proton pump inhibitor
- 22.04 Probiotic
- 22.05 Antacid
- 22.06 Laxative

Insulin
Leukotriene Receptor Antagonist
Local Anesthetic
Muscle relaxants
Nasal sprays
NSAID
- 28.01 Ibuprofen
- 28.02 Other
- 28.03 Cox-2 inhibitor

Oral contraceptive
Sedative, hypnotic
Steroids (inhaled)
Steroids (oral)
Steroid (topical)
Stimulants
Thyroid Agents
Vaccines
Vitamins
Other:
Antimalarial
Contraceptive (injectable)
Contraceptive (patch)
Dermatologicals
Emollients
Epinephrine
Immunologicals (topical)
Iron
Normal saline
Scabicide
Topical anesthetic
Antianxiety
Beta blocker
Estrogen (topical)
Cerumenolytic
Emetic
Hemostatic
56. Mast cell stabilizer
57. Antiarrythmic
58. Anticholinergic
59. Antiemetic
60. Keratolytic
90. Equipment
91. Formula
92. Immunization
93. Lab or x-ray
94. Medication given in clinic

11. Category of reason *(multiples may be checked; circle primary reason):*

____ 1. Illegible Order

If yes:

- ____ 1.01 MD signature illegible
- ____ 1.02 Patient name illegible
- ____ 1.03 Med name illegible
- ____ 1.04 Illegible route
- ____ 1.05 Illegible frequency
- ____ 1.06 Illegible length of treatment
- ____ 1.07 Illegible amount to be dispensed
- ____ 1.08 Entire prescription illegible
- ____ 1.09 Illegible dose or dose units
- ____ 1.10 Illegible strength or strength units
- ____ 1.11 Illegible date
- ____ 1.12 Illegible weight or weight
- ____ 1.13 Illegible directions for use

____ 2. Dose error

If yes:

____ 2.01 Overdose
____ 2.02 Underdose
____ 2.03 Dose omitted (from order/when dispensed)
____ 2.04 Dose units omitted
____ 2.05 Dose form incorrect
____ 2.06 Extra dose(s)
____ 2.07 Missed dose(s) (not given/taken)

____ 3. Route error

If yes:

____ 3.01 Route omitted
____ 3.02 Route incorrect

____ 4. Frequency error

If yes:

____ 4.01 Frequency omitted
____ 4.02 Frequency incorrect

____ 5. Length of Treatment Error

If yes:

____ 5.01 Length of treatment omitted
____ 5.02 Length of treatment incorrect

____ 6. Directions Error

If yes:

____ 6.01 Directions for use omitted
____ 6.02 Directions for use incorrect
____ 6.03 Directions for use incomplete

____ 7. Strength Error

If yes:

____ 7.01 Strength omitted
____ 7.02 Strength incorrect
____ 7.03 Strength incomplete
____ 7.04 Strength without units

____ 8. Amount to be dispensed error

If yes:

____ 8.01 Amount to be dispensed omitted
____ 8.02 Amount to be dispensed incorrect
____ 8.03 Amount to be dispensed without units

____ 9. PRN without indication

____ 10. Weight Error

If yes:

____ 10.01 Weight omitted
____ 10.02 Weight incorrect
____ 10.03 Weight units missing

____ 11. Date Error

If yes:

____ 11.01 Date omitted

____ 11.02 Date incorrect

____ 12. Inappropriate use of abbreviation

____ 13. Other, specify: _____

____ 14. Substitution

If yes:

____ 14.01 Wrong drug given

____ 14.02 Wrong patient received drug

____ 14.03 Wrong drug ordered

____ 14.04 Other :_____

____ 15. Failure to recognize drug-drug interaction

____ 16. Inadequate follow-up of therapy

____ 17. Use of inappropriate drug

____ 18. Avoidable delay of treatment

____19. Patient had documented allergy to medication prescribed

12. Person Primarily Responsible ___

1. Physician
2. Nurse practitioner
3. Physician's assistant
4. Nurse in office
5. Pharmacist in office
6. Pharmacist in pharmacy
7. Parent/Legal guardian
8. School nurse
9. Babysitter/daycare provider
10. Patient
11. Other _____
12. None
13. Insurance
14. Person who takes phone orders

13. Other people responsible ___ ___ ___

1. Physician
2. Nurse practitioner
3. Physician's assistant
4. Nurse in office
5. Pharmacist in office
6. Pharmacist in pharmacy
7. Parent/Legal guardian
8. School nurse
9. Babysitter/daycare provider
10. Patient
11. Other _____
12. None
13. Insurance
14. Person who takes phone orders

14. Any work resulting from Medication Error? *(Choose all that apply)*

____ 1. Patient contacted provider (phone)
____ 2. Patient contacted provider (email)
____ 3. Patient contacted RN (phone)
____ 4. Patient contacted RN (email)
____ 5. Provider contacted pharmacy
____ 6. Pharmacy contacted provider
____ 7. Patient contacted pharmacy
____ 8. Labs
____ 9. Office visit
____ 10. ED visit
____ 11. Hospitalization
____ 12. Consults
____ 13. Other medications
____ 14. Other, specify: _____
____ 15. None

15. At what level did this error occur? *(Choose all that apply)*

____ 1. Physician order
____ 2. Pharmacy dispensing
____ 3. Transcription
____ 4. Patient administration
____ 5. Monitoring
____ 6. Can't tell

16. Severity of Error *(Choose only one):*

____ 1. ADE
2. Potential ADE
3. Medication error, not ADE or Potential ADE
4. Exclude
5. Rule violation

17. Category of complication ____

1. None
2. Bleeding
3. CNS
4. Allergic/cutaneous
5. Metabolic
6. Cardiovascular
7. GI
8. Renal
9. Respiratory
10. Marrow Depression
11. Other _____
12. Eyes
13. Ears
14. Nose
15. Throat
16. Reproductive
17. Musculoskeletal
18. Skin

18. Was the event intercepted before an injury occurred? ____

1. No *(END)*
2. Yes *(Go on to Q18)*
3. Unknown [PADE] *(END)*
4. No injury [PADE] *(END)*

19. If intercepted, then by whom? ____

1. Physician
2. Nurse practitioner
3. Physician's assistant
4. Nurse in office
5. Pharmacist in office
6. Pharmacist in pharmacy
7. Parent/Legal guardian
8. School nurse
9. Babysitter/daycare provider
10. Patient
11. Other _____
12. None
13. Insurance
14. Person who takes phone orders

DATAFORM 5A

Medication Error Identification and Classification Form
For Multiple Errors

1. Study ID Number: ___ ___-___ ___ ___ ___

2. Case Number:

a.	___ ___ ___	f.	___ ___ ___
b.	___ ___ ___	g.	___ ___ ___
c.	___ ___ ___	h.	___ ___ ___
d.	___ ___ ___	i.	___ ___ ___
e.	___ ___ ___	j.	___ ___ ___

6. Reviewer ID Number: ___ ___

7. Stage of error discovery

_X_	1. Dataform 1:	Prescription Screening Form
____	2. Dataform 2A/2B:	10-day Follow-Up Form
____	3. Dataform 3A:	6 Week Follow-Up Form
____	4. Dataform 4:	Chart Review Form

8. Brief description (e.g. inappropriate dose): _____

6. Target prescription
(One that had been reviewed)

_2_ 1. No Name of Drug_____
2. Yes: Prescription # _____ *(from dataform 1)*

12. Category of reason *(multiples may be checked; circle primary reason):*

____ 1. Illegible Order

If yes:

____ 1.01 MD signature illegible
____ 1.02 Patient name illegible
____ 1.03 Med name illegible
____ 1.04 Illegible route
____ 1.05 Illegible frequency
____ 1.06 Illegible length of treatment
____ 1.07 Illegible amount to be dispensed
____ 1.08 Entire prescription illegible
____ 1.09 Illegible dose or dose units
____ 1.10 Illegible strength or strength units
____ 1.11 Illegible date
____ 1.12 Illegible weight or weight
____ 1.13 Illegible directions for use

____ 2. Dose error

If yes:

____ 2.01 Overdose
____ 2.02 Underdose
____ 2.03 Dose omitted (from order/when dispensed)
____ 2.04 Dose units omitted
____ 2.05 Dose form incorrect
____ 2.06 Extra dose(s)
____ 2.07 Missed dose(s) (not given/taken)

____ 3. Route error

If yes:

____ 3.01 Route omitted
____ 3.02 Route incorrect

____ 4. Frequency error

If yes:

____ 4.01 Frequency omitted
____ 4.02 Frequency incorrect

____ 5. Length of Treatment Error

If yes:

____ 5.01 Length of treatment omitted
____ 5.02 Length of treatment incorrect

____ 6. Directions Error

If yes:

____ 6.01 Directions for use omitted
____ 6.02 Directions for use incorrect
____ 6.03 Directions for use incomplete

____ 7. Strength Error

If yes:

____ 7.01 Strength omitted
____ 7.02 Strength incorrect
____ 7.03 Strength incomplete
____ 7.04 Strength without units

____ 8. Amount to be dispensed error

If yes:

____ 8.01 Amount to be dispensed omitted
____ 8.02 Amount to be dispensed incorrect
____ 8.03 Amount to be dispensed without units

____ 9. PRN without indication

____ 10. Weight Error

If yes:

____ 10.01 Weight omitted
____ 10.02 Weight incorrect
____ 10.03 Weight units missing

____ 11. Date Error

If yes:

____ 11.01 Date omitted
____ 11.02 Date incorrect

____ 12. Inappropriate use of abbreviation

____ 13. Other, specify: _____

____ 14. Substitution

If yes:

____ 14.01 Wrong drug given
____ 14.02 Wrong patient received drug
____ 14.03 Wrong drug ordered
____ 14.04 Other :_____

____ 15. Failure to recognize drug-drug interaction

____ 16. Inadequate follow-up of therapy

____ 17. Use of inappropriate drug

____ 18. Avoidable delay of treatment

____19. Patient had documented allergy to medication prescribed

12. Person Primarily Responsible ___

1. Physician
15. Nurse practitioner
16. Physician's assistant
17. Nurse in office
18. Pharmacist in office
19. Pharmacist in pharmacy
20. Parent/Legal guardian
21. School nurse
22. Babysitter/daycare provider
23. Patient
24. Other _____
25. None
26. Insurance
27. Person who takes phone orders

13. Other people responsible ___ ___ ___

1. Physician
15. Nurse practitioner
16. Physician's assistant
17. Nurse in office
18. Pharmacist in office
19. Pharmacist in pharmacy
20. Parent/Legal guardian
21. School nurse
22. Babysitter/daycare provider
23. Patient
24. Other _____
25. None
26. Insurance
27. Person who takes phone orders

14. Any work resulting from Medication Error? *(Choose all that apply)*

____ 1. Patient contacted provider (phone)
____ 2. Patient contacted provider (email)
____ 3. Patient contacted RN (phone)

____ 4. Patient contacted RN (email)
____ 5. Provider contacted pharmacy
____ 6. Pharmacy contacted provider
____ 7. Patient contacted pharmacy
____ 8. Labs
____ 9. Office visit
____ 10. ED visit
____ 11. Hospitalization
____ 12. Consults
____ 13. Other medications
____ 14. Other, specify: _____
__X__ 15. None

15. At what level did this error occur? *(Choose all that apply)*

__X__ 1. Physician order
____ 2. Pharmacy dispensing
____ 3. Transcription
____ 4. Patient administration
____ 5. Monitoring
____ 6. Can't tell

16. Severity of Error *(Choose only one):*

__3__ 1. ADE
2. Potential ADE
3. Medication error, not ADE or PADE
4. Exclude
5. Rule violation

DATAFORM 6

ADE Incident Identification Form

1. Study ID Number: ___ ___-___ ___ ___ ___

2. Case Number: ___ ___ ___

3. Reviewer ID Number: ___ ___

4. Stage of ADE discovery
   ____ 1. DF 1: Prescription Error Form
   ____ 2. DF 2A/2B: 10-Day Follow-Up Form
   ____ 3. DF 3A: 6 Week Follow-Up Form
   ____ 4. DF 4: Chart Review Form

5. Did the ADE involve one of the target prescriptions? ____
   1. No Provider #: ___ ___ - ___ ___ ___
   2. Yes
   3. Unknown

6. Brief description of ADE: _____

7. Was this incident due to a medication error? ____
   1. No *(Go on to Q8)*
   2. Yes *(Skip to Q12)*
   3. Unknown *(Skip to Q12)*

8. Name of drug involved _____

9. Dose and frequency of drug _____

10. Route of drug ____
    1. PO
    2. Topical
    3. Subcutaneous
    4. Rectal
    5. Otic
    6. Eye
    7. Inhalation
    8. Other, specify: _____
    9. Not specified
    10. Nasally

11. Category of drug: ____

1. Analgesic (narcotic)
2. Analgesic (non-narcotic, non NSAID)
   - 2.01 Acetaminophen
   - 2.02 Other
3. Antianemia
4. Antibiotic
   - 4.01 Cephalosporin
   - 4.02 Clindamycin
   - 4.03 Macrolides
   - 4.04 Misc. antibiotics
   - 4.05 Ophthalamic preps.
   - 4.06 Otic preps.
   - 4.07 Penicillin or derivative
   - 4.08 Quinolones
   - 4.09 Sulfa
   - 4.10 Tetracyclines
   - 4.11 Topical
   - 4.12 Other
   - 4.13 Nitrofuran antimicrobial
5. Anticoagulant
6. Anticonvulsant
7. Antidepressant
8. Antifungal (oral)
9. Antifungal (topical)
10. Antihelmintics
11. Antihistamine (all forms)
12. Antihypertensive
13. Antineoplastic
14. Antipsychotic
15. Antituberculosis
16. Antitussive
17. Antiviral (all forms)
18. Bronchodilator (inhaled)
19. Bronchodilator (oral)
20. Decongestant
21. Diabetes (Oral agents)
22. GI meds
    - 22.01 Antiflatulent
    - 22.02 H2 blocker
    - 22.03 Proton pump inhibitor
    - 22.04 Probiotic
    - 22.05 Antacid
    - 22.06 Laxative
23. Insulin
24. Leukotriene Receptor Antagonist
25. Local Anesthetic
26. Muscle relaxants
27. Nasal sprays
28. NSAID
    - 28.01 Ibuprofen
    - 28.02 Other
    - 28.03 Cox-2 inhibitor
29. Oral contraceptive
30. Sedative, hypnotic
31. Steroids (inhaled)
32. Steroids (oral)
33. Steroid (topical)
34. Stimulants
35. Thyroid Agents
36. Vaccines
37. Vitamins
38. Other:
39. Antimalarial
40. Contraceptive (injectable)
41. Contraceptive (patch)
42. Dermatologicals
43. Emollients
44. Epinephrine
45. Immunologicals (topical)
46. Iron
47. Normal saline
48. Scabicide
49. Topical anesthetic
50. Antianxiety
51. Beta blocker
52. Estrogen (topical)
53. Cerumenolytic
54. Emetic
55. Hemostatic
56. Mast cell stabilizer
57. Antiarrythmic
58. Anticholinergic
59. Antiemetic
60. Keratolytic
95. Equipment
96. Formula
97. Immunization
98. Lab or x-ray
99. Medication given in clinic

12. Category of complication ____

1. Bleeding
2. CNS
3. Allergic/cutaneous
4. Metabolic
5. Cardiovascular
6. GI
7. Renal
8. Respiratory
9. Marrow Depression
10. 11.Other _____
11. Eyes
12. Ears
13. Nose
14. Throat
15. Reproductive
16. Musculoskeletal
17. Skin

13. How long did it last? ____
1. Less than one day
2. 1-3 days
3. 4-7 days
4. 8 days to 1 month
5. More than 1month
6. Unknown
7. Disabling
8. Lab abnormality only

14. Was there any other evidence of the ADE? *(eg. Endoscopy showing ulcer)* ____
1. No
2. Yes, specify: _____
3. Don't know

15. Was the patient taking other medication in the 24 hours prior to the event ____
1. No *(Skip to Q17)*
2. Yes *(Go on to Q16)*
3. Don't know *(Skip to Q17)*

16. List the known drugs the patient was taking in the 24 hours prior to incident:

Name of drug	Category *(use table from Q11)*	Name of drug	Category *(use table from Q11)*
a.		f.	
b.		g.	
c.		h.	
d.		i.	
e.		j.	

17. Did the patient have a documented previous allergy or reaction to the drug that caused the adverse drug event? ____
1. No
2. Intolerance (e.g. nausea, headache)
3. Allergy (reaction not documented)
4. Allergy, not anaphylaxis (e.g. rash)
5. Anaphylaxis
6. Other _____

18. Did the patient have a documented previous allergy or reaction to other drug ____
1. No
2. Intolerance (e.g. nausea, headache)
3. Allergy (reaction not documented)
4. Allergy, not anaphylaxis (e.g. rash)
5. Anaphylaxis
6. Other _____

19. Was the drug stopped? ____
1. No
2. Yes
3. Don't know
4. Not applicable

20. Was a specific antagonist given? ____ 1. No
2. Yes, specify: _____
3. Don't know

21. Did this adverse drug event result in an additional visit?	_____
	1. No *(Skip to question Q23)* 2. Yes *(Go on to Q22)*
22. If yes, how many of each visit (indicate all that apply)	1. _____ Clinic visits 2. _____ Emergency room visits 3. _____ Hospital admissions 4. _____ Admissions to long-term facility 5. _____ Phone call 6. _____ Email contacts 7. _____Other_____ _____ 8. _____Other _____
23. Was the event caused by a medication that required outpatient blood monitoring?	_____
	1. No *(Skip to Q25)* 2. Yes *(Go on toQ24)*
24. If yes, was there elevated/abnormal level with the event?	_____ _____ _____
	1. No 2. Yes (specify level and abnormality)
25. Was there regular monitoring of the blood level prior to the event?	_____
	1. No 2. Yes

26. Relevant lab values: (at visit or most recent prior to visit)

Test name	Value	Date
a.		
b.		
c.		
d.		
e.		
f.		

DATAFORM 7

ADE and Near Miss Incident Classification Form

1. Study ID Number: ____ ____-____ ____ ____ ____ ____

2. Case Number: ____ ____ ____

3. Reviewer ID Number: ____ ____

4. Classification of incident *(Choose only one)* ____
   1. ADE
   2. Near Miss
   3. Medication Error
   4. Exclusion

5. Confidence regarding above judgement? ____
   1. Little or no evidence
   2. Modest confidence
   3. Medium confidence
   4. Strong confidence
   5. Very certain confidence

6. Severity of ADE or PADE *(Choose only one)* ____
   1. Fatal
   2. Life-threatening
   3. Serious
   4. Significant
   5. Not an ADE or Near Miss

7. Preventability—Implicit (choose only one) ____
   1. Error intercepted
   2. Definitely preventable
   3. Probably preventable
   4. Probably not preventable
   5. Definitely not preventable

8. Could this event have been prevented by any of the following checks?
(Choose all that apply)

___ ___ ___ ___ ___ ___ ___ ___

1. Computerized physician order entry (basic design which ensure complete field legibility and signature)
2. CPOE with drug decision support
   2a. Drug-weight or drug dose check (guided dose algorithms)
   2b. Drug-allergy check
   2c. Drug-drug check
   2d. Drug-lab check
   2e. Drug frequency check
   2f. Drug-route check
   2g. Drug-pt. characteristic check: renal function
   2h. Drug-pt. characteristic check: age
   2i. Drug-pt. characteristic check: pregnancy
   2j. Drug-pt. characteristic check: other, specify: _____
   2k. Drug duration
3. Electronic transmission of prescription
4. Clinical pharmacist
   4a. Discussing ordering
   4b. Discussing administration/monitoring
   4c. Monitoring/dispensing
5. Changes in staffing for:
   5a. Physicians
   5b. Nurses
   5c. Pharmacists
   5d. Other, specify: _____
6. Changes in training for:
   6a. Physicians
   6b. Nurses
   6c. Pharmacists
   6d. Other, specify: _____
7. Changes in hours for:
   7a. Physicians
   7b. Nurses
   7c. Pharmacists
   7d. Other, specify: _____
8. Changes in communication between:
   8a. Physicians and patients
   8b. Nurses and patients
   8c. Physicians and pharmacists
   8d. Physicians and RNs, PAs, NPs, etc.
   8e. Parents and other caregivers (babysitter, school)
   8f. Other, specify: _____
   8g. Pharmacists and patients
9. Other, specify:

   _____
10. None
11. Drug specific guidelines
12. Pre printed template

13. Insurance Coverage

9. Complete the following table

	Yes	No	Unsure
9.1 Are there any previous reports of this reaction in the Literature to your knowledge?	Y	N	U
9.2 Was the condition present before the administration of the drug in question?	Y	N	U
9.3 Could a non-pharmalogical clinical condition explain the change noted?	Y	N	U
9.4 Was the amount of the drug used too much for this patient?	Y	N	U
9.5 Is there objective evidence of toxicity (eg. from body fluids, biopsy, blood levels, but NOT rash or vital signs)?	Y	N	U
9.6 Did the patient received an antagonist to the drug?	Y	N	U
9.7 Was the antagonist effective?	Y	N	U
9.8 Did the patient undergo therapy other than the antagonist directed at the condition in question?	Y	N	U
9.9 Was the therapy effective?	Y	N	U
9.10 Does the patient have a known allergy or intolerance to the drug?	Y	N	U
9.11 Was this reaction a rash, hives, itching, or anaphylaxis?	Y	N	U
9.12 Was this reaction a commonly reported sensitivity to this medication (eg. Nausea to opiates)?	Y	N	U

10. Was the event ameliorable? ____ 1. Yes
2. No

Paediatric Ambulatory Communication Survey

Provider Demographics Form

Complete this page once for each provider

1. Provider ID Number: ___-___ ___

2. What type of health care provider are you?

    a. Paediatrician
    b. Family practitioner
    c. General practitioner
    d. Other physician
    e. Nurse practitioner
    f. Physician assistant
    g. Other health care provider

3. Are you of Hispanic or Latino family background?

    a. Yes
    b. No

4. Which of the following describes your race? Choose all that apply.

    a. White
    b. Black or African-American
    c. American Indian or Alaska
    d. Asian
    e. Native Hawaiian or other Pacific Islander
    f. Other race: _____

5. Do you speak any foreign languages well enough to speak with non-English speaking patients?

    a. Yes, I speak
        1. Spanish
        2. French
        3. Russian
        4. Portuguese, including Portuguese Creole
        5. Haitian or French Creole
        6. Vietnamese (Hmong)
        7. Other
    b. No

6. In what year did you graduate from medical school? _____

Paediatric Ambulatory Communication Survey

Provider Demographics Form

Complete this page once for each provider

1. Provider ID Number: ___-___ ___

2. What type of health care provider are you?

    h. Paediatrician
    i. Family practitioner
    j. General practitioner
    k. Other physician
    l. Nurse practitioner
    m. Physician assistant
    n. Other health care provider

3. Are you of Hispanic or Latino family background?

    c. Yes
    d. No

4. Which of the following describes your race? Choose all that apply.

    g. White
    h. Black or African-American
    i. American Indian or Alaska
    j. Asian
    k. Native Hawaiian or other Pacific Islander
    l. Other race: _____

5. Do you speak any foreign languages well enough to speak with non-English speaking patients?

    b. Yes, I speak
        8. Spanish
        9. French
        10. Russian
        11. Portuguese, including Portuguese Creole
        12. Haitian or French Creole
        13. Vietnamese (Hmong)
        14. Other
    c. No

6. In what year did you graduate from medical school?

Annex 2- The Drug Chart

Barnet and Chase Farm Hospitals NHS
NHS Trust

In-Patient Prescription Sheet for Barnet/Chase Farm/.....Hospital (please insert name)

WARD	DRUG ALLERGIES (Please write "none" if no allergy detected)	AFFIX PATIENT LABEL HERE
CONSULTANT		Hospital No. M/F Surname First Names D.of B
H. OFFICER/SHO/PRHO	HEIGHT IN CM / WEIGHT IN KGS	
BLEEP NO.	DATE OF ADMISSION	T.T.A. DISPENSED / DATE / PHARM.

HOW TO USE THE PRESCRIPTION SHEET

Doctor

A. Ensure ward name, patient's name and hospital number are filled in correctly.
B. Use your normal signature to legalise prescribing.
C. Use capital letters and approved names for drugs. Only use brand names when important for bio-availability reasons.
D. Write doses of less than 1mg in **micrograms** (in full).
E. Prescriptions are valid for thirty days. Start a new chart every thirty days.
F. Discontinue drug by a vertical line through the prescribing side and the administration record; sign and date the discontinuation.
G. When changing dose and/or frequency, discontinue drug and represcribe on a new line. **DO NOT** alter existing instructions.
H. Tick the administration times required or write in new/additional times.

Nurse

A. Ensure ward name, patient's name and hospital number are filled in correctly.
B. Check the entries in every section to avoid omissions.
C. Only administer if prescription is legible and drug correctly prescribed, and inform prescriber.
D. Nurse's initials should be recorded in block letters.
E. When a drug is not given at correct time, record the appropriate code in the nurse administration box in red.
N. Patient away from ward
F. Patient could not receive drug, e.g. Nil by mouth. Vomiting
R. Patient refused drug
U. Drug not available – Inform doctor
O. Other reason-record in Nursing Evaluation.

Remember to use the '5 RIGHTS': Right patient, Right drug, Right dose, Right time, Right route.

ADDITIONAL PRESCRIPTION CHARTS IN USE (please tick)

Sliding scale insulin ☐
Patient controlled analgesia ☐
Weekly insulin chart ☐

Other (specify):

When the additional charts are discontinued

Please delete with a vertical line and sign. **(I)**

Abbreviations for route of administration:

Intravenous	I.V.
Intramuscular	I.M.
Subcutaneous	S.C.
Oral	P.O.
Topical	TOP
Sublingual	S.L.
Vaginal	P.V.
Rectal	P.R.
Inhalation	INH
Nebulisers	Neb

Dosage Abbreviations

grams	g	millilitres	ml
litres	l	millimoles	mmol
milligrams	mg	millimol/litre	mmol/l
micrograms	no abbreviations		

FOR PHARMACY USE:

ONCE ONLY/PREMEDICATION DRUG/MEDICINES SUPPLIED OR ADMINISTERED UNDER PATIENT GROUP DIRECTIONS

DATE	TIME	DRUG (Approved name)	DOSE	ROUTE	ADDITIONAL INSTRUCTIONS	PRESCRIBER'S SIGNATURE	ADMINIST' SIGNATURE	PHARMACY

PATIENT'S NAME:- **ADMINISTRATION DATE**

REGULAR DRUGS

			TIME	TICK														
DRUG (Approved name)	Route	Dose and Frequency	06.00															
			08.00															
	Start Date	Stop Date	12.00															
			14.00															
Prescribers signature & name	Pharmacy		18.00															
			22.00															
INSTRUCTIONS FOR ADMINISTRATION																		
DRUG (Approved name)	Route	Dose and Frequency	06.00															
			08.00															
	Start Date	Stop Date	12.00															
			14.00															
Prescribers signature & name	Pharmacy		18.00															
			22.00															
INSTRUCTIONS FOR ADMINISTRATION																		
DRUG (Approved name)	Route	Dose and Frequency	06.00															
			08.00															
	Start Date	Stop Date	12.00															
			14.00															
Prescribers signature & name	Pharmacy		18.00															
			22.00															
INSTRUCTIONS FOR ADMINISTRATION																		
DRUG (Approved name)	Route	Dose and Frequency	06.00															
			08.00															
	Start Date	Stop Date	12.00															
			14.00															
Prescribers signature & name	Pharmacy		18.00															
			22.00															
INSTRUCTIONS FOR ADMINISTRATION																		
DRUG (Approved name)	Route	Dose and Frequency	06.00															
			08.00															
	Start Date	Stop Date	12.00															
			14.00															
Prescribers signature & name	Pharmacy		18.00															
			22.00															
INSTRUCTIONS FOR ADMINISTRATION																		
DRUG (Approved name)	Route	Dose and Frequency	06.00															
			08.00															
	Start Date	Stop Date	12.00															
			14.00															
Prescribers signature & name	Pharmacy		18.00															
			22.00															
INSTRUCTIONS FOR ADMINISTRATION																		
DRUG (Approved name)	Route	Dose and Frequency	06.00															
			08.00															
	Start Date	Stop Date	12.00															
			14.00															
Prescribers signature & name	Pharmacy		18.00															
			22.00															
INSTRUCTIONS FOR ADMINISTRATION																		

PATIENT'S NAME:- **ADMINISTRATION DATE**

REGULAR DRUGS

DRUG (Approved name)	Route	Dose and Frequency	TIME	TICK
			06.00	
			08.00	
	Start Date	Stop Date	12.00	
			14.00	
Prescribers signature & name	Pharmacy		18.00	
			22.00	
INSTRUCTIONS FOR ADMINISTRATION				

DRUG (Approved name)	Route	Dose and Frequency		
			06.00	
			08.00	
	Start Date	Stop Date	12.00	
			14.00	
Prescribers signature & name	Pharmacy		18.00	
			22.00	
INSTRUCTIONS FOR ADMINISTRATION				

DRUG (Approved name)	Route	Dose and Frequency		
			06.00	
			08.00	
	Start Date	Stop Date	12.00	
			14.00	
Prescribers signature & name	Pharmacy		18.00	
			22.00	
INSTRUCTIONS FOR ADMINISTRATION				

DRUG (Approved name)	Route	Dose and Frequency		
			06.00	
			08.00	
	Start Date	Stop Date	12.00	
			14.00	
Prescribers signature & name	Pharmacy		18.00	
			22.00	
INSTRUCTIONS FOR ADMINISTRATION				

DRUG (Approved name)	Route	Dose and Frequency		
			06.00	
			08.00	
	Start Date	Stop Date	12.00	
			14.00	
Prescribers signature & name	Pharmacy		18.00	
			22.00	
INSTRUCTIONS FOR ADMINISTRATION				

DRUG (Approved name)	Route	Dose and Frequency		
			06.00	
			08.00	
	Start Date	Stop Date	12.00	
			14.00	
Prescribers signature & name	Pharmacy		18.00	
			22.00	
INSTRUCTIONS FOR ADMINISTRATION				

DRUG (Approved name)	Route	Dose and Frequency		
			06.00	
			08.00	
	Start Date	Stop Date	12.00	
			14.00	
Prescribers signature & name	Pharmacy		18.00	
			22.00	
INSTRUCTIONS FOR ADMINISTRATION				

ORAL ANTICOAGULANT																	
DRUG (Approved name)	Time	Date															
		INR Result															
PHARM. SIGNATURE		Dose (mg)															
	18.00 hrs	Signature															
		Given															
DRUG (Approved name)	Time	Date															
		INR Result															
PHARM. SIGNATURE		Dose (mg)															
	18.00 hrs	Signature															
		Given															

VARIABLE DOSE MEDICATION																			
DRUG (Approved name)		Start Date	Change	Change	DATE AND MONTH														
	Time	Dose	Dose	Dose															
	6																		
Prescriber to tick the times required	8																		
ROUTE	12																		
SIGNATURE	14																		
	18																		
PHARM.	22																		
DRUG (Approved name)		Start Date	Change	Change	DATE AND MONTH														
	Time	Dose	Dose	Dose															
	6																		
Prescriber to tick the times required	8																		
ROUTE	12																		
SIGNATURE	14																		
	18																		
PHARM.	22																		

AS REQUIRED MEDICATION

SURNAME
FORENAMES HOSP. No.

DRUG (Approved name)			DATE															
			TIME															
ROUTE	DOSE/FREQUENCY	START DATE	DOSE															
SIGNATURE	PHARMACY		ROUTE															
INSTRUCTION FOR ADMINISTRATION			GIVEN BY															
DRUG (Approved name)			DATE															
			TIME															
ROUTE	DOSE/FREQUENCY	START DATE	DOSE															
SIGNATURE	PHARMACY		ROUTE															
INSTRUCTION FOR ADMINISTRATION			GIVEN BY															
DRUG (Approved name)			DATE															
			TIME															
ROUTE	DOSE/FREQUENCY	START DATE	DOSE															
SIGNATURE	PHARMACY		ROUTE															
INSTRUCTION FOR ADMINISTRATION			GIVEN BY															
DRUG (Approved name)			DATE															
			TIME															
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CONTINUOUS INFUSION

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FORENAME HOSP. No.

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