Medication Errors – Capture and Prevention by Pharmacy

by Mark Tomlin

This thesis is submitted in partial fulfilment of the requirements for the award of the degree of Doctor of Philosophy of the University of Portsmouth.

In collaboration with the Pharmacy Department, Southampton University Hospitals NHS Trust

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Abstract

Introduction
This thesis looks at the pharmacist’s contribution to the capture of medication errors and preventing harm reaching patients. It has several components: an analysis of annual surveys of interventions made by pharmacists at a large teaching hospital, a recoding of these surveys to see how many interventions were the result of prescribing errors, and an experiment in A&E where the pharmacist drafted the first prescription chart.

Methods
One-week surveys of pharmacist interventions were regularly made at Southampton General Hospital between 1999 and 2009. These were analysed for trends, then recoded to identify the proportion that were caused by prescribing errors. In addition, a controlled trial was conducted to investigate the effects on prescribing error rate, of a pharmacist obtaining an accurate medication history in A&E, then transcribing the data onto the first inpatient prescription.

Key findings
In the period 1999-2001, the average number of interventions in each week long survey was 575 and during 2005-9 it was 973. This was a statistically significant increase. More interventions were recorded as serious in the latter period.

The rate of interventions also increased from between one per every five and seven patients (31 to 45 prescribed items) to one per every one to two patients (8 to 20 items). The severity of interventions also increased, with between one and five deaths avoided each week. Almost three quarters of pharmacists’ interventions (73.9%) were triggered by prescribing errors, giving an error rate of 644 prescribing errors per week, or 6.2 per 100 prescribed items. These data are in contrast to the Trust submitting 918 error reports per year to the NPSA, the majority of which were administration errors reported by nurses.
Nearly a half (45.3%) of all prescribing errors occurred during the admission phase of the hospital episode. Two thirds (67.1%) of prescribing errors detected were errors of omission - things that had not been done. Prescribing errors of commission occurred mainly during the inpatient phase and errors of omission during the admission phase. A quarter of prescribing errors were planning errors. These were failures to follow guidelines, failures to review patients’ prescriptions, manage interactions, and adjust dosage in liver or renal failure or in response to TDM results.

One fifth (21.7%) of the patients had events or symptoms that contributed to the admission that could be explained by the medicines they were consuming. Over half of these were potentially avoidable by better monitoring or product selection.

A pharmacist working in A&E to obtain complete and accurate drug histories, then transcribing the data onto the first prescription, produced a trend to reduction in the generation of errors throughout the whole hospital episode.

**Conclusions**

Analysing pharmacist’s interventions is a useful method of investigation prescribing errors and ways to stop them happening. First prescriptions written by pharmacists should provide an effective means of reducing errors which may be promulgated throughout the hospital stay.
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DECLARATION

Whilst registered as a candidate for this PhD, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

Mark Tomlin
June 2011
List of abbreviations used in this thesis

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<td>CPOE</td>
<td>Computerised physician order entry</td>
</tr>
<tr>
<td>CUR</td>
<td>Clinical use review</td>
</tr>
<tr>
<td>DUP</td>
<td>Drug use process</td>
</tr>
<tr>
<td>FMECA</td>
<td>Failure mode effect and critical analysis</td>
</tr>
<tr>
<td>GMC</td>
<td>General Medical Council</td>
</tr>
<tr>
<td>IP</td>
<td>Inpatient</td>
</tr>
<tr>
<td>LOS</td>
<td>Length of stay</td>
</tr>
<tr>
<td>MAE</td>
<td>Medicine administration error</td>
</tr>
<tr>
<td>MAU</td>
<td>Medical assessment unit</td>
</tr>
<tr>
<td>MDS</td>
<td>Monitored dose system</td>
</tr>
<tr>
<td>MRA</td>
<td>Medication related admission</td>
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<tr>
<td>MRE</td>
<td>Medication related error</td>
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<tr>
<td>MUP</td>
<td>Medicines use process</td>
</tr>
<tr>
<td>MUR</td>
<td>Medicines use review</td>
</tr>
<tr>
<td>NPSA</td>
<td>National Patient Safety Agency</td>
</tr>
<tr>
<td>NPSA</td>
<td>National Patient Safety Agency</td>
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<tr>
<td>OPE</td>
<td>Omission prescribing error</td>
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<tr>
<td>PE</td>
<td>Prescribing error</td>
</tr>
<tr>
<td>PODs</td>
<td>Patient’s own drugs</td>
</tr>
<tr>
<td>PODTechs</td>
<td>POD technicians</td>
</tr>
<tr>
<td>PRN</td>
<td>As required</td>
</tr>
<tr>
<td>SE</td>
<td>Side effect</td>
</tr>
<tr>
<td>SEA</td>
<td>Significant effect audit</td>
</tr>
<tr>
<td>SUHT</td>
<td>Southampton University Hospitals NHS Trust</td>
</tr>
<tr>
<td>TDM</td>
<td>Therapeutic drug monitoring</td>
</tr>
<tr>
<td>TPN</td>
<td>Total parenteral nutrition</td>
</tr>
<tr>
<td>TS</td>
<td>Therapeutic substitution</td>
</tr>
<tr>
<td>TTO</td>
<td>To take out</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>WTE</td>
<td>Work time equivalent</td>
</tr>
</tbody>
</table>
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Chapter 1 Introduction
This research studies the roles and potential roles for pharmacists in the minimisation of medication related errors at various stages of the patient journey to, through, and leaving the secondary care environment. An overview of the research undertaken is provided in Section 1.11.3. This chapter discusses the generation of medication errors, key drivers behind initiatives to reduce them and strategies proposed for reducing them. It will be seen that pharmacists could make a difference at every stage of the medicines use process.

Medication errors are an unwanted aspect of modern medicine. The Hippocratic Oath\(^1\) insists that physicians will ‘do no harm or injustice’ to their patients. However the complexity of healthcare almost guarantees that errors will occur. Therefore how that risk of errors is managed in an organisation defines its attitude to safety.

Risk is simply the potential for an unwanted outcome. In general the more complex the activity the greater the risk and the more stages in the process the greater the number of risks. Risk management encompasses a series of activities including risk assessment, learning from mistakes, implementing changes as a result and reporting adverse events. This results in safer practice, enhanced patient care and reduced litigation.\(^2\)

‘Safety cultures’ that encourage open reporting and balanced analysis have a better performance than ‘blame cultures’ where there is fear of retribution for failure.\(^3\) Academic research about healthcare failures is well developed in Australia and America but is still in its infancy in the UK. The NHS is not good at learning lessons from these failures and research in this area is to be encouraged.\(^4\)

1.1 Industries with a safety culture
This section will discuss other complex industries that have a culture of safety to illuminate the management of risks. Many of the examples are taken from an American report into errors in healthcare entitled ‘To err is human’.\(^4\) This report was published in 2000 for the US National Research Council by the Committee on Quality

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1. Hippocratic Oath
2. Risk management
3. Safety cultures
4. To err is human
Healthcare is a complex system with multiple processes, entry pathways and feedback loops. It has similarities with space, air and train travel, as well as banking and nuclear power generation.

The public perception is that healthcare should operate like a train company. You book your ticket, enter the train, travel from A to B, disembark and arrive at your planned destination. Thus you book your elective operation (when it suits you), you are admitted, surgery goes to plan, you recover and are then discharged and continue on your life journey as if there had been no interruption.

Air travel is different to train travel because there are no train tracks, the weather may delay, divert or cancel your flight, there are others using the airspace and collisions have to be avoided and (rarely) you may crash and burn. So healthcare is more like air travel than train travel.  

Train travel, air travel and nuclear power are perceived as organisations that give a high priority to maintaining safe systems and the processes are much more reliable than healthcare. In air travel and banking a 1% error rate is acceptable; so why is this not tolerated in healthcare?

Healthcare differs from other industries because the damage is caused to a third party (the patient) whereas in an airline accident, the pilot is the first to know and the company damaged subsequently.

Train or aeroplane crashes provoke big enquiries because many people are injured at once. In healthcare, individuals may be harmed by single events or by the convergence of otherwise innocuous errors. There may be a large collective problem of errors in medical care but it is insidious and largely invisible to the general public. Therefore the journey of the patient through the healthcare system (particularly a hospital episode) may be more hazardous than they expect.
1.1.1 Complex systems

Many industries have linear systems or processes where steps are followed sequentially and there are few decision points or secondary pathways. These industries ensure a good product is delivered by careful selection of the raw materials and good quality control of the processes. Healthcare is much more complex with multiple entry points, multiple exits and many feedback loops. Indeed the raw material (the patient) is not in good working order, despite a perception that all patients enter the system in pristine condition.

Coupling is a mechanical engineering term that describes how processes are linked. Loosely coupled systems have time buffers that can tolerate processing delays, can reorder the sequence of production and can employ alternative methods or resources.

The engineering term ‘tightly coupled’ means that processes have few buffers and events proceed quickly from one stage to the next. When errors occur in tightly coupled systems, there is no time delay before disaster; there is no time to recover. The Kegworth air crash was not caused by an engine fire, but by the pilot switching off the remaining good engine. There was not enough time to correct this error of communication, despite the stewardess being able to see which engine was on fire. Errors arise from informational problems and incomplete knowledge. Time buffers (waiting lists) are used to manage entry into hospitals. However once inside the system, many medication processes are ‘tightly coupled’.

The objectives for safety are to make it difficult for individuals to make errors, and absorb errors that do occur i.e. permit their detection and correction before harm occurs. However the tightly coupled systems in hospital limit the usefulness of time buffers and a complex system tends to introduce steps that produce choices rather than an easy flow of processes.

Further differences are also apparent. The patient may be treated by multiple modes (surgery, drugs, radiotherapy, or counselling). The intended outcome many be full recovery, an improvement in their health status, stabilisation of their condition, or palliation before death.
1.1.2 The role of practitioners

Serious errors are unusual to practitioners and lots of trivial errors produce noise. Practitioners (components of the system) become familiar with frequent, apparently inconsequential errors, but remain unfamiliar with disasters.

Historically, this has built a perception that disasters occur because an individual practitioner has failed. The answer therefore has been to punish, disqualify or shame that practitioner so they either improve their performance or are dismissed. The individual is sanctioned and given rules to follow until they improve their performance. Retraining is perceived as part of the disciplinary process.

Healthcare practitioners are usually well trained and motivated to avoid patient harm. There is a clear public expectation that no harm should occur. Healthcare workers know that errors do occur, but most do not produce harm to patients. Where harm does occur, the burden to the patient is fully comprehended and produces a period of remorse and then blame. The blame culture is perpetuated by findings that depressed doctors are six times more likely to make medication errors.

The prescriber who kills a patient is shocked and confused as to what went wrong. In many cases they were repeating practice undertaken a thousand times before. The problem with this belief system is that even well motivated workers make mistakes; one cannot just re-train so mistakes will not be made.

In order to protect future individuals from harm, it may be more effective to change the system as a whole to reduce the likelihood of repetition and future accidents. New technology and processes are continually being incorporated into healthcare in order to improve the outcomes for patients. However constant vigilance is required to ensure new errors are not being introduced.

All humans err frequently. Systems that rely on error-free performance are doomed to fail. The difficulty is changing perceptions so that healthcare learns from other industries to change systems to make it safer for patients.
1.1.3 Impact of the media

The role of the media is crucial in raising public awareness about disasters in all industries.

The Challenger spaceship disaster and the Three Mile Island nuclear accident were significant engineering errors that raised awareness in the general public about safety cultures in space travel and nuclear power generation. This was partly because they produced newspaper headlines, and detailed background stories over many weeks.

In healthcare, the media publicise individual deaths rather than large cohorts of patients. So there is a tendency to produce anecdotal reports of deaths of famous people or personal tragedies to which the public can easily relate; for example: reported cases of amputation of the wrong leg, or accidental overdose of a child, or death from an anticancer drug. A hospital in the USA was fined approximately £12,500 for giving (1,000 times) overdoses of an anticoagulant to three children including the newborn twins of actor Dennis Quaid and this case gained wide media coverage. However such reporting tends to spread alarm, rather than an understanding of what is really happening throughout the healthcare system.

1.1.4 Definitions

Before exploring the impact of medicines misadventures further, it is worth defining the meaning of some commonly used terms.

1.1.4.1 Adverse Event (AE)

An adverse event has been defined as – an injury caused by medical management rather than the underlying condition of the patient.

In 1997 there were two significant studies in the USA looking at AEs producing hospital admissions. In the Colorado and Utah study in 1992, an AE occurred in 2.9% of hospital admissions. A similar study in New York, Harvard Medical Practice in 1984 showed 3.7% hospital admissions experienced an AE. In the former study, 6.6% of AEs led to death; in New York, the figure was 13.6%. From this it was
extrapolated that in the US in 1997 there were nationally, 33.6 million admissions and 44 to 96 thousand Americans died each year as a result of medical errors in hospital. This would make medical adverse events the eighth leading cause of death; higher than car accident deaths (43,000), breast cancer deaths (42,000), and deaths from AIDS (16,000).4

1.1.4.2 Preventable adverse event (PAE)

A preventable adverse event is an adverse event attributable to a medical error.4 PAEs are a subset of AEs. A negligent adverse event (NAE) represents a subset of PAEs. In negligent PAEs the provider fails to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question. While many PAEs involve drugs, many do not.

Figure 1.1 shows the linkage between the concepts of AEs, PAEs and NAEs.

Figure 1.1 Relationship between different types of adverse events in medical practice. (see text for definitions).

1.1.4.3 Preventable adverse drug events (PADEs)

PADE is the term used to describe PAEs that are related to drugs. This thesis will only be examining PAEs that are associated with medication. In the New York
study\textsuperscript{11}, 58\% of AEs were PAEs, including 27.6\% that were NAEs; In the Colorado and Utah study\textsuperscript{10}, 53\% were PAEs including 29.2\% NAEs. In this study it was estimated that 2\% of admissions to hospitals in the US were the consequence of PADEs, representing a cost of $2billion nationally.

A study in 1988 by Dubois \textit{et al.} \textsuperscript{12} showed that of 182 deaths from 3 conditions (cerebrovascular accident, myocardial infarction and pneumonia) in 12 hospitals, at least 14\% and possibly as many as 27\% might have been prevented.

\textbf{1.1.4.4 Adverse drug event (ADE)}

Complications arise in defining an adverse drug event. Not surprisingly, different publications have produced different definitions.

The World Health Organisation (WHO) defines an ADE as a detrimental response that may be related to medication that is undesired and unintended, excluding therapeutic failure, poisoning, and overdose.\textsuperscript{13} An ADR (adverse drug reaction) is a subset of ADEs and is unavoidable. A meta-analysis showed that on average 5.3\% of hospital admissions were associated with ADRs.\textsuperscript{14}

However a therapeutic failure could fall into any of the groups shown in Table 1.1, which uses the choice of antibiotics as its theme. Example 1 could be regarded as a therapeutic failure consistent with action on poor evidence. Example 2 might be poor practice. Example 3 would be a PAE as defined above. Examples 4 and 5 are medication errors or PADEs. Similarly, overdose could be accidental, deliberate or the result of a prescription.

Bates \textit{et al.}\textsuperscript{15} defined an ADE as ‘\textit{any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment}’.
<table>
<thead>
<tr>
<th>Reason</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Poor selection of drug due to inadequate data</td>
<td>Choosing penicillin V for an infection where there is evidence that the infection is actually due to Pseudomonas, which is intrinsically resistant.</td>
</tr>
<tr>
<td>2 Poor procedure</td>
<td>Not collecting samples so that a choice can be informed or confirmed.</td>
</tr>
<tr>
<td>3 Poor selection on the basis of inaccurate data</td>
<td>Choosing penicillin V because the laboratory inaccurately reported sensitivity of the organism.</td>
</tr>
<tr>
<td>4 Poor selection of drug despite good data</td>
<td>Choosing penicillin V due to mis-reading the laboratory report that clearly states resistance to penicillin V.</td>
</tr>
<tr>
<td>5 Poor prescribing</td>
<td>Choosing penicillin V for a sensitive organism but using a sub-therapeutic dose by mistake.</td>
</tr>
</tbody>
</table>

A more helpful definition of medication errors used by Phillipps et al.\textsuperscript{16} is: ‘any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient or consumer’. This definition is associated with some useful quantitative data that enable the reader to appreciate the size of this problem.

Tomsen et al.\textsuperscript{17} presented a systematic analysis of 29 studies showing that ambulatory care in the US had an incidence of 14.9 ADEs per 1000 person months. Preventable ADEs represented 5.6 ADEs per 1000 patients (21% of all ADEs) and half of the preventable ADEs required hospitalisation. Although ADEs represented only one fifth of AEs they are in general, the most studied because computerised data is often available on what is prescribed, the medicines use process is studied in detail, and the outcomes of treatment are recorded on death certificates. Circumstances around other AEs are frequently more opaque.
1.1.4.5 Adverse drug reaction (ADR)

An ADR is defined by the WHO as an effect that is ‘noxious and unintended, and which occurs at doses used in man for prophylaxis, diagnosis or therapy’\textsuperscript{13}. ADRs can be sub-classified into type A: usually predictable from the drug’s pharmacology and dose dependent (e.g. respiratory depression from opiates) and type B: not predictable from the pharmacology, relatively rare, idiosyncratic and often more hazardous when compared to type A reactions (e.g. liver toxicity associated with troglitazone). ADRs are thus a refined subset of ADEs, where some systematic assessment has lead to an assumption that the drug actually caused the ADE\textsuperscript{18}.

Summarising, and with reference to Figure 1.2, the broad term of adverse drug events (ADEs) encompasses true adverse drug reactions (both A and B ADRs) and medication errors, which may or may not lead to patient harm. Many will be preventable (PADEs).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1_2.png}
\caption{Figure 1.2 Illustrating Adverse drug events (ADEs) in a Venn diagram (see text for definitions)}
\end{figure}
Some indirect adverse events are preventable (e.g. falls from postural hypotension caused by drugs) and some are not. Some adverse drug reactions are predictable and therefore preventable (e.g. penicillin anaphylaxis in a patient who has had a previous reaction) and some unpredictable (e.g. a patient given penicillin for the first time). All medication errors are theoretically preventable; the challenge is to design systems that make them less likely to occur.

Some patients will be admitted to hospital because of adverse drug reactions (both A and B) some from indirect events and some from medication errors. Collectively these can be called medication related admissions (MRAs) and are feature of this research.

### 1.1.5 Patient Safety

The concept of patient safety is that patients do not suffer from accidental injury. However the concept differs from reality because the reality is not absolute. The truth is that medicines do cause adverse events and not all are preventable. Getting the public to accept this unpleasant truth is a challenge. Not all errors result in harm. If organisations can learn from the errors that occur to create an environment with safer systems of working and staff who are alert to the risks then harm can be prevented, limited or eliminated.

According to the US Committee on Quality of Healthcare, quality of care in health has three components:

1. Safe Care,
   - Is identifying forces in the external environment that can drive quality improvement in the delivery system (regulatory/legislative and economic incentives);
2. Best Practice
   - Is the provision of services in a manner that is consistent with current medical knowledge and best practices;
3. Customisation
   - Is the ability to meet customer-specific values and expectations. It permits the responsiveness to individual values and preferences.
In the American system the committee wanted to create market place incentives to direct values, culture and priorities of healthcare organisations and reward performance beyond the minimum.

Quality improvement has been described as a design concept that raises the ceiling of performance so that patients receive a higher level of care. Patient safety programs are designed to raise the floor, so that fewer patients are harmed.\textsuperscript{19} Thus patient safety is a minimum standard and quality improvement is an aspirational goal above the patient safety level.

1.1.6 The UK position

In effect, the US report ‘To err is human\textsuperscript{14} was direct marketing to patients about medical errors. The impact was tangible, with near saturation coverage in the media over three days.\textsuperscript{20}

The UK responded with ‘Organisation with a memory’ (OWAM).\textsuperscript{3} This report called for the NHS to adopt an open culture of reporting and learning lessons from failures. However the implied effect was that this culture change would happen immediately and the effect would be to eliminate errors. The report defined an adverse event as an event or omission arising during clinical care and causing physical or psychological injury to as patient. It reported that historically individuals may learn from their mistakes but those around them fail to do so.

The authors proposed that human error could be managed by either blaming the individual for their carelessness or blaming the system. In order to prevent repetition, the system must be investigated to uncover the hidden traps that allowed the error to occur; i.e. how and why did the defences in the system fail?

Hard barriers are physical, e.g. layout of rooms and the environment. Soft barriers are procedures, protocols and people. Surmounting both types of barrier can be used to reduce the chance of errors occurring.
Although death resulting from medical errors was as common as car crashes, the public appears to have a lower tolerance for them. Research suggests that as many as 10% of admissions or 850,000 patients have adverse health care events each year in the NHS hospital sector, probably costing the NHS more than £2 billion a year. A reduction of medication errors would help to decrease liability and litigation costs, which affect the whole economy in an unacceptable way; and their prevention and associated cost savings would allow more money for effective and innovative medical treatments.

In 2000, the NHS set up the National Reporting and Learning System. This was a mandatory reporting system for adverse health care events and near misses based on sound standardised reporting systems and clear definitions. It was established as a single overall data base for analysing and sharing lessons from incidents and near misses, as well as litigation and complaints data. This encouragement of a reporting and questioning culture in the NHS moved away from ‘blame and encourages a proper understanding of the underlying causes of failures.

After OWAM came Building a Safer National Health Service. This went further in describing how the NHS might achieve this culture change. The preferred method of that time was to set goals and targets. The famous quote from this publication was that by 2005, the NHS would ‘reduce by 40% the number of serious errors in the use of prescribed drugs’. At the time medication related errors accounted for 20% of clinical negligence litigation. However due to the lack of research data and definitions, the baseline for medication errors was not clear. It was thought likely that setting up a safety culture and National Reporting and Learning System would initially increase the number of reports.

In 2008, the UK Healthcare Commission stated that quality in the NHS had improved. One of the standards with the highest annual improvement was compliance rates with standards, which increased to 94% from 91% in the annual period. Improved compliance, it can be suggested, should reduce medication errors.
1.1.7 The role of human beings

Human beings, in all lines of work, make errors. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing.

If airline pilots can ask their juniors to report any mistakes they make – why does this appear to not be possible in healthcare? Pilots are trained to anticipate and deal with system failure and see human error as normal. These are important principles to incorporate into healthcare. As described in the previous section, in the UK, progress has been made; but it is not a universally accepted principle.

Healthcare professionals are expected to exercise proper care in their work. If they neglect to do so and their patients are harmed they can expect to be criticised. However, the rules of negligence limit the numbers that are prosecuted. This is because a successful claim of negligence requires the plaintiff to address five elements: duty of care, breach of duty, factual causation, legal causation and harm. If any one of the elements is not proved, the whole case is lost. This is both complex and a difficult legal test. Systems need to be made safer but individuals must be held to account in particular if there is evidence of gross negligence or recklessness or of criminal behaviour.

It is worth remembering that errors do not respect seniority and experience. A recent study in Edinburgh found that during one week, 10% of trainee doctors and 6% of consultants made prescribing (i.e. drug-related) mistakes.

1.2 Error theory

1.2.1 Errors

Reason defined an error as ‘the failure of a planned sequence of mental or physical activities to achieve its intended outcome when failures cannot be attributed to chance.’ An error is therefore a preventable adverse event (PAE). These can be subdivided into two types. The first is an execution error, where a planned action fails to
be completed as intended. The second is a **planning error**, where the wrong plan is chosen to achieve an aim.

In a 1984 New York study of AEs, the most common event was a drug complication (19%); other events included wound infections (14%) and technical complications (13%). Less common adverse events included: transfusion errors, wrong-site surgery, surgical injuries, preventable suicides, restraint related injuries or death, hospital acquired infection and other treatment related infections, falls, burns, pressure ulcers and mistaken identity. This then demonstrates that studies of this type are likely to unearth a rich mixture of planning and executions errors.

Medication related errors (MREs) occur frequently in hospital; not all result in actual harm, but those that do are costly. Furthermore, by no means all are preventable. A study of 4,000 admissions to tertiary hospitals over six months found 247 ADEs and 194 potential ADEs. Extrapolated event rates were 6.5 ADEs and 5.5 potential ADEs per 100 non-obstetrical admissions, for mean numbers per hospital per year of approximately 1,900 ADEs and 1,600 potential ADEs. Of all the ADEs, 1% were fatal (none preventable), 12% life-threatening, 30% serious, and 57% ‘significant’; twenty-eight percent were judged preventable. Of the life-threatening and serious ADEs, 42% were preventable, compared with 18% of significant ADEs.

Reason stated that when large systems fail it is due to multiple faults that occur together in an unanticipated interaction, creating a chain of events in which the faults grow and evolve; their accumulation results in an accident. He further defined errors as slips, lapses or mistakes as below.

**Slips or Lapses**

A slip or lapse occurs when the action conducted is not what was intended – an error of execution. A slip is observable and a lapse is not. Turning the wrong knob is a slip; not being able to remember the right sequence of knobs from memory is a lapse.
**Mistake**

Here, the action proceeds as planned but fails to achieve its intended outcome because the planned action is wrong. A mistake could occur from a lack of knowledge of the situation. In a mistake the original intention is inadequate – a failure of planning.

A slip would be prescribing a dose of 10mg instead of 1mg. A lapse would be not remembering the dose. A mistake would be selecting the wrong drug because the diagnosis is wrong. ‘Slip’ does not imply minor. So an error is either an error of execution (slips or lapses) or an error of planning (mistake). These distinctions are shown diagrammatically in Figure 1.3.

![Figure 1.3 Diagram of errors (after Reason\(^5\)).](image)

Failure to follow a pattern is a slip (i.e. a failure of skill or task execution). Slips may be a loss of automatic subliminal concentration, such as monitoring a prescription but also worrying about something else. Another slip would be a failure to describe something precisely, resulting in the wrong pattern being retrieved.

A memory lapse is a loss of attention such that one cannot remember which pattern one is following. Causal factors may be being busy, stressed, in an unfamiliar or
hostile environment or simple boredom. The memory first retrieves commonly used patterns and if nothing fits the scenario, it follows common logic pathways. Mistakes (planning failures) are where the logic rule has failed or synthetic function has not produced the ideal solution.

1.2.2 Theory of cognition and its relationship to errors

Most errors result from aberrations in mental functioning. Automatic and unconscious processing is the norm in most daily activities. The human brain is a pattern recognition system; it looks for what it has seen before; indeed optical illusions are possible because of this. The theory is that conscious thought is required for problem solving which requires attention because it is slower than the routine auto processing.

Conscious thought may be split into rule-based thinking (logic or common sense) and synthetic thought. Expertise is the accumulation of a store of patterns that novices need to learn. Experts use the rule based logic for anything that does not fit a known pattern and only use synthetic processing as a last resort because it takes more energy and concentration.

The complex coincidences that cause systems to fail could rarely have been foreseen by the people involved. When an accident is investigated the reviewer is privileged by knowing that something did go wrong. This introduces a bias because causes may seem obvious retrospectively, but prospectively, causes are often concealed from practitioners. This bias of hindsight misleads a reviewer into simplifying the accident or error, and overlooking several contributory factors. Multiple participants often have incomplete data that are only apparent when viewed as a whole – simplistic solutions may emerge that do not identify what really went wrong.

In cognition, the weakest process is short term memory of plans and problem solving pathways. The risk from this can be minimised by simplifying processes. For example, using the same intravenous pump throughout the hospital so all staff know how to use it. Another might be using the same strength of noradrenaline in all ITUs. Standardisation increases pattern recognition. It makes it easier for everyone to
remember how to calculate the dose and prepare the product. Buying ready-made syringes would eliminate the risk altogether. Is there a trade-off with efficiency? All these processes add time, but maybe they save time (and lives) in the long run.

### 1.2.3 Latent and active errors

Medication related errors may be either latent or active; the difference being in the lengths of time that pass before human failures are shown to have an adverse impact on safety.\(^5\) Active errors occur at the level of the front line operator and their effects are felt almost immediately. Latent errors tend to be remote from the direct control of the operator and include things such as poor design, incorrect installation, faulty manufacture, bad management decisions and poorly structured organisations.

The active error is the nurse giving the overdose. The latent error is the doctor not knowing the correct dose, but unwilling to look it up. The doctor asks a colleague who partially remembers and without checking, prescribes the dose of a different antibiotic.

Latent errors may be hidden in the design of routine processes. They may never come to the surface – people work around problems (design defects) so they are often not recognised for what they are. This may be compounded by ‘normalisation of deviance’\(^5\) where small changes in behaviour became the norm and expanded the boundaries, so that additional deviations became acceptable.

A focus on active errors may ignore larger and more important latent errors. Events may lead to new procedures that prohibit the particular behaviour but do not prevent it from re-occurring.\(^5\) Accidents are rarely single events, humans do not intend harm. Local repairs may occur but leave the latent failure unchanged so creating a false sense of security.

In 2004, an Australian tertiary hospital interviewed junior doctors to find out what caused errors. Causes were multifactorial, with a median of 4 (range, 2–5) different types of performance-influencing factors per error.
Lack of drug knowledge was not the single causative factor in any incident. The factors in new-prescribing errors included team, individual, patient and task factors. Factors associated with errors in re-prescribing were environment, task and number of weeks into the term. Defences against error, such as other clinicians and guidelines, were porous, and supervision was inadequate or not tailored to the patient, task, intern or environment. Factors were underpinned by an underlying culture in which prescribing was seen as a repetitive, low-risk chore.27

Having acknowledged that medication related errors can never be eliminated from the healthcare system, the following section discusses ways in which they can be described and evaluated.

1.2.4 Coding error severity
The National Co-ordinating Council for Medication Error Reporting and Prevention (NCC MERP) developed a coding system for error severity levels. A tabulated form of this appears in Table 1.2.

Table 1.2 Definitions of severity (NCCMERP) (adapted from references 27 & 28)

<table>
<thead>
<tr>
<th>Harm</th>
<th>Reached patient</th>
<th>Intervention required</th>
<th>Duration of harm</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>No Error</td>
<td>No</td>
<td>0</td>
<td>Circumstances that have the capacity to cause error</td>
</tr>
<tr>
<td>B</td>
<td>No</td>
<td>No</td>
<td>0</td>
<td>An error occurred but the error did not reach the patient (e.g. omission)</td>
</tr>
<tr>
<td>C</td>
<td>No</td>
<td>Yes</td>
<td>0</td>
<td>An error occurred that reached the patient but did not cause harm</td>
</tr>
<tr>
<td>D</td>
<td>No</td>
<td>Yes</td>
<td>Monitoring or preventive action</td>
<td>0</td>
</tr>
<tr>
<td>E</td>
<td>Yes</td>
<td>Yes</td>
<td>Temporal</td>
<td>An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention</td>
</tr>
<tr>
<td>F</td>
<td>Yes</td>
<td>Yes</td>
<td>Temporal</td>
<td>An error occurred that</td>
</tr>
</tbody>
</table>
may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation

<table>
<thead>
<tr>
<th>G</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Permanent</th>
<th>An error occurred that may have contributed to or resulted in permanent harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Death avoided</td>
<td>An error occurred that required intervention to sustain life</td>
</tr>
<tr>
<td>I</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Death</td>
<td>An error occurred that may have contributed to or resulted in the patient’s death</td>
</tr>
</tbody>
</table>

The classification is thorough; but a simplification of this was thought to be more appropriate for studies of large numbers of errors described by the author in Chapter 3.

The author selected the severity index of incidents according to the classification of several authors, including Devine et al. 29 which was based on the work of Hatoum and colleagues 30 and contained just 7 categories; this is summarised in Table 1.3.

### Table 1.3 Definitions for a severity index.

<table>
<thead>
<tr>
<th>Incident reached patient</th>
<th>Morbidity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No</td>
<td>incidents occurred but stopped before reaching patient</td>
</tr>
<tr>
<td>1</td>
<td>Yes</td>
<td>incidents occurred (reached patients) but no injury sustained – may have required monitoring/investigation/minor treatment;</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>minor injury – no change in vital signs, but required monitoring/investigation/minor treatment</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>temporary morbidity – some changes in vital signs, required monitoring/investigation/simple treatment</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>significant changes in vital signs, required transfer to a higher care level/emergency surgical intervention/antidote</td>
</tr>
<tr>
<td>5</td>
<td>Yes</td>
<td>major permanent loss of function/disability</td>
</tr>
<tr>
<td>6</td>
<td>Yes</td>
<td>Death</td>
</tr>
</tbody>
</table>

19
1.2.5 Concept models of errors

A study in 1995\textsuperscript{6} examined the medical records of all admission to two tertiary hospitals over a six month period and detected 334 errors causing 264 ADEs. Approximately 6.5\% of all admissions suffered an ADE; sixteen were major system errors, and seven system failures accounted for 78\% of all errors. The two most important causal factors were poor dissemination of drug knowledge to doctors (29\% of errors) and inadequate availability of patient information, such as laboratory tests (18\% of medical errors).

These data demonstrate that the culture of blame is outdated and it must be more effective to change the system as a whole to reduce the likelihood of accidents. Two major objectives for improving safety were firstly, to make it difficult for individuals to make errors, and secondly, to absorb errors that do occur i.e. permit their detection and correction before harm occurs.

The error pathway to patient harm may be complex. This has been illustrated using a number of concepts, the most famous of which is the Swiss Cheese Model.

1.2.5.1 Swiss cheese model

Reason first suggested the model of a number of barriers (slices of cheese) that are interposed between the hazards and the outcomes to be avoided (see Figure 1.4).\textsuperscript{31} The barriers represent the defences and the holes in the slices of cheese represent the weaknesses in those defences. The holes allow propagation of failures so that hazards can turn into losses such as accidents or other negative outcomes.
Hazards

Harm

Defensive Barriers

Holes are active and latent errors

Figure 1.4 The Swiss Cheese model – adapted from Reason \(^ {31}\).

The model has been used to describe error generation, and ways to avoid them in a range of industrial settings. In a healthcare environment, error avoidance might start with examining a number of important medication errors to see what barriers to their generation had been penetrated (the cheese slices) and how this could be prevented in future. For example, identical twin children, where only one needs medication, have a high risk of ‘wrong person’ errors. The cheese slices might then be manipulated to try and avoid future incidences (i.e. the holes never align) by for example, better medicine labelling, better twin labelling or better carer counselling.

1.2.5.2 Bow Tie model

The oil company Shell used a ‘bow-tie’ model combining the concepts of fault and event trees to explain how industrial hazards become real; this is illustrated in Figure 1.5. Hazards arise from various engineering activities, but maintenance tasks and schedules, and projects/activities would normally be in place to stop them from producing a harmful event (on the left hand side of the diagram) or propagating its effects (on the left hand side), ultimately causing harm to people, assets or the environment. \(^ {4,28,32}\) While this model has found favour in the pharmaceutical industry
and some medication errors analyses, it is more complex than Reason’s Swiss Cheese model when attempting to describe the generation of medication errors.

Figure 1.5 The bow – tie model adapted from Shell and illustrated in reference 4.

1.3 Detecting errors

In this section the author describes the different methods of detecting and recording medication errors. The advantages and disadvantages of the different methods are then summarised in Table 1.4.

1.3.1 Analysing medical records

A cohort of patients is selected and have their notes read through. Reviewers can record changes in diagnosis and treatments, detect medication related admissions and monitor pharmacist entries relating to prescribing errors.

1.3.2 Prescription chart review

This can be either active review of charts in use in clinical areas or retrospective review after discharge. The review can either be of charts from a particular clinical area or those containing a particular drug. The quantity of pharmacists’ ‘green pen’
annotations is an indicator of how much work has been put into bringing prescriptions up to acceptable standard.

1.3.3 Self-reporting
Prescribers report errors they have made to be logged on an anonymised database.

1.3.4 Detection by other prescribers
Prescribers report errors made by their colleagues that they have corrected.

1.3.5 Observation of practice
Trained observers record errors in the drug usage process seen in practice. This can be overt or covert.

1.3.6 Trigger signals
Scanning prescriptions for trigger drugs (e.g. antihistamines or naloxone) may signal otherwise unreported errors; or scanning biochemical and haematology laboratory reports for significant trend changes in biochemistry that might indicate the emergence of abnormalities due to an ADR.

1.3.7 Interviewing prescribers
Medical students or junior doctors may be interviewed about attitudes to prescribing errors. Alternatively they may be interviewed about general prescribing errors they have made. Those who have recently been found making errors could be interviewed about specific errors they have made.
1.3.8 **Electronic prescriptions that are cancelled within two hours**

Some electronic prescribing systems can detect prescriptions that have been changed soon after they were initiated, as a signal of likely error. One study using this method\textsuperscript{35} identified that the main reasons orders were discontinued were drug-disease reconsiderations, drug-drug interactions, and patient preferences. Physicians frequently reported they caught their own mistakes. Most of the changes, not surprisingly, were drug and dosage changes.

1.3.9 **Combination methods**

Combining errors made from notes with interviews of those making entries or interviewing prescribers after pharmacist interventions have been made, could reveal causative factors. Combinations may increase the range of errors detected, or depth of detail.

1.3.10 **Failure Modes, Effect and Criticality Analysis (FMECA)**

FMECA is a process of speculating on possible errors, then designing processes to prevent them from occurring. This has been used to reduce errors in IV potassium administration in paediatric intensive care.\textsuperscript{36} A request form was produced that forced the collection and recording of specific data before processing by pharmacy could proceed. This presented the doctor with relevant data so they should have been able to evaluate hazards before prescribing. Nurses could not order without this prescription and form. This procedural intervention reduced the number of patients receiving potassium with creatinine>2mg/dL from 28% to 14% and the number given high strength potassium infusions decreased from 3% to zero.

FMECA is prospective, whereas the traditional method of root cause analysis works backwards from an event to look for causes. FMECA describes the process in detail, examines possibilities of how and where things could go wrong (failure modes) and estimates the frequencies and consequences of a whole range of possible outcomes.\textsuperscript{28}
FMECA is a well described tool that identifies possible failure modes and gauges what their effect will be, even before they take place. It allows both quantitative and qualitative evaluation of the criticality of each failure mode. Criticality indices may be calculated by multiplying three components: likelihood of occurrence, severity and detection—on the basis of known or estimated data. FMECA compares the top critical events in different process organisations, allowing a simple measurement of the potential impact of new solutions on patient safety. For example, in the study by White *et al.* who used FMECA in paediatric and neonatal ITU, the likelihood of occurrence (incidence) for each failure mode could be classified from 1 to 10, the severity of the potential effect for the patient from 1 to 9, and the chance of detecting the failure before it affected patient safety from 1 to 9. Estimates were obtained by team consensus for all failure modes, taking into account the local context and workload.

Another FMECA project, calculated yearly costs for achieving a criticality reduction of 1 per day. Thirty-one failure modes were identified with a total criticality index of 4,540. The most critical was microbial contamination of extemporaneously prepared IV preparations; ready to use syringes reduced the criticality score by 1,292 (46,500 per day). Employing a clinical pharmacist reduced the score by 1201 (72,060 per day) and a double-check by nurses reduced the score by 996 (59,780 per day).

The major benefits of using FMECA as a proactive risk analysis method are its simplicity and the quantitative evaluation it allows by combining the three complementary factors. The evaluation can be easily performed by the users and developers themselves, with the help of a moderator, and the time required is limited to a few working lunches for the team and a few hours analysis for the moderator. The analysis identifies the top critical events and quantifies the potential impact of process modifications, even before they have been implemented, which is very helpful for prioritising actions to be taken.

With FMECA, the highest identified criticality failures are having lethal doses available, complex mathematical calculations or setting of infusion pump flow rates, not checking patient identity bands, and having excess stock available. These
<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages and</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Analysing medical records</td>
<td>Detects errors of diagnosis and delays</td>
<td>Only reveals those that are documented, and time consuming. Rarely detects supply and administration errors. Time consuming.</td>
</tr>
<tr>
<td></td>
<td>May detect errors that do not reach the patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May detect medication related admissions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May capture pharmacist’s warnings if they write in the notes.</td>
<td></td>
</tr>
<tr>
<td>2 Prescription chart review</td>
<td>Good detection of corrections made by pharmacist but detection of pharmacist green pen may just be annotations Detects re-admissions and changes made</td>
<td>Will not detect verbal interventions that produce new prescriptions by doctors. Some administration errors detected (delays and omissions)</td>
</tr>
<tr>
<td>3 Self-reporting</td>
<td>May reveal causes of error</td>
<td>The prescriber may be unaware they have made an error so unable to report. Reporting may be inhibited by concerns about perceived status and fears of litigation or performance review. Culture may produce a bias to administration errors</td>
</tr>
<tr>
<td>4 Detection by other prescribers</td>
<td>Practiced prescribers so sharing on ward round leads to team learning</td>
<td>Correction maybe informal changes so not reported.</td>
</tr>
<tr>
<td>5 Observation of practice</td>
<td>Observers must be knowledgeable or trained.</td>
<td>Cannot detect errors due to data omission or poor prescribing. Very time-consuming</td>
</tr>
<tr>
<td>6 trigger signals</td>
<td>Good for detected ADEs, shows promise and could be cheap if automated</td>
<td>Will only detect errors associated with triggers.</td>
</tr>
<tr>
<td>7 Interviewing prescribers</td>
<td>Good for detecting explanation of why prescribing events occur but Relies on honesty and ability to recall.</td>
<td>Really needs some prompts. Nor good for prevalence data. Participation might be difficult without authority champion</td>
</tr>
<tr>
<td>8 Electronic prescriptions that are cancelled within two hours</td>
<td>Rapid, constant method for detecting and teaching errors.</td>
<td>Shows promise if system is capable</td>
</tr>
<tr>
<td>9 Combination methods</td>
<td>Comprehensive capture of positive finding but still systemic bias of under-reporting.</td>
<td>More expensive</td>
</tr>
<tr>
<td>10 FMECA</td>
<td>Intensive process review good for predicting errors and building defences, requires expertise and enthusiasm</td>
<td>Experience needed for prediction. Barriers may not be easy to create</td>
</tr>
<tr>
<td>11 Pharmacist interventions</td>
<td>Periodic study can capture nearly all prescribing errors Poor at capturing administration errors. Continuous data capture is time consuming</td>
<td>Not good for administration errors</td>
</tr>
</tbody>
</table>
were addressed by minimisation strategies such as having a standard infusion handbook with rate charts and protocols for the administration of specific drugs.\textsuperscript{39}

The major limitation of FMECA is unavoidable subjectivity in the selection of failure modes and the determination of the criticality indices.\textsuperscript{37,40}

### 1.3.11 Pharmacist interventions

Pharmacists review drug charts in use in the clinical areas. They add additional information (annotations) to charts to increase clarity of the prescriber’s intentions. These annotations may assist nurses administering unusual medicines. The pharmacist may discuss the item with prescribers to either prompt completion (e.g. signature) or question choice of drug or details such as dose. These discussions intervene in patient care. Interventions provide information, education or advice. In the absence of a prescriber these interventions may be recorded in the notes. However it is more usual for them to be verbal messages to nurses, or added to a doctor’s job list. If these interventions are recorded, subsequent analysis may reveal useful patterns of data deficiency, types of prescribing errors or as an educational tool for pharmacists and junior doctors.

Summarising, each of the methods of error detection described above and in Table 1.4 has its own advantages and disadvantages. Using a single method constantly will show fatigue; so either periodic study, as in the present research, or rotation of method might maintain rigour. Many medication errors are not recognised nor detected as the data is hidden in different sources. Some errors can only detected by integrating the data, either electronically or by someone like a pharmacist. Many systems might be biased due to the nature of the primary investigator or the subject investigated. Some of these features are discussed below.

### 1.3.12 Voluntary adverse event reporting

Nurses have a culture of reporting errors and are more numerous that other healthcare professionals. So these schemes have a bias towards administration errors. Doctors have a culture of not reporting, so voluntary reporting schemes have almost no
participation. In contrast in Chapter Five the author will show that pharmacist intervention reports show a significant bias towards prescribing errors.

Successful error-reporting systems are non-punitive, confidential, independent, timely, responsive, and system oriented and are based on expert analysis. One example of a successful reporting system is Medmarx, established in 1998 by the United States Pharmacopeia (USP). Medmarx is an internet-accessible, voluntary medication error-reporting program available to institutions by subscription.41

This database was used to analyse patient-controlled analgesia (PCA) related errors and found that whilst errors were reported across all phases of the medication-use process, the majority occurred during drug administration. Prescribers often issued incomplete, duplicated, or contradictory orders. This suggests that prescribers only make ‘silly human errors’ that would be eliminated by a good electronic prescribing system. Pharmacists are aware that prescribing errors are not limited to the technical aspects of prescribing. Over one third of errors (38%) involved an improper dosage or quantity, 17.4% involved an omission and 17.3% an unauthorized or wrong drug. Overwhelmingly, human factors were the main cause of PCA errors. Distractions (37.8%) and inexperienced staff (26.3%) were leading contributing factors. Administration errors involved the wrong drug, amount, or concentration, often because the PCA device was mis-programmed. Clearly, training staff how to use PCA equipment was important, and the potent drugs used were high on the ‘risky drugs’ list. Similar drug names and product packaging (11.6%) were also implicated. This study gives a useful list of likely causes of medication errors generally.

The Vermont Oxford Network covered 54 hospitals and used a voluntary reporting system for all types of errors in the NICU.19 In 1989 it started a four-year, prospective study to identify medication errors in the paediatric intensive care unit and NICU; 315 errors were reported for the 2,147 neonatal and paediatric intensive care patients (representing 23,307 patient days). Almost half (47%) of the medication errors reported were either the wrong medication, wrong dose or schedule or infusion rate. The study also found that infants who required more intensive levels of care were at greater risk for medication error. In 2001 this network reported that 5.5% of
administered NICU medications had an identified error, and potential adverse drug events occurred eight times more frequently in the NICU than in adult populations.

In the UK, the National Patient Safety Agency (NPSA) collects and analyses incidents reported through a voluntary scheme. Adverse events are defined as any ‘unintended or unexpected incident, which could have, or did, lead to harm for one or more Patients receiving NHS funded healthcare’. The function of the NPSA, particularly with regards to rating the severity of the reports it receives, is discussed in later chapters.

In general, voluntary reporting systems have major defects. They may under-report incidents owing to lack of feedback, time constraints, fear of shame, blame, litigation or professional censure and unsatisfactory processes. In particular, nurses may fail to recognise errors of administration or forget to report, be reluctant to report or not report errors that they feel to be innocuous. In the latter study, a review of incident reports over 7 months from intensive care or high dependency units showed errors to be linked to drug administration in 61% of cases and prescribing in a further 26%.

A recent study attempted to augment a voluntary reporting scheme, with targeted and non-targeted chart review and direct observation on the ICU by adding a code for ADEs (the E-code) on the computerised discharge system. This was then analysed to compare how often the discharge E-code correlated with ITU observations. Reviewing discharge summaries indicated a detection rate of approximately 20% (48 of 245) for adverse medical events; of these, 54% were ADEs. Further study may be needed using an ICU discharge note or the transfer note from the ICU to the ward to identify more ADEs.

In another study, nurses and office staff were asked to report all communications with community pharmacists regarding prescription problems over a period of six months from seven primary care offices in Vermont, USA. Analysis of this voluntary prescribing-error-reporting system yielded 216 reports. Nearly 90% (142/165) of errors were severity Category B (errors that did not reach the patient) according to the National Coordinating Council for Medication Error Reporting and Prevention Index
for Categorizing Medication Errors. Nineteen errors reached the patient without causing harm (Category C); and 4 errors caused temporary harm requiring intervention (Category E). Errors involving drug strength were found in 30% of reports, including 23 prescriptions written for strengths not commercially available.

Ashcroft and Cooke\textsuperscript{49} undertook a retrospective analysis of medication-related incidents reported to an on-line incident-reporting scheme in a large (1000-bed) teaching hospital in the UK. Over a 26-month period, there were 495 medication-related incidents reported, of which 38.6% were classified to be a “near miss”. Medication related incidents were reported most often at the stages of administration (230, 46.5%) and prescribing (192, 38.8%). Pharmacists produced 51.9% of reports, and doctors produced 9.1%. Pharmacists reported the majority (155, 80.7%) of prescribing incidents.

Tenfold errors in calculation of paediatric drug doses are more plausible than in adults because of the wide range of sizes, weights and age in this population. A Canadian study in 2006 \textsuperscript{50} examined paediatric tenfold errors using various detection methods. Errors were reported during a voluntary reporting period. Almost all errors were prescribing errors. The calculated incidence was 1 per 22,500 doses prescribed. Two tenfold errors where found in 1678 orders in a chart auditing study of 1532 patients in the Emergency Department. Four tenfold errors were identified in eight mock resuscitations (125 orders for drugs). The study indicated that the incidence of tenfold errors in paediatrics varied dramatically when different detection approaches were used. The rate of tenfold errors may be especially high in resuscitation situations and is underestimated by spontaneous reporting.

\textbf{1.3.13 Observational studies}

There are both covert and overt sorts of observational studies. Covert observation is difficult because it has to be disguised observation such that ward staff are unaware of true purpose of study. The cover may be the suggestion of a different audit such as one concerned with drug distribution. Overt studies are more acceptable to staff and can be useful as a learning tool.
In one study, two pharmacists observed consecutive drug rounds by nurses on two wards and recorded all medicine related administration errors; the pharmacist only intervened if serious errors were observed. There was no change in error rate with repeat observation. There was no difference in error rate before and after the first pharmacist intervention. Also, there was no detectable effect of overt observation on rates of error. The authors concluded that observational error rates should not be affected by lack of knowledge errors, but overt observation might affect those from carelessness or lack of concentration.

A team of reporters actively captured errors for 3 months in a tertiary care hospital in the USA. They generated 321 medication error reports. Eighty-one were disregarded because they were either unpreventable ADRs or risks justified by treatment benefits. Two-hundred and forty were analysed and 95 clinically manifested error. There were 94 near misses (not manifested or averted) and 51 were averted before they could cause patient harm. Of the manifested errors, 24% were uncontrolled infections associated with under dosing of anti-infectives, 4% were overdoses with anti-infectives, 4% represented CNS drug toxicity from overdose, and 4% uncontrolled pain due to under dosing. Almost three quarters of errors (72%) were from prescribing; of these, 39% were due to lack of drug knowledge and 18% because of failure to consider critical patient information. Dispensing and administration errors were largely associated with accidental slips or lapses reflecting poor performance. The authors cited the advantages of overt observation as mainly allowing in-depth analysis of the nature of errors and their causes and, consistent with others, that it produced more, reliable data than voluntary reporting which was associated with unreliable error frequency data.

### 1.3.14 Significant event audit

Significant event audit (SEA) is a process in which individual episodes are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care and to indicate changes that might lead to improvements. This is mentioned for completeness here. The method appears to work best when team relationships are well established, but could be implemented in new teams to help members understand each others’ roles.
1.4 **The medicines use process**

Medication errors can occur at any stage of the medicines use process (MUP), an overview of which is provided here. Pharmacists hold key knowledge about drugs and the details of the MUP. The basis of this thesis is to explore errors that arise in this process.

1.4.1 **Overview of MUP**

The MUP covers the stages of prescribing, dispensing, administering and monitoring the effects of the medicine; this is illustrated in Figure 1.6.

**Figure 1.6 The medicines use process (MUP)**

In hospital it is possible to go directly from prescribing to administration by using the drugs stored routinely on the wards. Also drug preparation may be part of the supply or administration process. This is because pharmacy may supply reconstituted, ready-to-use products or they may require reconstitution or dilution on the ward. Monitoring should occur throughout the process, but some staff may only perceive that it occurs before prescriptions are written. The review stage is important to ensure that prescribing objectives have been achieved and side-effects minimised. Review also confirms or modifies the diagnosis.
The ultimate objective of the MUP is that each prescription item is reviewed and supplied by the pharmacist so that the nurse can administer each medicine in the correct dose, formulation and frequency, via the correct route by the correct method at the right time to the right patient. Most preventable errors occur during the prescribing stage of the MUP. During the prescribing process, thoughts are transformed into decisions, by which a series of actions are triggered, ultimately resulting in patients receiving their medication.\textsuperscript{54}

In principle this is a simple linear process, and is perceived as such by the healthcare professionals involved. However there are multiple hidden feedback loops, external influences and complex communications involved.\textsuperscript{4} This is especially problematic where the first hospital prescription is illegible, incomplete or unwittingly ambiguous. The prescriber may not be aware that the drug is available in multiple formulations (e.g. nifedipine) or that different formulations have different doses and frequencies (e.g. diclofenac 50mg TDS and 75mg SR BD). This is fundamental to why so many errors occur.

The prescribing process includes assessing the need for a medicine, the choice of a medicine, and the technical aspects of writing a prescription. The dispensing process includes receiving the prescription, checking for legality and clarity, assessing safety and appropriateness, the technical supply function and delivery to the patient or carer.

Administration covers identifying those medicines that are needed, initiating supply on request (if appropriate) and selecting the prescribed medicine. It also includes preparing for administration, the technicalities of administering a medicine and relevant record keeping.

Monitoring covers patient consent and compliance as well as appropriate tests before and after administration to assess the patient’s response and safety.

\subsection{1.4.2 Supply errors}

There is a large literature on dispensing errors but this is not the focus of this thesis.
Dispensing errors may be caused by selecting the wrong patient on a list, working from a label rather than the prescription, workload pressures, interruptions, prescription tracking, phone calls. Automated dispensing machines linked to barcode scanning increase effectiveness and efficiency of the process for unit dose systems, but only a few studies show improvement of medication safety upon implementation of automation; most are inconclusive.

1.4.3 Errors in medicine preparation

If the pharmacy provides a solid dose form there is no preparation stage, unless the patient has difficulty swallowing in which case the nurse may crush the tablet. In this case the pharmacy could eliminate this preparation stage, but only if they knew a liquid was required. Crushing a slow release tablet or one designed not to be crushed could have adverse effects. Thus the pharmacy might supply a product that is suitable for the route of administration prescribed but this may be unsuitable for the way in which the nurse is going to administer the product. Errors may be caused because preparation is seen as part of the administration process. It may be that redesign would incorporate preparation into the supply process to reduce error generation. Thus pharmacy would supply ready-to-use products.

This is an important concept for injectables, especially with intravenously administered drugs, because of serious consequences. Intravenous drugs can be given as a bolus (over 2-5 minutes), a short infusion (30-120 minutes) an intermittent infusion (run over four hours, three times a day) or as a continuous infusion. Steps to ensure the correct administration of bolus doses and to reduce mistakes in making up drugs that require multiple step preparation will have the greatest effect on error rates.

Several institutions have implemented decentralised pharmacy intravenous admixture units to decrease both microbiological contamination and medication errors of preparation. Error rates have been reported as 71% poor technique by nurses on wards, compared with 2% by skilled pharmacy technicians. A 4-year study of aseptic preparation in pharmacy showed that just 0.49% of doses were in error.
Preparation on wards was associated with a higher error rate. The highest risks were observed with cytotoxics. These were associated with 40% of errors. Other injectables were associated with 27% of errors. Labelling errors occurred most frequently (34.2%), then transcription errors (11.1%) and then incorrect expiry (7.5%). These staff were focussed on preparation, yet mistakes were still made.

It is not clear if cytotoxic preparation is more complex and therefore prone to error, or if the consequences are more obvious, so minor faults are manifested in patients. It is unclear if the consequences of giving these toxic agents are a true effect of the drug or a fault in its preparation.

A recent review of parenteral product preparation across secondary care acute trusts in the north of England showed that whilst parenteral nutrition and cytotoxics were almost all prepared in pharmacy parenteral preparation units, there were still 53 strong potassium solutions, 40 different epidural and 20 different intrathecal preparations processed.

Clinical pharmacy should confirm the need for such a diverse range of preparations and assess the potential for minimising risk by standardising practice where possible. Generally it would appear the preparation of intravenous products is safer when this forms part of the pharmacy supply process. However this may produce further unintended consequences in terms of product labelling.

1.4.4 Errors in product identification

Physically selecting a product on a shelf for administration requires differentiation of products from the same company or of similar name or from a range of strengths. Similarly coloured company logos and formats have been implicated in incorrect product selection. Ward stock is designed to limit the choice of medicines in a particular area or speciality. This also helps doctors choose from a smaller range but particularly assists nurses in selecting the right product to administer. Confusion can also arise with brand names and pharmacists are encouraged to endorse all drug names with the generic or British Approved Name (BAN). International Non-proprietary names (INNs) can contribute to errors when BANs have previously been
used; e.g. levothyroxine has been confused with liothyronine and mercaptamine (previously cysteamine) confused with mercaptopurine.  

The NPSA and designers from the Royal College of Art have developed new guidelines for the labelling and packaging of injectable medicines. The guidelines recommend simple changes to design, such as using paper labels and coloured print, to help distinguish similar medicines from each other and prevent mistakes in administering the drugs. Dominant key information should be a generic name that can be read at a glance. A two dimensional bar code includes batch number and expiry date, and a unique product identifier.

1.4.5 Errors in administration

In the community, the patient usually administers the medicine themselves. This involves a complex series of influences including beliefs about healthcare and values placed on lifestyle. This influences consent and concordance and may significantly differ from what the prescriber intended. There may also be a carer who is largely untrained. Again this is not the focus of this thesis.

In hospital, medicines administration is undertaken mainly by nurses and there is a worldwide literature on this. In outline the drug administration process in the UK involves periodic ‘drug rounds’ with the nurse pushing a trolley, containing non injectable medicines, around the ward. Usually one nurse is involved but in some hospitals, there is a second checker who may be a nurse or a healthcare assistant.

For injections, a separate process operates, usually with one nurse preparing the product for administration and a second confirming that the product has been prepared correctly and the correct patient identified. One nurse then administers the medicine, usually alone.

Incompatibilities between IV drugs, when admixed for administration, represent a preventable adverse drug event. Appropriate and timely pharmaceutical advice is mandatory to prevent incompatibilities that could lead to patient harm.
A 6-month UK study over 10 wards identified 249 errors with intravenous drugs with at least one error in 212 cases (49%) out of 430 drug doses. The errors were classified as 1% potentially severe, 29% potentially moderate, 19% potentially minor. Most errors occurred when giving bolus doses or making up drugs that required multiple step preparation.60

Workers in a 2004 study on an 18-bed SITU in the US conducted a daily check on all continuous IV infusions. The infusions were checked for charting, concentration, rate, and dose against the patients’ height and weight (actual, ideal and ‘dry’); 71 patients had 202 infusions and 106 errors were detected per 1000 patient days. Almost all (94%) of non-weight based doses were correct; but more than 10% were incorrect for weight based dosing. Although the difference was not statistically significant, the authors point out the greater potential for calculation errors among the latter.61

Interruptions to the administration process have a negative impact on memory by requiring individuals to switch attention from one task to another. The nurse undertaking the drug round may also be the most senior nurse who has to respond to phone calls and visits by medical staff. Returning to a disrupted task requires completion of the interrupting task and then regaining the context of the original task. In an observational study from Australia, 62 over half (53.1%) of all administrations were interrupted and 74.4% of total drug administrations had at least one procedural failure. Approximately 70% of procedural errors had no interruptions, but of those that were interrupted, 84.6% had up to three interruptions. For each interruption, there was a 12.1% increase in procedural failures and a 12.7% increase in clinical errors. One quarter of administrations had at least 1 clinical error and of these, 25.3% had no interruptions, whilst 38.9% had up to 3 interruptions.

Summarising, interruptions in the administration process are significant events in terms of error generation. However procedural errors may still occur without any interruptions.

To improve patient focus some wards have been divided into smaller teams (called team nursing) looking after 6-10 patients. One advantage of this is that because the
‘drug round’ takes less time there are fewer interruptions and medicines are likely to be administered at the correct time. However this introduces more multitasking and if it does not increase the nurse: patient ratio there be more mental leaping to different tasks. In the USA they have experimented with small-ream team nursing and have now returned to the ‘single task at one time model’ where a nurse is allocated to give all medicines on that floor rather than participate in a team nursing; this has been reported to have had a favourable effect: it kept interruptions at bay and that nurse knew her medicines and the patients better.63

1.5 Prescribing

Prescribing errors represent a key target for clinical pharmacy interventions and a key feature of the author’s research.

1.5.1 Prescribing errors

Dean et al. used a Delphi technique to reach a practitioner-derived consensus on a definition of ‘prescribing error’. The definition finally adopted was:

‘A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice’.64

The prescribing stage of the medicines use process is linked to the diagnosis. It is generally perceived that a precise diagnosis is formed followed by evidence based treatment options. Whilst this does happen, there a more common presumptive diagnoses followed by preliminary treatment. If this treatment is successful, it confirms that the presumptive diagnosis was correct. If the initial treatment does not improve symptoms; then the presumptive diagnosis may be incorrect.28 Thus planning errors in prescribing may sometimes be an inevitable consequence of this second routine to the final diagnosis.

Prescribing has two phases: a decision making stage; the second is the technical process of writing the prescription. The decision making phase focuses on whether to
treat, by what modality and includes choosing a therapeutic group. The technical phase of writing the prescription ensures clarity, precision, legality and completeness. Most error studies focus on the technical phase, but the decision making phase may produce more significant, but subtle errors.65

It should be noted however, that failures to adhere to standards such as hospital or national guidelines, or the drug’s product licence, are not usually classified as prescribing errors.64 This latter clause relates to the perception that these rules break with clinical freedom and are part of managing medicines use. However it can be argued that these rules are intended to improve safety of the medicines use process. Formularies were originally invented to decrease the quantity of knowledge that a junior doctor had to learn, thus decreasing errors of recollection. Non-formulary prescribing may produce latent errors that ultimately harm patients.

1.5.2 Prescribing - Decision phase

The first stage of prescribing is that of drug choice. It is presumed that the evidence base of various medicines is first considered and combined with clinical experience. However it is likely that pharmaceutical industry marketing, paper authorship and sponsorship contribute to the decision.28 Logically, the therapeutic group should be selected before an optimal individual agent, but in many cases selection is made from a smaller list of ‘favourite’ agents.

Decisions then have to be made about route of administration, dose and frequency. In hospital, details such as strength and dilution of common medicines might be left to the nursing staff.

1.5.3 Prescribing – technical phase

The technical writing phase can be further divided into drug factors and patient factors. Drug factors are those relating to choice of drug, route, dose, and frequency. Patient factors relate to bodyweight, allergies, interaction with other medicines consumed, liver and renal dysfunction and concurrent disease. The last two factors may form part of a feedback loop into the decision phase.
Traditionally, prescriber training has been physician led but today, it has become increasingly complex. In many countries, the support of the clinical pharmacist at the point of prescribing is increasingly crucial to safe prescribing. \(^{28}\)

A university-affiliated acute general hospital in Hong Kong conducted a study into the time, nature, source and severity of medication errors. \(^{36}\) The authors reviewed all medication incident reports collected during January 2004–December 2006. The most common type of error was wrong strength or dosage (36.5%), followed by wrong drug (16.7%), wrong frequency (7.7%), and wrong formulation (7.0%). Most errors (80.2%) were detected before any drug was wrongly administered. The medications were administered in 212 cases (19.7%), which resulted in an untoward effect in just nine cases (0.8%). These results suggest that whilst errors may be relatively common, only a small proportion reach the patient and few of these cause ostensible harm.

Inpatient medication charts in a regional general hospital in New Zealand were audited annually from 1998 to 2007. \(^{66}\) Charts were assessed against predetermined standards for good-quality prescribing. Initially an unacceptable proportion of medication charts failed to document adequately one or more of the following: prescriber identification (58%), legible prescriptions (14%), route of administration (14%), a dose (11%), date (11%) or adequate patient identification (8%). Only 53% of charts had any information about medication alerts and 15% contained at least one verbal order. Interventions designed to address these deficiencies included educational strategies: e.g. feedback of audit results, education sessions for doctors and nurses on prescribing and medication errors and changes to systems: e.g. modifications to medication charts, development of hospital wide prescribing standards and an alert notification system. Serial audits showed progressive improvements in all items by 2007 including: legibility (97%), patient identification (100%), documentation of date (98%), drug dose (99%) and route (97%), use of medication alerts (98%) and the prevalence of verbal orders (<1%). Identification of prescribers remained suboptimal (81% in 2006 versus 53% in 2007). While the study only considered technical prescribing errors and there was no consideration of the clinical appropriateness of prescribing, it did demonstrate the benefits of education.
and awareness campaigns. However it is continual vigilance and assessment that compounds the benefits over time. As junior doctors rotate their placements every six months in the UK, this teaching must be repeated on a regular basis.

1.5.4 Types of prescribing error

Table 1.5 summarises the different knowledge deficiencies that causes errors. These are sorted into lack of knowledge about the patient, or the drug, or the technical aspects of prescribing.

Table 1.5 Knowledge deficiencies that cause prescribing errors (compiled from references 4, 6, 15, 16, 67, 68 & 69)

<table>
<thead>
<tr>
<th>Lack of knowledge</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The patient</strong></td>
<td></td>
</tr>
<tr>
<td>Allergy status</td>
<td></td>
</tr>
<tr>
<td>Changing renal function</td>
<td></td>
</tr>
<tr>
<td>Changing liver function</td>
<td></td>
</tr>
<tr>
<td><strong>The drug</strong></td>
<td></td>
</tr>
<tr>
<td>Name – look-a-like and sound-a-like abbreviations e.g. AZT, MTX</td>
<td></td>
</tr>
<tr>
<td>Details – dose, route, frequency</td>
<td></td>
</tr>
<tr>
<td>High risk drugs*</td>
<td></td>
</tr>
<tr>
<td><strong>The technical process</strong></td>
<td></td>
</tr>
<tr>
<td>Dose calculation</td>
<td></td>
</tr>
<tr>
<td>Decimal point – zeros before and after</td>
<td></td>
</tr>
<tr>
<td>Lack of standardisation</td>
<td></td>
</tr>
<tr>
<td>Data availability at point of prescribing technical and policy</td>
<td></td>
</tr>
<tr>
<td>Transcription errors (including cross out old chart and drugs)</td>
<td></td>
</tr>
<tr>
<td>Drugs that have been given before</td>
<td></td>
</tr>
<tr>
<td>Similar labelling and packaging</td>
<td></td>
</tr>
<tr>
<td>Multiple strengths of product</td>
<td></td>
</tr>
<tr>
<td>Complex protocols</td>
<td></td>
</tr>
<tr>
<td>Poor checking drug identity</td>
<td></td>
</tr>
<tr>
<td>Rule violation</td>
<td></td>
</tr>
</tbody>
</table>

*High risk drugs are: cytotoxics, opiates, potassium IV, dopamine, digoxin, heparin and insulin.

In 2009, 15 recommendations were made for reducing the risk of medication errors including the provision of sufficient undergraduate learning opportunities to make medical students from the UK safe prescribers and opportunities to practice skills that help to reduce errors. Two of the recommendations were for greater involvement of pharmacists and better systems for monitoring errors.
There have been calls for simple solutions to standardise the system, which can vary from one hospital to another. The possibility of a standardised prescription form is under active consideration across the UK.  

**1.5.5 Off-label and unlicensed prescribing**

Licensed medicines may be used for off label indications, doses and routes. However this may lack rigorous scientific scrutiny and introduces concerns about patient safety. The frequency of off-label drug use is largely unknown but estimates of 160 commonly used drugs have been made from a survey in 2001.

**1.5.6 Reducing Prescribing errors**

In 2007, The General Medical Council (GMC) and the Medical Schools Council established a Safe Prescribing Group that described competencies for junior doctors. The eight capabilities required to prescribe safely are listed in Table 1.6

<table>
<thead>
<tr>
<th>Competencies for junior doctors in prescribing</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ability to establish an accurate drug history</td>
</tr>
<tr>
<td>The ability to plan appropriate therapy for common indications</td>
</tr>
<tr>
<td>The ability to write a safe and legal prescription</td>
</tr>
<tr>
<td>The ability to appraise critically the prescribing of others</td>
</tr>
<tr>
<td>The ability to calculate appropriate doses</td>
</tr>
<tr>
<td>The ability to provide patients with appropriate information about their medicines</td>
</tr>
<tr>
<td>The ability to access information about medicines</td>
</tr>
<tr>
<td>The ability to detect and report adverse drug reactions</td>
</tr>
</tbody>
</table>

This requirement was to ensure that medical schools had clear objectives for training. The GMC commissioned research investigating the prevalence and causes of prescribing errors made by junior doctors. The EQUIP research was conducted by the University of Manchester and the report is discussed further in Chapter 5.

There is evidence that risks can be reduced by having a pharmacist present when decisions about therapy are made on doctors’ ward rounds. In Intensive Care, having a pharmacist present was reported to reduced ADEs by two thirds. A controlled study in 2003 set out to see if the same effect could be seen in general medicine wards. There were 165 patients in the study; overall pharmacists made 150 interventions and these were accepted by doctors on 147 occasions. The most
common were amendments to dosage, then addition of medicines to the discharge prescription. Looking at the preventable ADEs, the control group had 26.5 preventable ADEs per 1000 patient days and the active group had just 5.7 per 1000 patient days. This is a 78% reduction in errors; in addition there was a cost reduction.

A study in a Canadian paediatric A&E department\textsuperscript{75} looked at the impact of a tutorial on prescribing errors for doctors as part of their induction into this rotational post. A large proportion (40\%) of trainees committed a calculation error in a written pre-tutorial test. The study included a chart review over 18 days. Thirteen trainees prescribed 899 items and made 66 errors (12\%). This was the same for those who attended the tutorial and those who did not. So the answer is not as simple as raising awareness about prescribing errors. The same study showed that senior doctors committed fewer errors than juniors and junior doctors made fewer errors at the end of their rotation compared with at the start. So there was something about learning from experience. It was not clear if this was safer technique learned from mistakes or a human performance factor from lots of prescribing experience. The authors concluded that including pharmacists as part of healthcare teams was another effective intervention to reduce errors. Pharmacists detected errors that were not easily identifiable by physicians such as drug interactions, wrong diluents and incorrect infusion rates.

1.6 Impact of technology on error avoiding strategies

Having accepted the fact that medicine related errors can never be eliminated entirely, various strategies have been adopted to try and minimise them. This section describes some of them that have exploited technological advances with this objective in mind.

1.6.1 Electronic transfer of prescriptions

A Swedish study showed some interesting aspects of technology introduction. Firstly because complete data capture was possible in Sweden, a national study showed that 14\% of prescriptions were never presented to a pharmacy.\textsuperscript{76} So presumably products were prescribed that the patient decided were unimportant or not the reason they went to the doctor. The prescription refill rate was 57\%, but with a large variation with
drug class; for example, 87% with oral contraceptives, but just 20% with dementia drugs. This indicated that there was some disparity between what the doctor thought the patient needed and what they actually used and that this technology could detect such differences with ease.

Another study examined the collection of prescriptions by patients before and after the introduction of an electronic prescription transfer scheme. In total, 2,148 electronic-prescriptions and 414 paper prescriptions were analysed. Fifteen percent of paper prescriptions were not collected within 5 days but the figure was only 10% for electronically transferred prescriptions. It is not clear of the reasons for this, but patient beliefs about medication have a key influence on these early stages of the medicines use process.

Other technology solutions have been proposed and are under study. The most attractive approach might be a portable computer with wireless network and electronic prescribing to avoid handwritten prescriptions being misread.

1.6.2 Bar Coding

Point of care scanning of the drug product can display drug allergy alerts and administration instructions. The patient can also be scanned to confirm their identity and warn of problems. The FDA put into operation its plan that by 2007, all new human drug products and biological products would be bar-coded. This technology has been used for blood products, blood prescriptions and patients with success. However uptake has been poor due to the costs associated with this closed loop system. Other studies have shown mixed results for bar coding in terms of medication errors. One study has shown that barcode ordering of stock reduces transcription errors by nurses. However another study suggested that bar codes may increase errors, because the system works imperfectly and/or staff find workarounds. If the system is perceived to be inefficient, it is human nature to attempt to find ways of cutting corners, without realising that this may introduce risks that the system was designed to prevent. Nurses overrode the technology for 4.2% of patients charted and for 10.3% of medicines charted.
1.6.3 Unit specific formularies

Having electronic access to formularies that are specific to certain clinical groups (e.g. neonates) has been recommended to control errors.\textsuperscript{80} These formularies are controlled by pharmacists who enter drug files with specific dose calculations for the patient group. The improved access to information reduced errors and facilitated simplification and standardisation of practice.\textsuperscript{80}

1.7 Electronic prescribing

The next two sections discuss the literature on two important technologies that are collectively called electronic prescribing or e-prescribing. The first technology is computerised physician order entry (CPOE) and the second is clinical decision support (CDS). CPOE in its most basic form enables typing of prescriptions in such a way as to resolve technical prescribing errors. CDS provides access to protocols, policies and guidelines and other information to guide, or facilitate, the prescriber into making correct prescribing decisions so that clinical/planning errors are avoided. Literature on this subject is confusing in that the term CPOE can be used to encompass some very sophisticated features that are really CDS. Some papers discuss CDS as if it was just basic dose checking, whilst others use the term to include completely integrated clinical information systems.

1.7.1 Computerised physician order entry (CPOE)

A literature search on medication errors and adverse events produces many papers on CPOE. This is often presented as a huge step forward in error management; however one must be aware of publication bias and the promotional efforts of producers of systems selling very expensive solutions to this problem. Some sales pitches would have you believe that errors will never occur again. It is also important to assess how much installing a system compromises current care and how much an installed debugged system will decrease efficiency of future care.\textsuperscript{81}

The major reason to evaluate e-prescribing systems is to determine how their use improves or impairs clinical and process-related outcomes. According to Rosenbloom \textsuperscript{82}, there are documented risks involved in integrating such clinical systems into
healthcare processes. These risks generally fall into two categories. First, new technologies may not accomplish what they are designed to do. Second, introduction of new technologies may lead to unintended consequences such as patient harm or misused resources.

CPOE in its simplest form is an electronic application for writing orders that reliably produces legible, unambiguous prescriptions using standard names and eliminates poor handwriting and spelling. However it can be linked to the supply function using electronic communication so decreasing transcription errors. Most importantly, CPOE can incorporate various levels of clinical decision support at the point of ordering and can be integrated with pharmacy stock control and ordering systems.

CPOE also improves standardisation of the times that medicines are administered across all wards and can ensure that administration occurs at scheduled times without significant delays.

Electronic systems were first introduced into pharmacy in the 1970s to manage formularies and produce rapid communication with pharmacy. In some countries such as the Netherlands and Australia, pharmacy has considerable say over formularies via the technology; whereas in Germany and France, pharmacy is excluded. Poor connectivity with pharmacy may produce fewer inconsequential errors but more errors of a serious nature.

In 2002 only about 10% of US hospitals had fully adopted CPOE. In 2008 the majority of prescriptions in the USA were still handwritten, reflecting poor uptake of the technology in the intervening years. However, one UK study at Doncaster Royal Infirmary showed a reduction in transcription errors, moving from 37 to 96% transcription accuracy after installing an electronic prescribing system; in addition the quality of administration records improved from 65 to 100%.

The perception of users is crucial to the smooth introduction of CPOE. Difficulties can be created where insufficient training is provided.
One of the key benefits of CPOE may be to initially slow down prescribing by requiring extra data to be recorded (such as justified choices) and demand complete prescriptions. 90

A study of verbal orders (VOs) at a tertiary care children’s hospital, showed that the introduction of CPOE forced the reduction of VOs and unsigned VOs from 23% and 43% respectively to 10% and 9% respectively. 91 So CPOE may only be changing bad practice into better practice by enforcing a new requirement on doctors to follow hospital policy.

### 1.7.2 Adverse consequences of CPOE

CPOE systems can help hospitals improve health care quality, but they can also introduce new problems. They may create new work or extra work, disrupt workflow and make demands that practitioners find distressing. Forcing prescribers to enter all required data may promote safe care, but the additional alerts and passwords may be emotional challenging and take more time. Additional work may be created to support this crucial technology and paper output may actually increase. Entry into a computer may create the illusion of communication, whilst not producing certainty that the message has been received. 92

CPOE can generate new kinds of errors such as juxtaposition errors, in which clinicians click on the adjacent patient name or medication from a list and inadvertently enter the wrong order. 90,92

Human adaptability creates ‘workarounds’ where if prescribers cannot readily find the “correct” place to enter the data, they put it where it might fit. It is intuitive to the prescriber but the computer cannot find or process the information; or they enter ‘free text’ so all the advantages or correct spelling disappear. CPOE only manages error risk if prescribers use it, know how to use it and find it easy to use. Complex prescribing may not fit with the programming and causes frustration. 90
1.7.3 Effect of electronic prescribing on medicine administration errors

A UK study was set up to assess the effect of an electronic prescribing and administration system on the safety and quality of medicine administration in a UK hospital.\(^9\) The study was conducted on a surgical ward with electronic prescribing, automated dispensing, barcode patient identification and electronic patient records. The researchers observed medicine administration and monitored for medicines administration errors (MAEs) for ward stock and non-ward stock drugs.

Pre- and post-intervention MAE rates were 6.4 and 2.3% respectively for ward-stock drugs (95% confidence interval for the difference (CI) \(-5.8\) to \(-2.4\)%), and 14.6 and 13.7% for non-ward-stock drugs (CI \(-6.5\) to 4.7%). Excluding omissions due to unavailability, pre- and post-intervention MAE rates were 6.2 and 2.2% respectively for ward-stock drugs (CI \(-5.7\) to \(-2.3\)%), and 9.2 and 3.5% for non-ward-stock drugs (CI \(-9.3\) to \(-2.1\)%). Pre-intervention, 2,086 doses (96.3%) were documented correctly and 1,557 (95.9%) post-intervention (CI \(-1.6\) to 0.8%). There were five clinically significant documentation discrepancies pre-intervention (0.2%), and 33 (2.0%) afterwards (CI 1.1 to 2.5%). Timeliness of administration improved post-intervention \((P < 0.001;\) Chi-square test), as did administration of medication from unlocked areas (CI 4.7 to 7.3%) and supervision of patients taking oral medication (CI 17 to 23%).

Hence it appears that in this clinical setting at least, electronic prescribing can reduce MAEs for ward stock drugs and the need for interventions with both drug types. It can also improve timeliness and security of drug administration. However, there was an increase in potentially significant documentation discrepancies.

1.7.4 Clinical decision support (CDS) and errors

CDS is designed to improve the decision phase of the prescribing process and so reduce medication errors.\(^9\) Installing these complex systems requires patience and politics. Patients may be put at risk whilst links are established.

CDS can provide either basic (e.g. drug-allergy checking, dose guidance and formulary compliance, drug duplication and interaction checking) or advanced (e.g.
drug dosing support for renal insufficiency, laboratory tests required for certain medicines, drug-pregnancy risks, drug-disease alerts) guidance to the prescriber. There is a tendency for developers of CDS systems to provide excess alerts that are either overridden or make finely balanced decisions more difficult. Designing explicit guidelines should decrease the time to develop automation of medical knowledge. However reports in 2006 showed that successful integration had not happened.

CDS might provide support for dose calculations and dilutions and this would be important in neonates and paediatrics where these errors are the most common. Dose banding based on age and/or weight is common but doses have to be checked in specialist books such as the BNF for Children.

A 2008 systematic review looked for evidence that CPOE and CDS combined prevented ADEs. The review found 543 citations but only identified 10 studies that met inclusion criteria. CPOE with CDS contributed to a statistically significant decrease in ADEs in 5 (50.0%) of the 10 studies. Four studies (40.0%) reported a non-statistically significant reduction in ADE rates, and 1 study (10.0%) demonstrated no change in ADE rates.

One example of an area where CDS has been used successfully is in patients with renal dysfunction.

1.7.4.1 CDS in patients with renal dysfunction

CDS offers the potential to improve the selection of a dose for a patient with renal dysfunction - an area of concern for junior doctors. A CDS system in the US generated alerts for inappropriate prescriptions based on the renal function of inpatients. The rate of inappropriate first prescriptions did not differ significantly between intervention and control periods (19.9% vs. 21.3 %). The alerts did reduced these ‘errors’ with junior doctors (odds ratio 0.69), but not with senior doctors (odds ratio 1.88).
Another randomized trial in the US\textsuperscript{100} conducted within the long-stay units of a large long-term care facility, tested the introduction of alerts related to medication prescribing for residents with renal insufficiency. The alerts were displayed to prescribers in the intervention units and hidden but tracked by the investigators in control units. The rates of alerts were nearly equal in the intervention and control units: 2.5 \textit{versus} 2.4 per 1,000 resident days. The proportions of dose alerts for which the final drug orders were appropriate were also similar: relative risk 0.95 (95% CI: 0.83-1.1). For other alert categories, significantly higher proportions of final drug orders were appropriate in the intervention units: relative risk 2.4 for maximum frequency (95% CI: 1.4- 4.4); 2.6 for drugs that should be avoided (95% CI: 1.4- 5.0); and 1.8 for alerts to acquire missing information (95% CI: 1.1- 3.4). Overall, final drug orders were considered appropriate significantly more often in the intervention units-relative risk 1.2 (95% CI: 1.0- 1.4). The authors concluded that clinical decision support for physicians prescribing medications for long-term care residents with renal insufficiency could improve the quality of prescribing decisions.

1.7.4.2 CDS in other areas
The use of CDS in other areas has produced mixed results. A Dutch CDS system for general practitioners issued reminders about decreasing prescribing of antibiotics and asthma/COPD prescriptions. Antibiotic prescribing decreased from 39.7 to 28.2 per 1000 patients per GP; however the difference was not statistically significant.\textsuperscript{101}

Twenty-nine residential care units (containing 1,118 long-term care residents) in the US were randomized to having a CDS (intervention units) or not (control units).\textsuperscript{102} Both intervention and control units had computerised order entry. Within intervention units, 411 adverse drug events occurred over 3,803 resident-months of observation time; 152 (37.0\%) were deemed preventable. Within control units, there were 340 adverse drug events over 3,257 resident-months of observation time; 126 (37.1\%) were characterized as preventable. There were 10.8 adverse drug events per 100 resident-months and 4.0 preventable events per 100 resident-months on intervention units. There were 10.4 adverse drug events per 100 resident-months and 3.9 preventable events per 100 resident-months on control units. Comparing intervention and control units, the adjusted rate ratios were 1.06 (95\% CI: 0.92-1.23) for all
adverse drug events and 1.02 (95% CI: 0.81-1.30) for preventable adverse drug events. The authors concluded that computerized provider order entry with decision support did not reduce the adverse drug event rate or preventable adverse drug event rate in the long-term care setting. Alert burden, limited scope of the alerts, and a need more fully to integrate clinical and laboratory information may have affected efficacy.

Excess alerts generated by CDS systems may lead to alert overload, fatigue and rapid override; on the other hand, simple drug interaction alerts provide inadequate information that can cause annoyance without value. It has proven difficult to replicate the doctor-pharmacist interaction that takes place during a discussion.\(^{81}\)

Guchelar \textit{et al.}\(^{28}\) concluded that it was possible that alerts for drug interactions, duplicate medication, drug overdoses and allergies improved medication safety but no broad scientific evidence for this hypothesis could be found in the literature.

A survey of over 3,000 US hospitals in 2009\(^{103}\) found that only 1.5% had a comprehensive electronic-records system (i.e., present in all clinical units), and an additional 7.6% had a basic system (i.e. present in at least one clinical unit). Computerized provider-order entry for medications had been implemented in only 17% of hospitals. Respondents cited capital requirements and high maintenance costs as the primary barriers to implementation. This study suggests that the evidence from systems so far is not sufficient to make computerized prescribing mandatory.

1.7.4.3 \textbf{The ten Commandments of CDS}

Gross \textit{et al.}\(^{86}\) have proposed ten commandments for making sure that CDS systems are effective. These are shown in Table 1.7.
Table 1.7 Ten commandments for CDS (after Gross et al. 86)

<table>
<thead>
<tr>
<th>No.</th>
<th>Rule</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Speed is everything</td>
<td>this is what information system users value most</td>
</tr>
<tr>
<td>2</td>
<td>Anticipate needs and deliver in real time</td>
<td>deliver information when needed</td>
</tr>
<tr>
<td>3</td>
<td>Fit into the user’s work flow</td>
<td>Integrate suggestions with clinical practice</td>
</tr>
<tr>
<td>4</td>
<td>Little things can make a big difference</td>
<td>improve usability to “do the right thing.”</td>
</tr>
<tr>
<td>5</td>
<td>Recognize that physicians will strongly resist stopping</td>
<td>offer alternatives rather than insist on stopping an action</td>
</tr>
<tr>
<td>6</td>
<td>Changing direction is easier than stopping</td>
<td>changing defaults for dose, route, or frequency of a medication can change behaviour</td>
</tr>
<tr>
<td>7</td>
<td>Simple interventions work best</td>
<td>simplify guidelines by reducing to a single computer screen</td>
</tr>
<tr>
<td>8</td>
<td>Ask for additional information only when you really need it</td>
<td>The more data elements requested, the less likely a guideline will be implemented</td>
</tr>
<tr>
<td>9</td>
<td>Monitor impact, get feedback, and respond</td>
<td>If certain reminders are not followed, readjust or eliminate the reminder</td>
</tr>
<tr>
<td>10</td>
<td>Manage and maintain your knowledge-based systems</td>
<td>both use of information and currency of information should be carefully monitored</td>
</tr>
</tbody>
</table>

1.7.5 Clinical Information systems (CISs)

Clinical information systems should integrate electronic health records with pathology results to save time pulling information together. For example prescribing anticoagulants should be accompanied by relevant results about blood clotting. If data are only keyed in once, this not only saves time but reduces errors.

A review of CIS in the USA in 2007 showed that medication errors were reduced when it was used. Significant reductions were seen in prescribing errors related to drug allergy detection, excessive dosing and, incomplete or unclear orders. Pharmacists were also twice as likely to identify dosages requiring adjustment for renal insufficiency when the integrated technology was in place and more than six times more likely to detect drug levels outside of the therapeutic range. 73 administration-related errors were intercepted through electronic bar-code scanning for every 100,000 doses charted. 94 In this study, pharmacists were authorised to change any product or associated details (e.g. vial size, tablet strength, solution concentration) without requiring a doctor’s co-signature. The primary source of
prevented (i.e., intercepted) error reports was through documentation of pharmacists’ clinical interventions. A statistically significant increase in the rate of pharmacist interventions was observed after implementation of the integrated pharmacy information system, laboratory information system, and CIS with clinical monitoring tools. There was a notable doubling of renal dose adjustment and a six fold increase in orders for therapeutic drug monitoring.

1.8 **Errors in critical care**

The following sections look at just one area of practice of particular interest to the author, where specific studies on medication errors have been undertaken. Many of the types of error encountered here are common to other clinical areas, but the specialised environment often magnifies the importance of the error and compounds its production. The role of the pharmacist in this area is also discussed.

1.8.1 **The critical care environment**

The ICU brings together high-risk patients with multiple co-morbidities who require urgent, complex interventions from a number of different health care professionals in a technologically integrated environment. It has been calculated that a single dose of a single medication in a critically ill patient may require the correct execution of 80–200 steps. The ICU is organisationally complex with tightly coupled processes, high instrumentation, and multiple interactions between different professional groups.

A literature review in 2009 found that, on average, 1.7 medical errors occurred each day in an ICU, and many patients suffered a potentially life-threatening error during their stay. Medication errors were the most common type of error and accounted for 78% of serious medical errors in the ICU.

In intensive care, patients are exposed to twice as many medications as those in general medical wards. In addition, critically ill patients differ from most other hospital patients because they have limited ability to participate in their medical care and lack the physiologic reserve to tolerate additional injury.
A 647-bed US academic medical centre (containing more than 120 ICU beds) conducted a retrospective evaluation of voluntarily reported medication errors over 4.5 years. The study compared reported medication errors in intensive care, and general care units for adult patients. There were a total of 3,252 medication errors reported, with 541 occurring in ICUs and 2,711 occurring in general care units. In the ICUs the primary type of medication errors was prescribing and in the general care units it was omission. Medication errors were associated with harm in 12% of ICU cases and 6% of cases in general care units. Voluntary reporting is likely to be biased towards those healthcare professionals who report. On general wards this may predominantly be nurses where on ITU this may be the pharmacist. On general wards omissions are most frequently reported. On ITU these are still likely occur but prescribing errors are more significant and therefore take priority when reporting.

A UK study showed that 1% of inpatients experience ADEs related to IV fluids and intravenously administered drugs. Infusions of drugs and fluids are still poorly understood in most ward areas. These are crucial management issues on ITU.

An Australian study reviewed all ICU patient case notes for 6 months in 2001 (n = 524) and similarly in 2002 (n = 536). This was before and after the introduction of a real-time microbiology browser and computerized decision support system for isolate directed antibiotic prescription. This tool streamlined collation and clinical use of microbiology results linked to common antibiotic sensitivities and guidelines. There was a significant reduction in the proportion of patients prescribed broad-spectrum antibiotics (carbapenems, cephalosporins and vancomycin) and an increase in the number of switches to narrower spectrum antibiotics, thus decreasing the selection pressure for MRSA and Clostridium difficile. These are two highly significant adverse events, associated with prolonged hospital stay and increased mortality.

Errors in the administration of parenteral drugs to patients in intensive care are common and pose a serious threat to patient safety. In 2007, 113 ITUs in 27 countries, including 17 in the UK, participated in a 24-hour observational study on medication administration errors where a questionnaire was completed for each patient (1,328 in total). One third of patients had at least one medication error with a recorded error rate of 74.5 per 100 patient days. The most frequently reported error
was a time delay before administration, followed by missed medicines and dosing errors.\textsuperscript{107}

In the intensive care setting, patients who are the victims of an error have been shown to have a higher 28-day mortality than those who experience no errors.\textsuperscript{107}

A US study involving five ITUs identified 187 medication errors during 5,744 observations (3.3%). The most frequently reported errors were wrong infusion rate (40.1%), dose omission (14.4%), improper dose (11.7%) and wrong dose timing (13.9%); and the most common drugs involved were cardiovascular drugs and sedatives.\textsuperscript{108}

Medication reconciliation may improve patient safety in the ICU, and an updated list of medications should be maintained, including long-standing medications, the reasons for starting new medications and their planned stop dates and the reasons for discontinuing or holding old medications. Engaging pharmacists in this role has been proposed for some time.\textsuperscript{104}

Errors in ICU can occur at any stage of the patient’s journey through it. A Canadian study reviewed the hospital records of consecutive ICU discharges at one academic and two community hospitals throughout 2002.\textsuperscript{109} Eligible patients were prescribed at least one of six medication groups before hospitalization: statins, antiplatelets/anticoagulants, L-thyroxine, non-prn inhalers, acid-suppressing drugs and allopurinol. A total of 1,402 charts were eligible for the study and 834 had prescriptions for at least one of the medication groups. One third (33%; 251/834) of patients had one or more of their chronic medications unintentionally omitted at hospital discharge.

A study was conducted to compare the ITU discharge medications with the patient’s regular medications and documentation of allergies. Screening the data before hospital discharge would have prevented an average of 10 medication errors per week in a single 14-bed surgical ICU.\textsuperscript{110}
1.8.1.1 Strategies for prevention of errors in critical care

*Keep prescribing simple*

Prescribing should also be kept as simple as possible and prescribers should be given education and feedback, access to drug information and advice from clinical pharmacists. They should work in an environment where the importance of correct prescribing is recognised by senior staff. Increasing complexity is known to increase error rates and the large numbers of incidents associated with gentamicin and vancomycin, which are complicated to prescribe and monitor, suggest this is important in medication practice.\(^{45}\)

*Adoption of CPOE*

One study showed that following the introduction of computerized physician order entry in the ICU, the proportion of prescriptions with errors decreased from 6.7% to 4.8%.\(^{111}\) A comparison of paper-based prescribing and computerized physician order entry showed that the number of prescription errors was significantly lower in the ICU that used computerized entry (3.4% v. 27%, \(p < 0.001\)). The number of reported adverse drug events following electronic prescribing with CDS implementation, decreased from 28 to 4 (\(p < 0.02\)).

*Introducing pharmacists specialising in critical care.*

Several studies have demonstrated the value of having specially trained pharmacists present in the ITU in the reduction in medication errors; either through frequent informal teaching and encouragement in the use of computerised decision support systems\(^{106}\); dealing with patients with multiple risk factors or altered pharmacokinetics\(^{104}\); systematic review of medication orders and reviewing drug costs\(^ {73}\); and participation on ICU ward rounds.\(^ {73}\)

1.9 Temporary secondary care loop

As previously mentioned, medication errors can occur at any stage of the patient’s journey through a healthcare episode. This thesis is concerned with events that occur in hospital – the temporary secondary care loop of the patient journey. The loop
represents a temporary change from the health status of normal life and encompasses the phases of admission, inpatient care and discharge from secondary care, described below. The process is illustrated in Figure 1.7.

Figure 1.7 The temporary secondary care loop.

Medication Errors creep into all stages and phases of this process. Transfer of location or carer is always associated with potential error and good communication is crucial. Admission and discharge to hospital are significant data pinch points, where efficient communication is critical.

Medication Related Admissions (MRAs) may be drug related side-effects, allergy or more indirect events such as a fall related to postural hypotension from an alpha blocker.

1.9.1 Admission

A study in Leeds over 5 months in 2004 looked at 1,006 admissions to general surgical and medical wards. Three hundred and twenty-four patient safety incidents were found in 230 of the 1,006 patients admitted (22.9%); 270/324 (83%) were found by case note review alone, 21(7%) were found by a routine incident reporting system and 33(10%) were found by both methods. Case note review identified 110/1006 (10.9%) of admissions that had at least one patient safety incident resulting in patient
harm. Just 5% of these incidents were also revealed by voluntary reports. Case note review was clearly the most sensitive at detecting these events.

This study shows that a large proportion of admissions were related to patient safety issues and medication related admissions were only a sub-group of this cohort. Nevertheless, they may be involved in related events such as falls. In this study the patient safety incidents fell into three categories:

Group 1 – pressure ulcer, fall, drug problems, operation cancelled, peri-operative complications (excluding infections), patient dissatisfaction or miscellaneous;

Group 2 – unplanned transfer to ITU, unplanned return to operation, inappropriate or self discharge, unplanned readmission; and,

Group 3 – infection.

Medication related hospital admissions are reported as representing between 4 and 30% of all admissions, and up to one third of medication related hospital admissions are reported as due to prescribing errors.

**1.9.2 Inpatient activity**

The effect of an American clinical pharmacist’s interventions was studied in 2005. The patients were from a 651-bed tertiary care teaching hospital and were prescribed highly active antiretroviral therapy (HAART). The pharmacist recorded interventions in the first 6 months of being appointed and reviewed charts over the previous six months for comparison. There were 199 admissions with human immunodeficiency virus (HIV) admitted over the study period. A total of 73 HAART errors were confirmed in 41 patients. These included: incomplete regimen (the commonest), incorrect dosage, incorrect schedule, medication–disease interaction, incorrect formulation, incorrect antiretroviral, duplication of therapy, and drug–drug interactions. The duration of each error was measured from the time of the initial incorrect order until a correct order was placed or until the patient was discharged. There was no significant difference in the frequency or type of prescribing when
comparing the pre-intervention and intervention phases. The median length of time until an error was corrected, however, was significantly shorter during the intervention phase (15.5 hours) than the pre-intervention phase (84 hours).

The impact of a program of pharmacist-led changes was studied in orthopaedic patients in 2008 in the US. The changes included improved chart surveillance by pharmacists, a newly developed medication/history form given to and reviewed with patients before surgery, in-service education of preoperative nursing staff, patient database form changes, and requests for patients to bring their medications in on admission. Before the changes, medication errors were detected in 62% of orders overall. Of these, 43% were found to be of moderate or high potential for harm. After the institution of the above measures, overall errors were reduced by 31%; moderate/high risk potential harm was reduced by 64%; and errors of omission were detected twice as often.

These changes are typical of specialist clinical pharmacy activities in the UK and will be explored in more depth in Chapter 3.

1.9.3 Discharge

The Care Quality Commission recently reported on studies of patient discharges from NHS hospitals and stated that hospitals needed to improve the quality and timeliness of information sent to a patient’s GP when they are discharged from hospital.

In hospital the discharge process is more complicated than first inspection suggests. Within the pharmacy, many changes are made to the original discharge prescription because it does not match the inpatient chart or introduces new anomalies. Thus the original draft will often not match the final list. If the first draft is transmitted to the GP this would explain the CQC findings. In addition on admission to hospital many medication changes are deliberately made to avoid medication related problems (including the reason for admission) and would therefore be different from the GP record.
An Australian study indicated that on average, dispensing pharmacists intervened on 180 occasions per month to clarify and amend prescriptions. Resolution of these medication anomalies at discharge had resulted in considerable delays to patients and reduced the availability of beds for newly admitted patients. The inaccurate and slow production of discharge prescriptions was attributed to the inexperience and immense workload of junior doctors. A new system was introduced where the prescriptions were prepared electronically and printed by the pharmacist for confirmation and signature by the doctor. The pharmacist also prepared an electronic advice form detailing any medication changes and the reasons for the changes. They studied 40 cases before and after introduction of the new service. The authors concluded that the pharmacist-initiated e-script transcription service had been successfully implemented. The discharge process was faster with the time taken from decision to discharge to actual discharge decreased by 34% (p = 0.02). The time spent by dispensing pharmacists in clarifying and amending discharge prescriptions decreased from 9.5 to 1.5 minutes per patient. The time spent by doctors in preparing discharge prescriptions fell from 15 to 2 minutes per patient. There were also fewer prescribing errors; the number of errors decreased from 0.83 to 0.1 per patient (p = 0.0005) and from 0.0962 to 0.0137 per item (p = 0.011). The authors concluded that combining a prescribing role with the medication safety elements of electronic prescribing and medication reconciliation resulted in significant improvements in the quality, accuracy and timeliness of discharge prescriptions.

1.9.4 Re-admission

Data from the NHS information centre on readmissions to hospital shows that between 1998 and 2006, in inpatients aged 16-75 years, there was a 22% increase to 8.6 readmissions per 100 discharges. In the over 75 years cohort, the rate was 13.6 readmissions per 100 discharges. In 2007 the Health Minister Andy Burnham stated that ‘we need more research to help us understand the often complex underlying causes of readmission.’ As data from this research will show, a major contributor to readmission is the large number of medication errors made during the discharge process in secondary care.
1.9.5 Medicines reconciliation

Medicines reconciliation has been defined as a process of deriving the most accurate list of all medicines a patient is taking and using this list to provide care for a patient. The medication list should include prescription, herbal, over-the-counter preparations and supplements.\textsuperscript{118}

It involves a process of comparing a patient's medication orders to all medications that the patient has been taking to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. Reconciliation should be conducted at every transition of care in which new medications are ordered or existing orders are rewritten and could therefore be carried out at any of the boundaries shown in Figure 1.7.\textsuperscript{119}

Medication reconciliation is composed of five steps: creation of a current medication list; listing of medications to be prescribed; comparison of those medication lists; development of clinical recommendations; and communication with appropriate caregivers and the patient.\textsuperscript{119}

The first 24 hours of a hospital admission are important for clinical decisions. The first inpatient chart is written based on a drug history and an initial or working diagnosis. It is therefore important that the list of medicines consumed prior to admission is both accurate and complete. This might impinge on the cause of the admission and the resolution of adverse events. One paper has indicated that 50-60\% of initial drug charts are written incorrectly.\textsuperscript{120} Initial omissions here can be promulgated through a whole episode of hospital stay and result in readmission.\textsuperscript{120}

A prospective study in 2005 in Canada\textsuperscript{121} examined patients consuming at least four medicines at time of admission. It compared the medicines prescribed on admission with a comprehensive drug history. The researchers asked the admitting medical team which changes were intentional. Out of 523 admissions, 151 patients were enrolled into the study; 81 (53\%) had at least one unintended discrepancy and 46\% were omissions. Nearly two thirds (61\%) were of no consequence but 38.6\% were judged to have caused moderate to severe discomfort or clinical deterioration. Six percent of
patients experienced inadvertent omission with serious consequence. This study clearly identified a need for a better method of ensuring an accurate medication history at the time of admission.

### 1.9.6 Medication related admissions

Medication errors arising before admission can result in transfer from primary to secondary care. The primary/secondary interface can be a challenge but where hospital pharmacists have identified medication related admissions, it has been possible to gather together key stakeholders to talk about medication errors. Various studies have attempted to assess the magnitude of the problem; results from key studies are shown in Table 1.8 and show that the problem is a sizeable one.

**Table 1.8 Key literature showing the proportion of hospital admissions that are drug related admissions.**

<table>
<thead>
<tr>
<th>Percentage of all admissions</th>
<th>Country</th>
<th>Reference (events or ADRs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.9</td>
<td>UK</td>
<td>123 (events)</td>
</tr>
<tr>
<td>3.1</td>
<td>UK</td>
<td>124 (ADRs)*</td>
</tr>
<tr>
<td>5.1</td>
<td>Canada</td>
<td>125 (events)*</td>
</tr>
<tr>
<td>5.4</td>
<td>France</td>
<td>126 (events)</td>
</tr>
<tr>
<td>6.5</td>
<td>UK</td>
<td>127(ADRs)</td>
</tr>
</tbody>
</table>

*These report the results from meta-analyses.

As a patient is admitted to hospital there is an abrupt change in responsibility for medicines from patient to care provider. The patient often assumes the healthcare provider automatically knows the complete medication list, so does not remember nor record the details. The communication could be improved if there were electronic health records and a system of transfer when the patient moves from home to hospital. Patients who are booked for elective admission should be reminded to bring in a list of their medicines because this has been shown to decreased medicine reconciliation errors by 50%. For emergency admissions through A&E this is more difficult as patients often forget to bring in their medicines.
A Study in Merseyside\textsuperscript{127}, one of the most thorough of its type (see Table 1.9) found that 1,225 admissions (6.5\%) were related to an ADR and in 80\% of these, there was a direct link to the specific drugs they were taking. These patients had a median length of stay of eight days and occupied 4\% of hospital bed capacity. Most ADRs were predictable from the known pharmacology of the drugs and many represented known interactions and were therefore likely to be preventable. Two percent of patients admitted with an ADR died, suggesting that adverse effects may be responsible for the death of 0.15\% of all patients admitted.

The NPSA issued technical guidance on medicines reconciliation in 2007.\textsuperscript{129} This advised Trusts that pharmacists should be involved in medicines reconciliation as soon as possible after admission. All healthcare organisations that admit adult inpatients should put policies in place for medicines reconciliation on admission. In a systematic review\textsuperscript{130}, pharmacist-led interventions appear to be the most cost-effective ways of preventing medicine errors.

A Welsh study in a district general hospital in 2007\textsuperscript{131}, prospectively looked at 200 acute medical admissions. A pharmacy technician worked with a pharmacist, and compiled an accurate drug history. The pharmacist investigated any discrepancies between the history and the inpatient chart. A multidisciplinary team coded the discrepancy using an NPSA risk assessment tool; 123 patients had at least one error. There was a total of 234 errors or an average of 1.9 per patient. Almost two thirds (62\%) of medication history errors were drug omissions, 25.2\% incorrect doses and 8.6\% incorrect drugs. The majority (189; 79\%) were judged to be minor, 46 (20\%) moderate, and 1 (0.4\%) of major consequence.

\textbf{1.10 The developing role of the pharmacist in error prevention.}  
In the 1980s, hospitals produced formularies that limited the range of products stocked in the pharmacy. A formulary is a collaborative project between doctors and pharmacists who examine the evidence supporting the efficacy, safety and cost of products as they enter the market. Their original purpose was to simplify the choices available to junior doctors. A limited list of products reduces the amount of teaching required for safe prescribing. It is part of ensuring that appropriate products are
selected for patients – a risk management function. This process has undergone considerable change including the increased prominence of the cost saving component.

At the same time, ward pharmacy evolved to move the supply function out from the pharmacy onto the wards. This was an expansion of the risk management component of the dispensing process. It was conceived to trap errors earlier in the prescribing process. The pharmacist’s understanding of how medicines were used increased as did the way in which errors were generated. Junior pharmacists were then taught by their senior colleagues how to identify prescribing errors. This educational role was improved by capturing data on the interventions that pharmacists made. Pharmacists were also able to identify errors in the administration of medicines to patients.

Clinical pharmacists emerged who spent the majority of their time looking for prescribing and administration errors; they advised doctors and nurses on the safest way to use medicines, before a prescription was written. Pharmacists are now fully involved in the management of medicines at policy level and in the management of medicines risks. Pharmacists attend consultant/registrar ward rounds to assist in the selection of therapeutic group and individual drugs within groups. This is to avoid contra-indications and adverse effects but also to reduce the likely errors in the delivery of care. We have seen earlier that this is more effective that just visiting the ward.74

Pharmacists are involved in the training of junior doctors to address lack of knowledge about medicines and how they should be used safely thus managing risk through education and sharing of experience. They are also helping to reduce medication related errors at the admission and discharge phases of the patient’s journey. The hospital pharmacist is best placed to oversee the quality of the entire drug distribution chain from prescribing, drug choice, dispensing and preparation to the administration of drugs and can fulfil a vital role in improving medication safety.

A key function for the hospital pharmacist is to review the medicines of individual patients; during this process prescription anomalies and errors can be detected and reconciled quickly before harm occurs. In addition, medication reviews can improve
patients’ understanding and confidence about their medicines and so improve long term outcomes. If this was to occur before and after entering the secondary care loop (see Figure 1.7) then many interface problems could be resolved. The existing and potential roles for pharmacists in reducing medication related errors are discussed further in the ensuing chapters.

All of the research presented in this thesis was carried out in Southampton University Hospitals NHS Trust. A brief overview of this environment appears in the next section.

1.11 Southampton University Hospitals NHS Trust
Southampton University Hospitals NHS Trust (SUHT) serves a local population of 560,000 and provides tertiary services for three million people. The Trust includes three hospital sites of which Southampton General is the largest with about 1000 beds in 50 wards. In 2009 the trust admitted 114,000 inpatients and 100,000 patients attended A&E. SUHT contains more than 1,300 beds and employs 7,000 staff, including 260 in pharmacy. The pharmacy contains a total of 220 whole time equivalents including 82 (69 WTE) pharmacists. In 2009, the dispensary was issuing approximately 500,000 items per year or nearly 1000 items per week-day; 350,000 items were issued as ward stock and a further 80,000 products were dispensed aseptically. The pharmacy also answered approximately 5,000 medicine enquires through its Medicines Information department.

1.12 Research overview

1.12.1 Research contextualisation
In the literature review, the author has described publications on the safety culture and how it should improve patient safety. The pivotal American report ‘To err is human’ applied the safety culture and principles of quality improvement into healthcare. ‘An organisation with a memory’ translated these principles into healthcare in the UK and commented that the culture of the NHS needed to change to one that openly learnt from errors. OWAM also stated that the NHS was not good at learning lessons from these failures and research in this area was to be encouraged. The conceptual model
and theory of errors have been described to inform this culture change to one of learning from errors.

Methods of detecting medication errors have been described, with an emphasis on prescribing errors. The impact of technology has been discussed, with a focus on CPOE and CDS. Whilst some perceive that this technology will eliminate prescribing errors, the literature shows that new errors can be created.

Building a safer NHS\textsuperscript{33} was published in 2001 to implement OWAM. This was accompanied by the birth of the National Patient Safety Agency (NPSA) to collect and analyse adverse events and learn lessons from them.

Alan Milburn, the then Secretary of State for health, wrote the forward for the DOH paper.\textsuperscript{22} He called for more research into errors in healthcare and set a number of targets for the NHS to reduce them. However due to the lack of research data and common definitions of medication errors there was no clear baseline data from which to work. Pharmacists had been reluctant to publicise the interventions that they make. Their role is largely hidden from the public eye and the media.

There was little published data that described a stable UK data set that had been compiled over a number of years and which could be used to explore trends. However this data were being generated at SUHT. The data were initially disorganised and there was uncertainty about how it could be presented. The author decided to conduct further studies to add to existing data, and analyse and share them.

1.12.2 Aims of this research

The overall aim of this research was to quantify medication related events and prescribing errors and to measure the contribution of the pharmacist in their management.
1.12.3 Research objectives

To conduct a study into a pharmacist obtaining complete drug histories and writing the first hospital prescription.
To analyse a cohort of hospital admissions to determine if the cause of admission was medication related.
To describe, quantify and analyse for trends the risk management activities of pharmacy.
To organise and analyse data on pharmacist intervention audits that have been conducted regularly in one organisation and analyse trends over a decade.
To analyse a dataset of pharmacist interventions to determine the proportion that were caused by prescribing errors.

1.12.4 Chapter summary

Chapter Two discusses the scope of clinical activities of pharmacists that occur in addition to drug supply. These clinical pharmacy activities included obtaining drug histories, interpreting drug concentrations, enhancing discharge of patients, monitoring the effects of medicines and solving problems that occurred in the use of medicines. The activities are quantified in a series of annual surveys at SUHT and analysed for trends.

Chapter Three discusses the interventions of pharmacists at SUHT. The interventions are categorised into different types, financial motivation and the outcomes. If the pharmacist had not intervened there would be consequences for patients and these are assessed in terms of the likely severity. The impacts of the interventions with highest severity are also discussed. The data are gathered from annual, week-long surveys over a decade.

Chapter Four describes a project set in the Accident and Emergency (A&E) department at SUHT. The study quantifies the proportion of admissions that may be medication related. It examines the effects of a pharmacist obtaining drug histories from patients and writing the first hospital prescription. It looks at the anomalies and
errors that are prevented by this intervention, throughout the patient journey through the hospital. Patients’ views on medication issues and their care are also reported.

Chapter Five looks at the dataset of intervention surveys from Chapter Three. These are re-coded to determine where the pharmacist intervened to prevent a prescribing error from reaching the patient. The proportion of interventions that are related to prescribing errors is determined. The PEs are further divided into those that were acts of omission or commission. An examination is then made of whether the PEs occurred on admission, discharge or inpatient phases of the temporary secondary care loop. There is an exploration of what remains if prescribing errors are eliminated from the intervention dataset.

Chapter Six discusses the findings of the research in the round, focussing on the potential of the pharmacist to prevent errors and reduce patient harm, and provides suggestions for future work. Chapter Seven provides overall conclusions from this research.
Chapter 2 Pharmacy activity surveys

This chapter outlines some of the activities of pharmacists and their contribution to more than just the supply of medicines. Pharmacists supply medicines, but they also contribute to ensuring that drugs are used safely, educate healthcare staff and optimise the way that medicines are used. The different components of ‘clinical activities’ are described, discussed and quantified.

Whilst it is relatively easy to count the number of items issued it is more difficult to quantify clinical activities and their contribution to patient care. At Southampton, surveys of clinical pharmacy activities have been conducted on a regular basis since 1979. This chapter describes surveys undertaken between 1990 and 2009, under the author’s direction. In these surveys the pharmacists completed report forms that described and quantified what they did. This chapter is an analysis of the reports from these surveys. In Chapter 3 the data are considered in more detail.

2.1 Introduction

Everyone has a view of what ‘chemists’ do from their perception of community pharmacies: they supply medicines from prescriptions. Community pharmacists also offer advice on how medicines should be used, and make sales of non-prescription medicines. In addition the new pharmacy contract has expanded activities to include medicine use reviews (MURs), smoking cessation services, syringe and needle exchange, pregnancy testing, Chlamydia screening and many other public health services.132

This chapter will look at how these activities translate into hospital pharmacy practice. Firstly, hospital pharmacies can be registered as community pharmacies so they can also sell over-the-counter (OTC) products; but this is a very minor activity, if it exists at all. Hospital pharmacies supply medicines to patients in beds and on discharge back to the community. The advisory role of pharmacists in hospital is a major activity; the range and depth are explored in this chapter. The focus is on risk management activities rather than supply of medicines, but this function is included for completeness.
2.1.1 Patient access to hospitals

Patients may attend hospital outpatient clinics to see specialists. The specialist may issue a hospital outpatient prescription that can only be dispensed from the hospital pharmacy. Alternatively the specialist may issue FP10 (HP) prescriptions; these are similar to those from general practitioners in that they can be dispensed by community pharmacies, but are paid for by the hospital. The specialist may write recommendations of treatment for the GP to prescribe.

Patients may also attend hospital Accident and Emergency (A&E) departments for urgent assessment and treatment before returning to full health or the care of their general practitioners. A&E attendees may receive medicines for their treatment in the A&E department but do not usually visit the hospital pharmacy.

Some patients may visit a clinical area in the hospital for a few hours to be assessed. Others may have short surgical procedures but are discharged without occupying a hospital bed overnight. These patients are called day cases. Many will receive medicines during the day but will be discharged, possibly with prepared packs of painkillers or antibiotics, without visiting the hospital pharmacy.

Most hospital activity is focussed on delivering care to patients who are admitted to hospital through A&E to medical wards or urgent surgery. Unpublished data gathered at Southampton shows that these patients represent about a fifth of those who visit A&E. Other patients may present themselves to surgical wards directly without visiting A&E for elective surgical procedures. A complete hospital episode has an admission phase, an inpatient phase -which must include an overnight stay in a hospital bed- and a discharge phase as shown in Figure 2.1.
2.1.2 Supply of Medicines

Hospital pharmacies supply medicines to clinical areas on the premises, including theatres and wards. The largest numbers of medicines are supplied by the pharmacy department to wards to hold as stock, in anticipation of a prescription. Wards are organised into clinical specialties that are then grouped into directorates (e.g. surgical wards) to facilitate management and communication to groups of clinicians who care for similar patients.

Each ward has its own medicines stock list, agreed between senior nurses and pharmacists. Stock drugs are those that are commonly prescribed in that clinical speciality. The stock list ensures that frequently used drugs are readily available. Nurses should be familiar with the cautions and appropriate use of all stock drugs. When ward stock medicines are used, replacements are ordered by pharmacy technicians and assistants, selected from pharmacy stores and delivered in boxes to the wards. This stock drug distribution process at Southampton, as with most other hospitals, has no routine oversight by pharmacists. Only medicines on the approved stock list should be supplied in this way. Any difficulties or unusual requests are
redirected to the dispensary or discussed with clinical pharmacists visiting that particular group of wards.

Approximately 55% (500,000 / 910,000) of the number of medicines supplied by pharmacy is delivered as individually dispensed items through the dispensary (unpublished data). Non-stock items are individually dispensed because they are expensive, toxic or associated with a high risk of errors. Items from the dispensary are for a particular patient and are authorised either directly by a prescription or a written request from a clinical pharmacist. The dispensary processes all outpatient and discharge prescriptions as well as inpatient items. Data from Southampton performance management statistics show that the pharmacy dispenses approximately one thousand items per day.

Some medicines are not commercially available and have to be prepared extemporaneously either in the dispensary or more usually, in a technical support area. The technical support area also prepares injectables such as parenteral nutrition, cytotoxics and reconstituted and ready prepared injections and infusions. This is known as the Central Intravenous Additive Service (CIVAS).

### 2.1.3 Supply of Information

In hospital the pharmacists in the dispensary may offer simple verbal advice about medicines in response to questions from patients and ward staff. However, most questions are referred from the dispensary to the Medicines Information centre. Here pharmacists can take phone calls from the general public; but their main work involves questions from healthcare professionals that require interrogation of databases, similar to a medical library. Pharmacists collate, analyse and summarise what is retrieved, often adding professional advice using their clinical experience from working on wards.

On the wards the clinical pharmacists have a substantial role in the provision of information about medicines. Apart from factual information, they share experience and offer professional advice about how to prescribe and use medicines safely. This
role has grown substantially over the last two decades. Chapter 3 analyses the contributions of clinical pharmacists in this area in more detail.

Pharmacists provide passive information to nurses in response to queries. They also annotate drug charts to provide information and guidance to enable nurses to administer medicines in a safe way. By annotating the drug chart the doctor’s intention is made clearer so the nurse is less likely to make a drug administration error. For example poor handwriting may allow amlodipine to be read as amiodarone. Annotating the chart clearly as amlodipine ensures that the nurse gives the correct drug. Writing the ingredients of co-dydramol on the chart and setting a maximum in 24 hours avoids an overdose of paracetamol; especially if paracetamol is itself also prescribed PRN (as required). This can be seen as the active provision of education or relevant information.

In addition, the pharmacist will actively intervene in the drug use process if they feel that an error is likely or the process could be improved. For example a macrolide antibiotic should not be prescribed with a statin due to an increased risk of muscle breakdown. Where co-prescription occurs the pharmacist would consult the doctor to ensure the prescribing is changed so that an alternative non-interacting antibiotic is prescribed. A patient who is allergic to penicillin may be prescribed co-amoxiclav because the junior doctor does not realise this contains a penicillin. Discussion between the pharmacist and the doctor results in an alternative treatment to which the patient is not allergic. In this way pharmacists may prevent prescribing, administration and supply errors from occurring, or reaching the patient. They may then prepare additional information or guidelines to junior doctors and nurses to reduce the risk of an error occurring again. This is an active pharmacovigilance role and has been reported to save many patients from harm.\textsuperscript{132,133,134}

2.1.3.1 The pharmacist as educator

Many problems are solved by simple education. The pharmacist possesses knowledge about the supply chain, formulary process and products that are available. So for example nifedipine is available in multiple formulations that are usually prescribed in
set frequencies specified in the BNF. Therefore a prescription for nifedipine 20mg twice daily should be given as plain capsules. However it is likely that the prescriber intended a ‘retard’ formulation that is given twice a day rather than plain capsules that are given three times a day. Similarly beclometasone inhalers are available in many strengths, so a strength should be specified or else the lowest strength will be given. Knowing which products are available as injections or liquid formulations can assist a patient with swallowing difficulties. Knowing which drugs are on the hospital formulary and which drugs are controlled under the Misuse of Drugs Act 1972 will affect the way that they are supplied to the ward. Many problems are solved by an explanation of a drug’s pharmacology. Being present on a ward enables the nurse, or doctor, to ask how a drug works. This is less likely to happen from the dispensary; indeed it is likely that the question will not be asked at all, missing an educational opportunity.

This sharing of knowledge and application of expertise is the heart of the educational input of pharmacists to other healthcare professionals.

2.1.4 Risk management functions for pharmacists

2.1.4.1 Risk management function in the dispensary

In the dispensary, pharmacists screen hospital prescription charts and resolve any anomalies that are detected. Pharmacy technicians and assistants then dispense and label any items required and these are checked by authorised senior technicians or pharmacists before release to the wards.

Prescription related anomalies in the dispensary include prescriptions that do not match legal requirements and doses outside usual practice. Medication errors are detected, where discharge prescriptions do not match inpatient prescriptions or patients’ own drugs (PODs) brought into hospital. Medicines prescribed on admission are only seen in the dispensary if the patient does not bring in sufficient of their PODs and it is not a ‘stock’ drug for the admitting ward. New prescribed items are usually ordered via a pharmacist visiting the ward.
In this way pharmacists in the dispensary detect errors that have occurred in the prescribing of medicines. The risk management role is centred on ensuring documentation is legible, legal, complete and unambiguous such that accurate dispensing of prescriptions is possible. They also ensure that doses are within the normal range quoted in the British National Formulary (BNF).

**2.1.4.2 Risk management function on the wards**

Pharmacists begin their training in the dispensary and are then introduced to the wards. Pharmacists who visit wards are called clinical pharmacists and their role is to scrutinise the selection and use of medicines in these clinical areas. They order the medicines that are not held as stock on the ward, ensuring that the prescribed usage is both safe and appropriate for the individual patient. This risk management activity is similar to that which occurs in the dispensary, but has greater depth due to the increased access to data, including patients’ notes, care plans and test results.

In addition, pharmacists can talk to patients and healthcare staff and oversee the best use of medicines. This activity includes detecting errors in prescribing and administration and ensuring that the most appropriate medicinal products are supplied. The junior doctors are in training and may be unaware of the choice of formulations available. For example the pharmacist may recommend and supply a liquid or dispersible formulation for those who have difficulty swallowing or are fed through a naso-gastric tube. This is part of optimising patient care and minimising risk.

There is an initial superficial screening of prescription charts on the ward. Where prescription inconsistencies alert the pharmacist to complex or anomalous use of medicines in a particular patient this triggers a detailed clinical usage review (CUR).

A CUR is where the pharmacist investigates more closely the clinical use of medicines in a patient and makes recommendations. This might include changing the chosen individual agent to another within the same therapeutic group. A medicines use review (MUR), as seen in community pharmacy practice, is conducted where
compliance might be a problem. For many patients the screening takes a few minutes, but a detailed review could take 20 minutes, or longer.

Clinical pharmacy covers a wide range of medical specialities that use different medicines with different monitoring requirements and so for example, the role of the pharmacist in oncology is different from that in critical care. Clinical pharmacists ensure that medicines are used safely and effectively. This contributes to the collective management of medicines in a hospital. Whilst cost effectiveness is a priority for the pharmacy, the clinical pharmacist’s primary goal is the management of risks in the use of medicines.

There are a number of common functions; some are specific for a group of patients and some are triggered by individual drugs. Whilst the pharmacy department ensures that clinical pharmacists are trained to fulfil their risk management roles, there is no collective consciousness about what pharmacists do in daily practice.

2.1.5 Surveys of pharmacist activity at SUHT

This thesis is about understanding errors that occur in the use of medicines and how pharmacists can prevent them translating into patient harm.

In order to capture and understand this activity, many hospitals conduct an annual point prevalence survey to record the interventions that pharmacists make. The data describe what pharmacists do and quantify their activities and their outputs. An analysis of data from recent surveys at Southampton is an important part of the author’s research because the intervention forms record the details of the contributions that clinical pharmacists make to patient care. The forms describe the practical problems that the pharmacist solves.

The surveys allow the collective analysis of clinical pharmacy activities. They demonstrate the value that pharmacists add to the safe and effective use of medicines. Analysis of these surveys categories the risk management role of pharmacists. Without this activity the potential for harm would be invisible. These data describe the check that pharmacists provide in the medicines use process to filter out errors.
More specialised surveys, in which the author was involved during his research and which impacted upon it, were conducted on a regional basis. These are described in the following section.

### 2.1.6 LENARD

The LENARD (local entry, near-miss and adverse event database) studies were commissioned by the NPSA (National Patient Safety Agency) and organised by the London and Southeast Regional Clinical Pharmacy Team. Under the author’s guidance, Southampton participated in the pilot and full studies. The LENARD studies were designed to collect data on errors and near-miss events detected or prevented by pharmacists, where the likely consequence would have been moderate, major or catastrophic; NPSA definitions of these terms are given in Table 2.1.

<table>
<thead>
<tr>
<th>Consequence Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>Death</td>
</tr>
<tr>
<td>Major</td>
<td>Permanent harm (loss of function) or semi-permanent, lasting greater than 1 year. or increasing length of stay (LOS) by more than 15 days or increasing level of care required by the patient of more than 15 days.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Semi-permanent damage likely to resolve within one year. Healthcare associated infections resulting in non-permanent harm. Increased LOS of 8-15 days or increased level of care for 8-15 days.</td>
</tr>
<tr>
<td>Minor</td>
<td>Non-permanent harm (less than 1 month) including healthcare associated infections resulting in non-permanent harm. Increased LOS of up to 7 days or increased level of care of up to 7 days.</td>
</tr>
<tr>
<td>None</td>
<td>No obvious harm.</td>
</tr>
</tbody>
</table>

The pilot study was focussed on all errors to try to identify high risk drugs. Later studies focussed on risks with antibiotics and another, on omitted doses. So during the
period 2002 to 2004, only specific errors were collected, and not the broader category of interventions by pharmacists.

2.2 Methods

2.2.1 Point prevalence activity studies

Point prevalence studies were useful because they showed the workload of the pharmacy department in screening hospital medicine charts for anomalies and errors. They also provided some useful denominators for ratios of prevalence of interventions made or prescribing errors detected by the pharmacy team.

The data collection form (see Appendix 1) was designed by the author to capture the number of patients seen on each ward. Patient names were recorded to avoid double counting, but at the end of the week-long study, only the number of patients was recorded. The forms also provided space to tally the number of newly prescribed items for each patient, the number of interventions made and the number of annotations added to the prescription chart. The forms were collected at the end of the week and data for each ward were counted, then entered into an Excel spreadsheet. Figures for each ward in a care group were added together and then summarised in tables.

Data in these surveys were captured over one week periods from 1990 to 2009. These were usually organised to coincide with an intervention survey (see Chapter 3). The activity study was designed to gather data on how many patients were encountered and the number of newly prescribed items that were reviewed. This could then be compared to the number of interventions in that week.

Data for 2002-4 are unavailable because of participation in a separate project called LENARD (see Section 2.1.6). When the LENARD project was completed, it was decided to return to the previous activity study methodology. For 2005 a particularly detailed study was conducted to look at all the parameters that could feasibly be collected (see Section 2.3.2).
2.2.2 **Drug History**

A drug history in this context was an interview with a patient and comparison of that history with PODs, recorded on the back of the hospital inpatient prescription. The drug history was then compared to what was prescribed on the first hospital inpatient prescription and the number of items reconciled was recorded. It may also have included comparison with a GP repeat prescription printout. Where there was doubt about the completeness or clarity of the data, the GP surgery was telephoned to confirm this data.

2.2.3 **Items Supplied**

Items supplied were those that were requested by the clinical pharmacist; this excluded the normal stock drugs. The supply was requested by the pharmacist either because no PODs were available or new medicines had been initiated. Complex forms of supply are described in the following sections.

2.2.4 *Monitored dosage systems*

Monitored dosage systems (MDS) contained medication in a tray divided into sections for each day of the week and mealtimes throughout each day. Tablets were then dispensed into each section of the tray every week to aid compliance. Patients who had difficulty remembering when to take different medicines were identified by the nursing staff. The pharmacist visiting the ward was notified and they subsequently talked to the patient to verify the need for an MDS, to check that the patient understood how to use the MDS and to identify their usual community pharmacist. The community pharmacist was contacted and the device was discussed. If the community pharmacy was willing to supply, then the hospital pharmacy dispensed the discharge medication in an appropriate device. In the study period, community pharmacists were not remunerated for the additional work involved in filling these devices and many were reluctant to undertake this. If the community pharmacist was unwilling to continue filling the MDS there was no point in the hospital supplying a device. These arrangements often required multiple phone calls prior to discharge.
2.2.5 Drugs requiring special monitoring

Monitoring was undertaken where use of a medicine required checking of various biochemical parameters. For example a potassium supplement such as Slow K prompted the pharmacist to check that the patient had recently had a blood sample analysed for potassium content. The pharmacist accessed the pathology computer to see if this had been done and whether the result was now normal. Similarly, a digoxin prescription prompted a check of serum creatinine and potassium. Rifampicin prompted a weekly check of alkaline phosphatase (ALP) and alanine transaminase (ALT) and international normalised ratio (INR). This is different from therapeutic drug level monitoring (see Section 2.4.3.3).

2.2.6 Advanced Dispensing of Discharge Medication (ADDM)

ADDM was where the pharmacist felt able to predict the majority (or all) of the discharge prescription. This was easiest on a surgical ward where the patient often went home on the same drugs as on admission, plus antibiotics and analgesics. The pharmacist wrote out the discharge medication on the TTO (to take out – discharge) form and arranged dispensing a day or two in advance. On the day of discharge the doctor added the analgesics and antibiotics as appropriate and signed the TTO prescription. If the analgesics and antibiotics were pre-packed on the ward, the pharmacist could approve release and the patient could go home immediately. If this was not possible the TTO and dispensed items were returned to the pharmacy for final amendment and additions. Although this process usually resulted in a faster discharge, each ADDM was additional work and responsibility for the pharmacist.

2.2.7 Therapeutic substitution

Therapeutic substitution was a hospital policy approved by the SUHT Drug and Therapeutics Committee. It was constructed from interventions made repeatedly by pharmacists that were always implemented by the doctor; for example changing times of administration of magnesium hydroxide, on a chart with digoxin, so they were separated by at least 2 hours. This avoided reducing the absorption of digoxin by up to 80%.
2.2.8 Review of patient care

During an activity study, when a pharmacist visited the ward they recorded the name (or initials) of every patient whose charts they reviewed. When two pharmacists covered one ward they were encouraged to use the same activity sheet. However this was not always possible; in which case, the pharmacist recorded the names of all the patients whose charts they reviewed and before analysis, patient identifiers were matched carefully to avoid duplicates.

2.2.9 Identification of newly prescribed items

On opening the drug chart on a Monday morning, the pharmacist counted every item prescribed (even if they were seen in the previous week) and this figure was recorded on the activity monitoring sheet next to the patient’s name. On Tuesday they recorded only those items that had been added since the chart was seen on Monday morning and so on, throughout the week, including weekends if the patient was seen. This produced a substantial workload on the Monday but diminished as the week progressed. If a chart was rewritten, all the re-prescribed items were recounted as the pharmacist had to check that no transcription errors had occurred. A second pharmacist may have visited the same ward the next day due to job sharing, sickness, absence or to cover for the first pharmacist where their skills were needed elsewhere. Whilst every effort was made to maintain consistency, staff shortage and sickness were a random confounding factor. Ideally one pharmacist visited the same ward throughout the week, providing an accurate reflection of the number of patients whose charts had been reviewed and an accurate count of the total number of items that had been screened.

2.2.10 Pharmacist screening activity

The activity count covered all the pharmacists who were employed by the pharmacy departments of SUHT, who covered approximately 1330 beds. This included Southampton General Hospital (about 1000 beds), and Princess Anne Hospital (200 beds), Royal South Hants hospital (130 beds).
The bed count remained fairly stable with small fluctuations over the study period. However a bigger variable was the number of charts the pharmacist screened on the wards. Each pharmacist visited between one and three wards. Pharmacists who worked in the main department were allocated 60-90 minutes for ward work, visiting one ward of less than 30 beds. Those pharmacists on permanent, or rotational, clinical duties spent from 100 to 300 minutes on wards covering two or three ward areas. Bed numbers varied from 15 to 100 depending on the level of complexity and specialism. The remainder of their allocated time was spent at meetings, developing clinical guidelines, auditing practice, teaching and learning programmes.

2.2.11 **POD technicians (PODtechs)**

Pharmacy technicians also visited the clinical areas to check that prescriptions matched the PODs that patients brought into hospital. Any anomalies were discussed with the patient, carers or relatives and if unresolved, were reported to the pharmacist for action. The pharmacist may have chosen to contact the GP or electronically access the patient’s medication record or repeat slip before discussing it with the junior doctors.

2.3 **Results**

2.3.1 **Results of activity point prevalence studies**

Results for activity surveys in early and more recent years are shown in Tables 2.2 and 2.3 respectively. Surveys were for single weeks in each year are reported. The weeks were chosen a few months in advance when the staff absence for holidays was minimal. They therefore varied from year to year. Results are displayed as bar charts in Figures 2.1 and 2.2 respectively.

The patient/item/intervention data were split into two parts: early years (1990-2001) and post- 2000 (2001-2009). This was to demonstrate possible changes over long periods of time.
Data from 2001 have been included in both tables to show the trend from before and after 2002-4 where there is a data gap due to the LENARD studies (as explained in Section 2.1.6)

**Table 2.2 Clinical pharmacists’ activity survey data for 1990-2001**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>210</td>
<td>634</td>
<td>327</td>
<td>1137</td>
<td>1000</td>
</tr>
<tr>
<td>New items</td>
<td>1505</td>
<td>4294</td>
<td>2056</td>
<td>8799</td>
<td>8000</td>
</tr>
<tr>
<td>Interventions</td>
<td>36</td>
<td>96</td>
<td>66</td>
<td>613</td>
<td>603</td>
</tr>
<tr>
<td>New Items per patient</td>
<td>7.2</td>
<td>6.8</td>
<td>6.3</td>
<td>7.7</td>
<td>8</td>
</tr>
<tr>
<td>Patients per Intervention</td>
<td>5.8</td>
<td>6.6</td>
<td>5.0</td>
<td>1.9</td>
<td>1.7</td>
</tr>
<tr>
<td>Interventions per 100 patients</td>
<td>17.1</td>
<td>15.1</td>
<td>20.2</td>
<td>53.9</td>
<td>60.3</td>
</tr>
<tr>
<td>Items per Intervention</td>
<td>41.8</td>
<td>44.7</td>
<td>31.2</td>
<td>14.4</td>
<td>13.3</td>
</tr>
</tbody>
</table>

**Figure 2.2 Trends in activity data for 1990-2001**

(Interventions are divided by four to enable the histogram to be plotted on the same Y axis scale).

**Table 2.3 Clinical pharmacists’ activity survey data for 2001-2009**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>1000</td>
<td>1414</td>
<td>1137</td>
<td>2004</td>
<td>1361</td>
<td>735</td>
</tr>
<tr>
<td>New items</td>
<td>8000</td>
<td>12779</td>
<td>8799</td>
<td>17955</td>
<td>8668</td>
<td>6142</td>
</tr>
<tr>
<td>Interventions</td>
<td>603</td>
<td>1197</td>
<td>910</td>
<td>912</td>
<td>1058</td>
<td>777</td>
</tr>
<tr>
<td>New items per patient</td>
<td>8</td>
<td>9.0</td>
<td>7.7</td>
<td>9.0</td>
<td>6.4</td>
<td>8.4</td>
</tr>
<tr>
<td>Patients per Interventions</td>
<td>1.7</td>
<td>1.2</td>
<td>1.2</td>
<td>2.2</td>
<td>1.3</td>
<td>0.9</td>
</tr>
<tr>
<td>Interventions per 100 patients</td>
<td>60.3</td>
<td>84.7</td>
<td>80.0</td>
<td>45.5</td>
<td>77.7</td>
<td>105.7</td>
</tr>
<tr>
<td>Items per Intervention</td>
<td>13.3</td>
<td>10.7</td>
<td>9.7</td>
<td>19.7</td>
<td>8.2</td>
<td>7.9</td>
</tr>
</tbody>
</table>
Figure 2.3 Trends in activity data for 2001-2009
(multipliers are different from those used in Figure 2.2 to enable the features of the histogram to be plotted on the same scale)

2.3.2 Detailed data from 2005

In 2005, additional activity data were recorded during the 7 days of study. This was not captured in other years but is presented in Table 2.4, to illustrate the depth and scope that could be captured and to give more detail of pharmacy activities.

<table>
<thead>
<tr>
<th>Number</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1941</td>
<td>Drug history items</td>
</tr>
<tr>
<td>77</td>
<td>Phone calls to GPs</td>
</tr>
<tr>
<td>1268</td>
<td>Items supplied</td>
</tr>
<tr>
<td>6</td>
<td>Monitored dosage systems (MDSs)</td>
</tr>
<tr>
<td>3691</td>
<td>Annotations</td>
</tr>
<tr>
<td>4579</td>
<td>Monitored items</td>
</tr>
<tr>
<td>20</td>
<td>TDM advice</td>
</tr>
<tr>
<td>1197</td>
<td>Interventions</td>
</tr>
<tr>
<td>3027</td>
<td>Discharge items screened</td>
</tr>
<tr>
<td>272</td>
<td>patients counselled on their medicines</td>
</tr>
<tr>
<td>117</td>
<td>advanced dispensing of discharge medicines (ADDM)</td>
</tr>
<tr>
<td>61</td>
<td>TPN bags prescribed</td>
</tr>
<tr>
<td>67</td>
<td>therapeutic substitutions</td>
</tr>
</tbody>
</table>

2.4 Discussion

Table 2.2 summarises data for the years 1990, 1992, 1993, 1999 and 2001. These years were chosen because complete data were available and they demonstrate a trend from the early part of the 1990s up to and including 2001. Intervention data were available for other years but data on all activities were not collected. Table 2.3 summarises the years 2001, 2005, 2006, 2007, 2008 and 2009. These years were
chosen because complete data were available and they demonstrate a trend from 2001 (before LENARD) and after the data gap (2005-9). The data were split into two to illustrate the underlying trend and the magnitude of the changes. Data for 2001 is repeated to provide a reference point for the two tables. Table 2.2 shows how ward cover and reporting of clinical pharmacy activity increased during the early years of the study. The later years, shown in Table 2.3 reflect a period of stable ward pharmacy cover.

2.4.1 Early years data

It can be seen that in the early 1990s, pharmacists at Southampton were only reviewing between 200 and 600 patients whereas from 1999 onwards, the number regularly exceeded 1,000. The number of items screened increased from 1500-4000 to approximately 8000. This was a period of rapid expansion of the clinical pharmacy service and a change from ‘supply outside the dispensary’ to a more clinical focus of activity. It was a time when the SUHT pharmacy department started to understand and focus on risk in drug usage rather than risk in supply.

In the 1980s, the role of pharmacists on the wards was focussed on an efficient supply process and compliance with the hospital formulary. Interventions were largely limited to ensuring prescriptions were complete to enable accurate dispensing.

So these early data reflect both growth of service as well as transformation of interventions into those directed at reducing clinical risk.

The number of interventions increased from less than 100 (36-96) to over 600 from 1999 onwards. So pharmacists were making more interventions and the increase was greater than the increases in the number of patients or items. It was a time of rapid development of knowledge of drug usage and application of pharmaceutical experience.

The number of new items per patient remained relatively stable over the period of the study, but the number of patients per intervention showed a downward trend. The number of items screened for each intervention also fell from 30-45 to 13-14. This reinforces the concept of more interventions being made for each prescribed item.
Anecdotally, in the 1990s, interventions became more clinical during the inpatient phase. Emphasis was also placed on facilitating patient discharge. Medicines reconciliation as a concept did not exist at that time. However in the author’s opinion, around the year 2000, awareness was developing that the admission phase (where the pharmacy department had no presence) was not as risk-free as pharmacists had previously assumed. This was where the idea for the research in Chapter 4 started to emerge.

2.4.2 Post-2000 data

During the second study period, there was a wide variation in the number of patients seen from 735 to 2004. Most of the data were between 1000 and 1414, with data from 2007 and 2009 as outliers. This was because these studies relied on all the clinical pharmacy teams contributing data over the same week. However due to staff vacant posts and sickness, some teams were unable to submit complete data. This is noticeable in 2009; if this year is excluded there is a trend from 1999/2001 of 600 interventions increasing to over 1000 in 2005-2008.

The 2007 data appear anomalous in terms of the numbers of patients and items. The data were obtained from a number of report sheets. It appears that there may have been a small amount of double counting of the contributions of POD technicians and pharmacists although every effort was made to avoid this. The number of interventions was obtained by counting the individual report forms and appears consistent with the historical trend.

With the exception of 2007, the number of items per intervention moved from the low teens (13-14) to below 10 and patients per intervention from about 1.8 downwards. Again the rate of interventions increased faster than the rate of increase in items or patient numbers. In the author’s opinion, these data reflect an increased confidence in the position of pharmacists within the clinical team and a move into a more proactive role. The 2005-9 data show a trend towards, on average, intervening on almost every patient. In practice this comprised an uneven distribution, with some patients receiving multiple interventions, whilst others required none.
If it were possible, in advance, to eliminate the patients who do not need a pharmacist’s intervention, then the whole process could be made more efficient.

Over the entire reporting period (1999-2009) the average number of items per intervention was 11.5. Between 2006 and 2009 there was an average of 11.3 items per intervention with 2007 being the largest deviation. This suggests that the average rate of intervention remained stable and was not increasing. The total number of interventions only increased because the number of patients seen was also rising.

The Labour Government proposed a 4 hour waiting target for A&E departments in 2001. This prompted a number of innovative ways of processing patients, including early referral from the emergency department to a medical assessment unit. One strategy at SUHT was to create a holding area after initial resuscitation and clerking, now called the medical assessment unit (MAU), where it was possible for pharmacists to intervene early on in the patient’s admission. Pharmacists did not routinely visit A&E, but in 2007 extra funding was awarded for a pharmacy team to work in the new acute medical assessment unit; this contributed to the trend in increasing the total number of interventions seen from this time onwards. Previously pharmacists simply wrote that they intervened wherever the drug history did not match the inpatient chart, but gave no further details. From 2007, pharmacists were encouraged to report each item that could not be reconciled between drug history and inpatient chart. This is likely to have increased the number of interventions made on admission to hospital.

2.4.3 2005 detailed data

In 2005, a greater depth of activity analysis was undertaken. Drug histories were taken by pharmacists and POD technicians. To improve reliability of the reconciliation the pharmacy staff tried to obtain two data sources that correlated, one of which was GP surgeries.

During the hospital episode the clinical pharmacists ordered 1,268 non-stock items from the dispensary. This is similar to the number of interventions (1,197) made for the same cohort of patients. This shows that the supply function was still a significant component of the pharmacist’s role.
Several other aspects of the data in Table 2.4 are worthy of further comment.

### 2.4.3.1 Monitored dose systems (MDSs)

The supply of an MDS is a significant undertaking. It involves considerable negotiation by the clinical pharmacist, preparation time in the dispensary and ongoing workload in the community pharmacy. The pharmacy staff were reluctant to supply medicines in an MDS and this was why only six were provided.

### 2.4.3.2 Annotations

Annotations were added to drug charts to clarify what the doctors had written, such as correctly spelling drug names; or provided information, such as cautions with handling, to facilitate nurse administration. Annotations included the addition of generic names where brand names were prescribed; this facilitated generic substitution. Annotations also added missing data, such as timing or strength of products, to make them complete. There were 3691 annotations made to drug charts; this is more than the number of interventions (1197), more than the number of items supplied (1268) and an average of 2.6 (3691/1414) per patient. This activity was frequent but did it add value? This activity involved no active communication to patients and healthcare staff. Annotations were considered to improve the efficiency of dispensing or administering the medicine. An annotation should reduce the risk of miss-interpreting a prescription, but there is no evidence that it does this. A study could be conducted to identify the justification of every annotation made. However determining what happens if they are not made would be more difficult.

Electronic prescribing might be expected to eliminate the need for annotations because prescriptions would then be typed in a standard format and contain all the relevant details. For example an annotation on an IV antibiotic may describe the recommended administration details (e.g. 100ml dextrose 5% over one hour). This is a significant activity that should be evaluated prior to implementing an electronic prescribing system.
2.4.3.3 Drugs requiring special monitoring

During the inpatient stay, 4579 items were monitored; see Section 2.2.5 for explanation. This was where the pharmacist checked the pathology computer for results such as changes in serum creatinine when ACE inhibitors were started. Some of this activity led to interventions if the data alerted the pharmacist to potential problems. For example when ramipril was started and the renal function deteriorated the pharmacist discussed the treatment with the doctor and it was changed to bisoprolol (a beta-blocker). This was perceived as a significant contribution to reducing risk, but it was not clear how many times this monitoring activity detected errors or produced an intervention. It can be seen that interventions in total represented only 26.1% (1197/4579) of all monitoring events and interventions were also made independent of monitoring. It should be possible to run a study to determine the conversion rate of monitoring into interventions to gain an impression of the impact that monitoring actually has on patient care.

2.4.3.4 Therapeutic drug level monitoring (TDM)

Drug level monitoring activities are different from the monitoring described in Section 2.4.3.3. Routine monitoring looks at the electrolyte, enzymatic or biochemical effects of the drugs that were prescribed. TDM relates to the determination of the concentration of the drug itself in the blood. The pharmacists requested that the drug plasma level be measured for a particular drug, advised on when exactly a blood sample should be taken, expedited the assay when drug clearance was changing rapidly; or when the results were available, made a plan for changing the dose or frequency. Sometimes the pharmacist calculated the pharmacokinetic parameters of a drug in a particular patient where problems were anticipated. There were only 20 of these events during the one week of study. This reflects the relatively low frequency of prescribing of these drugs. However when these drugs are prescribed, there is often a series of interventions in an individual patient, to ensure the drug is maintained at a safe, non-toxic but efficacious concentration in the blood. An example was managing gentamicin dosing in a patient with endocarditis. Optimal drug management in this scenario was crucial to survival or the successful outcome from a cardiac operation. So whilst this was a time consuming activity that occurred infrequently, it was one of the most important contributions to patient care made by clinical pharmacists.
2.4.3.5 Prescriptions for discharge from hospital (TTOs)

When the patient was ready to return home the doctor prescribed a discharge prescription, or TTO (‘to take out’). Pharmacists screened 3027 items on the ward to facilitate speed of dispensing discharge medicines. This was a very significant workload for the clinical pharmacists. It was undertaken to reduce delays in the dispensary. Sometimes it was possible to completely avoid the TTO going to pharmacy. Packs of antibiotics and analgesics were prepared in advance and stored on the ward. Many surgical patients only required the return of their PODS and the addition of antibiotics or analgesics. The ward screening and dispensing therefore facilitated a faster discharge process for the patient.

2.4.3.6 Advanced dispensing of discharge medicines (ADDM) scheme

Sometimes discharge prescriptions must go to pharmacy because new items have been added or changes made to existing medication. Wherever possible this was done under the ADDM scheme and there were 117 patients who benefitted from this. This is a much smaller number of events than ward screening because it relied on the ability of the pharmacist to predict confidently what would be needed. Clearly this was not possible on many occasions.

2.4.3.7 Patient counselling

Some patients required more detailed counselling about their medicines prior to discharge (similar to an MUR in community pharmacy). This was undertaken for 272 patients in the week of study. Each counselling session took up to 20 minutes to complete; so this represented another important workload for the pharmacist. However educating patients is an important contribution to patient care and should also reduce the risk of readmission. However it is one of the first tasks to be cut when there is a shortage of pharmacists.
2.4.3.8 Pharmacist prescribing of parenteral nutrition (TPN)

Pharmacists have traditionally advised on the formulation of parenteral nutrition. By the year 2000, pharmacists were drafting the parenteral nutrition which the doctor then signed. As soon as pharmacist prescribing became legal, three pharmacists trained as prescribers and after qualification and registration, started to prescribe TPN. This is now an embedded activity and one year after registering as supplementary prescribers, 61 TPN bags were prescribed in one week by pharmacists. In Critical Care areas, pharmacists prescribed all TPN after 2008. In other parts of the hospital half the bags were prescribed by pharmacists. This remains an important service to patients and a demonstrable contribution by pharmacists to front-line care. It also reflects a complete conversion from trainees to prescriber practitioners.

2.4.3.9 Therapeutic substitution (TS)

There were 67 therapeutic substitutions (see Section 2.2.7 for more details). This was where a protocol empowered the pharmacists to make changes directly for subsequent signature by a doctor. It was undertaken as an efficient use of time and to facilitate early correction of errors to prevent patient harm. Examples included directing that a statin should have been administered in the evening to optimise its effectiveness. It was a prelude to pharmacist prescribing. As more pharmacist become prescribers this activity is expected to diminish.

TSs were a hybrid form of activity between an intervention and prescribing. The number of TSs illustrated a level of confidence of the pharmacist to act (change the prescription) and a recognition by senior doctors, that this was a change that should be made. In contrast to ‘interventions’ which involved the discussion of an anomaly between pharmacist and doctor, where the pharmacist sought to verify that they had understood the clinical context correctly, whilst educating the prescriber about the optimal or safest use or prescribing of medicine, TS was where the pharmacists accepted responsibility for the clinical context and required no further clarification from the prescriber.
2.4.3.10 Overall observations

The 2005 data show the wide range of activities undertaken by pharmacists on the wards. It captures four new ways of working – prescribing TPN, managing TDM, TS, and ADDM.

Pharmacists have historically advised on the need for TDM. There have been many interventions concerned with incorrect sampling times and poor interpretation of the results.

The evolution of clinical pharmacy and arrival of pharmacist prescribers has enabled the pharmacist to lead and manage therapeutic drug monitoring on the wards they visit. The author is an independent pharmacist prescriber and during the course of this PhD, has moved from drafting TPN prescriptions to prescribing it. Furthermore, advising on TDM has changed into prescribing and adjusting doses for drugs requiring TDM. This has increased the pharmacist’s contribution and made this professional support more visible in the patient records. This is important because apart from intervention and activity studies the pharmacist contribution is largely invisible in the patient records.

ADDM and TS were innovative practices designed to improve efficient use of staff time and reduce risks to patients from errors. Medication use systems in hospital are constantly evolving to design out errors and improve patient safety

Chapter 3 looks in more detail at the interventions that pharmacists made in the drug use process.

2.4.4 Study limitations

The activity surveys reported in this chapter relied on all the clinical pharmacy teams contributing data over the same week. However due to staff vacant posts and sickness, some teams were unable to submit complete data or covering pharmacists may have been less diligent in their reporting. Variable reporting rates were an important but unavoidable feature.
2.4.5 Suggestions for future work

A study could be done to identify the justification of every annotation made. However, determining what happens if they are not made would be more difficult.

It should be possible to run a study to determine the conversion rate of pharmacists’ monitoring activities into interventions having a real impact on clinical outcome.

2.5 Conclusions

Clinical pharmacy is a collective term for a number of activities enumerated in the research: obtaining medication histories and reconciliation with inpatient prescriptions, ordering medicines, supplying monitored dosage systems, monitoring the effects of medicines, contributing to management of therapeutic blood level measurement, facilitating the dispensing of discharge medicines, therapeutic substitution, and reviewing prescribed medication. These are undertaken to ensure continuity of supply of medicines, and education of healthcare staff and patients, as well as playing an important role in the managing of risks with medicines. An intervention in the drug usage process is made when the pharmacist detects an anomaly in the data or where an error has occurred. As shown here, the quantification of these different functions can be determined by conducting periodic surveys. The key conclusions drawn from this section of the research are as follows:

- The clinical activity of pharmacists at Southampton increased in range and load. This is illustrated by the data on interventions. The number of interventions increased from less than 100 (36-96) in the early 1990s to over 600 from 1999 onwards. So pharmacists were making more interventions and the increase was greater than the increases in the number of patients or items.

- The number of new items per patient remained relatively stable over the period of the study, but the number of patients per intervention showed a downward trend.
• The number of items screened for each intervention also fell from 30-45 to 13-14. This re-enforces the concept of more interventions being made for each prescribed item.

• With the exception of 2007, the average number of items per intervention moved from the low teens (13-14) to below 10 and patients per intervention from about 1.8 to 1.2. Again the rate of interventions increased faster than the rate of increase in items or patient numbers.

• Over the period of the study, the contribution of the pharmacist increased in clinical areas, but not at the expense of traditional medicines supply.

Key finding

At Southampton clinical pharmacy activities have dramatically increased to now include an average of over 1000 interventions each week, for the 8000 medicines used in over 1000 patients. These clinical activities represent not only a large workload for pharmacy but a considerable contribution to patient care. Preventing and trapping errors that occur in the use of medicines is the main purpose of clinical pharmacy activities. This is in addition to supplying over 1000 non-stock medicines

This chapter has discussed the range of clinical pharmacy activities undertaken with some quantification. The number of patients, newly prescribed items and interventions has been compared in ratios from 1990 to 2009. The next chapter will look in more detail at the interventions made.
Chapter 3 - Intervention studies

3.1 Introduction

Chapter 2 described and quantified the range of activities undertaken by clinical pharmacists. In this chapter the interventions made are reported in more detail.

The senior pharmacists in the SUHT pharmacy department trained the junior pharmacists on the activities to be undertaken in clinical areas (wards). The pharmacists recorded the interventions that they made. The annual survey on clinical pharmacy activities was accompanied by an intervention survey. These data describe what pharmacists did, i.e. their outputs, and are analysed in this chapter.

Intervention surveys have been conducted in Southampton since 1979. Initially these were monthly but now annually, or in some years, twice a year. In the author’s opinion, monthly monitoring produced a diminishing number of intervention reports. This was based on the monthly reporting undertaken in the 1980s that showed a downward trend each month and was substantiated by feedback from participants. The motivation for pharmacists to participate was not sustainable as it became a significant workload and distracted from completing normal functions. Significant underreporting devalued the perception of the work undertaken. Undertaking this task every six or twelve months appreciably increased the number and clarity of the reports submitted.

Recording the individual contributions that pharmacists made to patient care was one of the ways of measuring clinical pharmacy activity. These were written in the pharmacist’s own words on intervention forms. The intervention forms were sorted into categories so they could be collated, quantified and summarised in surveys. Reports of these surveys were then compared. This chapter describes the conduct and analysis of intervention surveys conducted over 10 years, 1999-2009. The reports have been coded, summarised and analysed for trends. The analysis reveals what pharmacists did; it describes their risk management role and their educational function.
Each year a clinical pharmacy intervention report was completed. This quantified the work undertaken, tabulated the results and presented them graphically for feedback to staff who had collected the data. Preceding each study the previous year’s results were reported again and the structure and conduct of the project was explained to all new staff.

### 3.1.1 Justification of intervention surveys

Conducting an intervention survey involved considerable organisation and workload. It required all pharmacists, and PODtechs (see Section 2.2.11), to commit time to complete the forms and contribute to the project. This was only worthwhile if the collated data produced a useful output. Table 3.1 gives the justification for the effort required.

<table>
<thead>
<tr>
<th>Table 3.1 Justification for undertaking intervention surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>To provide quantitative and qualitative descriptions of the contribution of the pharmacist to patient care.</td>
</tr>
<tr>
<td>To provide quantitative and qualitative description of the contribution of the pharmacist to cost savings.</td>
</tr>
<tr>
<td>To provide a record of an intervention as evidence in case of complaint or legal action.</td>
</tr>
<tr>
<td>To enable the workload of pharmacists to be analysed.</td>
</tr>
<tr>
<td>To demonstrate what would be lost if vacant posts were unfilled.</td>
</tr>
<tr>
<td>To provide a source of educational data, that junior pharmacists could read to learn what their colleagues did when working on the wards.</td>
</tr>
</tbody>
</table>

Clinical activities were undertaken in the dispensary and by technicians who visited wards to validate patients’ own drugs (PODs). Patients were asked to bring in the medicines that they normally consumed at home and technicians (PODtechs) checked the PODs to ensure that they were fit for use in the hospital (i.e. that they were of suitable quality and had not expired). The details were recorded on the back of the prescription and compared with what was written on the hospital chart. If there were
inconsistencies, PODtechs obtained a printout/fax of what the patient’s general practitioner had prescribed for the patient. Anomalies between these three pieces of data were communicated to the pharmacist who decided on a course of action. This may have involved discussion with the patient. This was called medicines reconciliation.

Where PODtech triangulation of data revealed inconsistencies, these were recorded on the intervention forms and coded separately. Interventions made by the dispensary staff were also given separate codes but included in the analysis of the intervention survey.

3.2 Method

3.2.1 Study setting

All pharmacists who visited wards at Southampton took part in the annual intervention study. All pharmacists were briefed on the process in the week before the survey. This was to ensure all pharmacists, especially those new to the department, were familiar with what was expected from them and how the data would be gathered and processed. A5 forms were supplied for pharmacists to record their interventions and interventions made over a seven day period were recorded. A sample form is included in Appendix 2.

During a survey period of one week, the clinical pharmacists were asked to record their identity, that of the patient and the ward they were working on. This was in order to clarify any ambiguity and ensure the coding was a true reflection of what happened. The clinical pharmacists were asked to write in their own words what happened, what they did and the outcome. The forms were placed in boxes positioned around the department. These boxes were emptied every three to four days during the week of study and the following week, by a junior pharmacist allocated to the survey. On the Thursday after the study week a reminder notice was posted in the department news briefing.
3.2.2 Data collection

Two junior pharmacists (AFC pay band 6) were specifically briefed by the author on how to organise the study and their role. The role of these juniors was to motivate their colleagues to participate, explain or resolve queries, promote the process and collect the forms. The forms were then sorted into wards and directorates. If there were no forms from a particular ward, the juniors asked the relevant pharmacist for an explanation. This often prompted the appearance of the forms for that ward. It also identified absent staff, where wards were covered by others or those who had particular time pressures.

The junior pharmacists were taught the coding system and undertook a preliminary sorting and coding of all the forms. The juniors then drafted an annual report that built on the work from the previous survey. An analysis of interventions was provided to the directorate in an annual report of clinical pharmacy activity. The author read and approved the final report before it was issued. This process was organised by the author who supervised the data collection and checked that coding of the forms was consistent within and between surveys.

The annual intervention study also contained learning points in the conduct of the study that were used to improve subsequent studies. This meant that in practice the survey forms changed slightly over the 10 years of the study; the data in this chapter were coded, analysed and presented in standard form using the 2006 format (shown in Appendix 2).

While the pharmacy at SUHT had been running intervention studies since 1979, the author was personally responsible for their conduct since 1989. Over this period the coding and questions asked were gradually refined and the amount of data collected increased. Within the study period from 1999 to 2006 the form had no substantive changes. The content of the different categories was clarified to ensure consistent coding, but not changed. However in early 2007, a revision was made, after brainstorming between the author and senior pharmacy staff. This revision followed discussions with the associate dean and lead trust clinical tutor to capture data that would enable analysis of prescribing errors as part of a grant application. The data
categories remained consistent apart from a further subdivision of interface categories in 2007. Before 2007, inpatient (IP) drug omission was grouped with IP/TTO discrepancy to capture interface errors. In 2007, IP/TTO discrepancy was separated to identify errors of transcription. A new category ‘TTO error’ was introduced to identify non-transcription errors on the discharge prescription; for example: poor identification of the length of an antibiotic course. IP drug omission was captured within a new category called ‘first prescription error’. This refers to errors on the first inpatient chart written; it includes not only omitted drugs but also errors of detail such as dose and frequency.

During and after 2007 there was therefore greater clarity about errors that occurred at the interface of primary and secondary care. The 2006 format was chosen for data analysis because most of the data were already in this format and it enabled consistent analysis of trends. The 2007-9 original forms were re-coded to enable a complete analysis.

The intervention report form (see Appendix 2) had five main sections shown in Table 3.2.

Table 3.2 Main sections of the intervention form

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Space to write a description of the intervention.</td>
<td></td>
</tr>
<tr>
<td>Coding of severity or potential consequence for the patient if the intervention had not been made.</td>
<td></td>
</tr>
<tr>
<td>Categorising and subdividing the type of intervention made.</td>
<td></td>
</tr>
<tr>
<td>Sorting the intervention into whether it was undertaken for financial impact or not, and if financial, what sort of contribution (e.g. reducing costs, formulary compliance).</td>
<td></td>
</tr>
<tr>
<td>Sorting the outcome into positive, neutral or negative in terms of whether it was accepted by doctor or nurse and subsequent action undertaken in response to the intervention</td>
<td></td>
</tr>
</tbody>
</table>

3.2.3 Data coding

The intervention forms were coded in four sections:

1 – Severity or potential consequence for the patient (code number 1-6)
2 - Type of intervention (code number 7-19)
3 - Financial impact or motivation (code number 20-23)
4 - Acceptance of output by doctor or nurse (code number 24-28)

Each intervention could then be described by these four code numbers. The codes used for these four elements are described in the following sections. This coding formed the basis for analysis of the results.

### 3.2.3.1 Coding for severity or potential consequences

The intervention form was coded for severity of consequence to the patient if the pharmacist had not intervened. These consequences were classified using a severity scoring system published by an American assistant professor called Hind Hatoum and colleagues. who conducted an economic evaluation of 1027 pharmacist interventions from 1985. Twenty-five pharmacists, 12.5 whole time equivalents (WTE), submitted their best two interventions each day over a total of five weeks from a 530 bed tertiary teaching hospital in Chicago USA. They used an intervention ranking that scored 1 to 6:

1. *Adverse significance*: recommendation may lead to adverse outcome.
2. *No significance*: informational.
3. *Somewhat significant*: benefit of recommendation neutral depending on professional interpretation.
4. *Significant*: recommendations would bring care to a more acceptable and appropriate standard of practice.
5. *Very significant*: recommendation qualified by a potential or existing major organ dysfunction.

The descriptors were adapted into the scoring system that is described in Table 3.3, which includes notes on interpretation and some examples taken from the results of the author’s research.
Interventions with a score in the range 4-6 were called serious interventions. The serious interventions were compiled into a report and submitted to the risk management department. This was undertaken at the request of the Trust risk manager because the severity would justify reporting to the National Patient Safety Agency (NPSA). The serious interventions were then analysed for type of intervention.
Table 3.3 Severity or potential harm scoring based on the work of Hatoum et al.\textsuperscript{30}

<table>
<thead>
<tr>
<th>Score</th>
<th>Notes on interpretation</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score 1</td>
<td>The pharmacist has misread the clinical situation, or is missing clinical details that make their intervention irrelevant. To some extent this is reliant on the doctor’s response and potential attitude to being challenged. It is a detrimental comment by a pharmacist, arising from incorrect advice or advice inappropriate for the particular clinical situation.</td>
<td>For example “This patient has hyponatraemia, do you want to give Slow Sodium?” The doctor explains it is an excess of water not a sodium deficit.</td>
</tr>
<tr>
<td>Score 2</td>
<td>A straightforward information request either from memory, the BNF, or by referral to the pharmacy regional drug information centre (based at SUHT). The provision of data not directly connected to a patient or an enquiry before a prescription has been written.</td>
<td>‘What is the dose of amiloride?’ ‘Is atenolol a beta-blocker?’ ‘How do I spell clopidogrel?’</td>
</tr>
<tr>
<td>Score 3</td>
<td>A minor or routine intervention made by a pharmacist. It is usually concerned with details and it delays or disrupts the drug usage process but has a lower risk to patients. These are the simple human error or 'slip-of-the-pen' type of event. A routine error in the quality of prescribing or administration.</td>
<td>Missing signature or date. Theophylline S/R but no brand. Diclofenac 75mg BD but S/R not indicated</td>
</tr>
<tr>
<td>Score 4</td>
<td>A major intervention. It is the first in the serious intervention category. It is where the pharmacist has contributed significantly to patient care and probably changed and improved what the patient receives as part of their healthcare experience. Failing to intervene would have produced significant harm to the patient but not lethal and not as permanent as 5.</td>
<td>Patient with proven heparin-induced thrombocytopenia syndrome, given heparin. Normal antihypertensives or anti-arrhythmics not prescribed on admission.</td>
</tr>
<tr>
<td>Score 5</td>
<td>A major accident has been avoided. The prescribed medicine or dose would have significantly compromised liver or renal function. It includes a limitation of the consequences of an adverse drug reaction, or caution in the licence of a medicinal product. Failing to intervene would lead to a sub-lethal event at the level where the patient might have severely damaged an organ or body system.</td>
<td>An excessive dose of an aminoglycoside that would have destroyed kidney function.</td>
</tr>
<tr>
<td>Score 6</td>
<td>A life has been saved from inappropriate use of a medicine. It is usually where a doctor has prescribed a drug that is contra-indicated in a particular patient. This would be anaphylaxis to a drug to which the patient is known to be allergic, or an overdose of a toxic agent e.g. cytotoxics.</td>
<td>Tazocin in a patient with recorded penicillin allergy. Patient prescribed aminophylline infusion and ciprofloxacin. Failure to restart narcotic post-op so possible aneurysm rupture from pain.</td>
</tr>
</tbody>
</table>
3.2.3.2  Coding system for types of Intervention

The intervention was coded from 7 to 19. The interpretation of these categories appears in Table 3.4.

Table 3.4 Codings and interpretations for intervention type.

<table>
<thead>
<tr>
<th>Code/Title</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>07 – Documentation</td>
<td>A prescription is <em>illegible</em> when it is badly written such that the pharmacist (who is familiar with drug names) is unable to read it. Doubt over the drug name due to poor handwriting can produce serious errors. Use of neat block capitals and generic names is recommended. An <em>ambiguous</em> prescription is where a drug name is miss-spelt and/or could be mistaken for a different medicine. Where accurate dispensing or administration is not possible because the prescription is not clear or lacks essential descriptive details An illegal prescription is usually one where controlled drug details are missing or not conforming to regulations. It also covers <em>omission of details</em> such as date, signature, dose, route, timing, indication, strength or form to make the prescription legal. This would also be where the prescription is for the wrong patient.</td>
</tr>
<tr>
<td>08 – TTO/IP discrepancy or IP drug omission error. The discharge prescription (TTO) does not match the inpatient chart (IP). (Interface error)</td>
<td>Identification and management of a discrepancy between what has been prescribed for an inpatient (IP) and the proposed medication for discharge. The pharmacist confirms with the doctor that this is intentional or an error. Also where what is prescribed on the first in-patient prescription is not the same as the PODs or the details on a repeat slip or letter or a faxed copy from the general practitioner</td>
</tr>
<tr>
<td>09 – Choice of / need for drug</td>
<td>This could be where the drug prescribed is not licensed or indicated for the condition being treated (i.e. miss-selected therapeutic group). It could be that the drug chosen has an adverse side-effect profile in this particular patient or the pharmacist thinks that another agent in the same therapeutic group would be superior in some way. Or guidelines might suggest the use of a drug from a different therapeutic group. It may be that the symptoms have resolved and the treatment is no longer needed. It could be the prescription of a medicine that the patient has never received or does not need. It could be that national guidelines recommend a drug that has not been prescribed.</td>
</tr>
<tr>
<td>10 - Choice of dose/frequency or timing</td>
<td>Where the dose or frequency does not fit within the normal range for the drug compared with British National Formulary or other authoritative reference. It could be outside the normal range used in recognised clinical practice. The timing might not match usual practice.</td>
</tr>
<tr>
<td>11 – Choice of form/strength or route</td>
<td>The drug may not be available in the form prescribed or inappropriate for this patient (e.g. slow-release) or affecting compliance or bioavailability. The strength may be unavailable, impossible or inappropriate in this patient. This is not the same as when the strength is omitted, because this would be coded under documentation. The route may be inappropriate (e.g. nil by mouth) or unlicensed/unalusual or not match the drug name.</td>
</tr>
<tr>
<td>12 - Drug Duration</td>
<td>Asking about the length of therapy (especially antibiotics) to avoid prolonged or inappropriate courses of treatment or whether steroids need to stop.</td>
</tr>
<tr>
<td>13 - Pharmacokinetics/TDM.</td>
<td>Where the pharmacist has advised about the kinetics of a particular drug or undertaken a computer prediction of expected drug levels. Where pharmacokinetic calculations have been performed or doses recommended especially if a drug has a narrow therapeutic range. Dose reduction due to kidney dysfunction or advice related to therapeutic drug monitoring. Advice on the dose or frequency adjustment following a blood level result. It also includes advice to obtain a blood level and advice on normal ranges, timing of samples or reported data.</td>
</tr>
<tr>
<td>14 – Drug administration /incompatibility/calculations</td>
<td>A drug administration problem or question about how to administer in a particular patient. Identifying potential incompatibility or recommending how to combine or mix therapies. Checking a primary calculation of dose or infusion rate.</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>15 – Drug interaction / adverse drug reactions / side-effects / monitoring</td>
<td>Raising awareness or managing an interaction between two or more medicines. Avoiding a potential interaction by choosing alternative drugs. An intervention may alert a prescriber to potential side-effects or how to avoid them. This includes checking for allergies and choosing alternatives. Identifying symptoms that are potential adverse drug effects or drug related events and how to manage them. Monitoring pathology results to avoid or manage a side-effect.</td>
</tr>
<tr>
<td>16 - Drug supply/storage</td>
<td>Identifying or resolving problems of supply or storage of medicines.</td>
</tr>
<tr>
<td>17 - Other drug information</td>
<td>Providing information or education that does not fit other categories. It might include questions about drug availability on the hospital formulary, where no drug has been prescribed and it is not intended for a particular patient. It could be about the application process for inclusion on the hospital formulary. This includes providing financial predictions or analysis. Costing of patients or bids or pharmacy procedures.</td>
</tr>
<tr>
<td>18 – Nutrition</td>
<td>Drafting, advising on, or prescribing parenteral nutrition, nutrients, and vitamins. Raising awareness, preventing or managing refeeding syndrome.</td>
</tr>
<tr>
<td>19 – Therapeutic substitution</td>
<td>Use of a local policy that empowers pharmacists to make changes according to an agreed protocol. It is based on interventions previously made that were always accepted. The actions need to be written in the notes and subsequently countersigned by the doctor.</td>
</tr>
</tbody>
</table>
3.2.3.3 Financial motivation

The financial impact of pharmacist interventions (codes 20-23) was notoriously difficult to quantify. The financial code was therefore an indication of the motivation of the pharmacist making it. In other words, was it undertaken to improve compliance with the formulary, to provide cost analysis or to save money, or was it undertaken for clinical reasons (mainly for patient benefit). Coding for this section appears in Table 3.5. The non-financial interventions are discussed further in Chapter 5.

Table 3.5 Financial motivation codings and interpretation.

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Cost information/analysis</td>
<td>The provision of data on costs, or trends or analysis predicting costs or calculating costs of treatments or annual drug usage.</td>
</tr>
<tr>
<td>21</td>
<td>Formulary compliance</td>
<td>Information about the contents of the hospital limited list, the process of adding drugs to the formulary, progress of a particular applications for a new drug or managing non-compliance.</td>
</tr>
<tr>
<td>22</td>
<td>Attempt to decrease costs</td>
<td>Suggesting a cheaper drug or more economic use of a product or regime.</td>
</tr>
<tr>
<td>23</td>
<td>Non-financial</td>
<td>Where the primary motivation for the intervention was not financial even if the clinical decision avoids costs inadvertently or saves costs.</td>
</tr>
</tbody>
</table>
3.2.3.4 Outcome of intervention

The outcome of the intervention was how it was received by the healthcare team. Coding for this section appears in Table 3.6. There were three main categories: positive (24, 25 & 26), neutral (27) or negative (28). Code 24 was the most positive response where the doctor changed the treatment, whereas code 28 was where the pharmacist had inadequate information, experience or had produced the wrong conclusion.

**Table 3.6 Outcome of intervention codes and interpretation**

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>Treatment altered/implemented</td>
<td>A positive response that changes the treatment or fully accepts advice.</td>
</tr>
<tr>
<td>25</td>
<td>Chart altered</td>
<td>A positive response where the treatment is not changed but the chart is altered to make intention clear.</td>
</tr>
<tr>
<td>26</td>
<td>Information accepted</td>
<td>A positive response where data or advice is accepted but 24 or 25 do not apply.</td>
</tr>
<tr>
<td>27</td>
<td>Known/problem not pursued</td>
<td>A neutral response where either the information is already known or no action is taken at that time. Provision of information may still be worthwhile included checking or confirming that due consideration has been given to a specified aspect of therapy.</td>
</tr>
<tr>
<td>28</td>
<td>Treatment unaltered</td>
<td>A negative response: either inappropriate, not relevant or total rejection of suggestion/advice.</td>
</tr>
</tbody>
</table>
3.2.3.5. Severity rating scale validation

While the rating scale is closely similar to that established by Hatoum et al. shown in Table 3.3, it was important to investigate if the ratings assigned by the author were generalisable when used by other experienced clinical pharmacists in a study of this type.

To this end, a sample of 104 events was taken by random sampling from all those recorded in the study, stratified to contain examples of severity grades 2 to 6 as judged by the author. These were then presented, along with Table 3.3, to three clinical pharmacists from a variety of backgrounds, who were experienced in judging the severity of medication errors, drug interactions and side effects. The first (Rater A) was a Medicines Management Risk Lead (AFC band 8b) from SUHT; the second (Rater B) was an experienced Medicines Information Principal Pharmacist from SUHT who had used the rating scale in a similar but separate study and the third (Rater C), an experienced lecturer in clinical pharmacy from the University of Portsmouth School of Pharmacy (the author’s supervisor).

Each subject was asked to rate the 104 examples in isolation from the others and to email the results for analysis. This was accomplished firstly by calculating Cohen’s kappa for a comparison of the author’s ratings with each of the participants. To gain a sense of the overall level of agreement between all four assessors, Kendal’s coefficient of concordance was calculated using Minitab Version 15. To gain an impression of how each rater classified the events into the two broad categories of minor impact (severity grades 2 or 3; there were 46 rated by the author as such) and higher severity (grades 4-6; there were 58 rated by the author as such), a series of Chi-squared tests was conducted to investigate any differences in severity rating between the raters and the author and the four raters overall.

3.2.3.6. Statistical techniques

Results were analysed using mainly descriptive statistics. The Chi-squared test was employed to compare nominal data and a level of statistical significance of p<0.05 was accepted.
3.3 Results

3.3.1 Numbers of interventions

Data for week-long periods conducted from 1999 to 2009 using the standardised 2006 format are shown in Table 3.7 and Figure 3.1. There was a gap in the data between 2002 and 2004 where the LENARD studies were undertaken; see Section 2.1.6 for LENARD details. There was no breakdown of interventions in 2005. Total numbers of interventions are presented over the last 10 years. Two years (2001 and 2007a) had detailed, representative, and complete data sets; these are compared in more detail, in Section 3.3.2.2. They illustrate the data either side of the LENARD data gap. 2000a covered a survey in the early part of that year and 2000b later in that calendar year; as did 2001a and 2001b and 2007a and 2007b.

Table 3.7 Total interventions per week

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>613</td>
<td>492</td>
<td>739</td>
<td>425</td>
<td>608</td>
<td>1197</td>
<td>910</td>
<td>912</td>
<td>981</td>
<td>1058</td>
<td>777</td>
</tr>
</tbody>
</table>

Figure 3.1 Total interventions per week-long study over the period 1999-2009 (data for 2002 to 2004 were not collected – see text for reasons).

3.3.2 Severity or consequence coding

3.3.2.1 Severity rating scale validation

Cohen’s kappa can range from 0 (no agreement) to 1 (perfect agreement). Campbell and Machin interpret a result for Cohen’s kappa of 0.4 or less as representing
‘poor’, 0.4-0.6 as ‘moderate’ and between 0.6 and 1, increasingly ‘substantial’ agreement.

Values for Cohen’s kappa derived from the author’s validation experiment were 0.505, 0.731 and 0.898 for raters A, B and C respectively, indicating moderate agreement in one case and good agreement in two others.

Kendall’s coefficient of concordance, calculated for what is effectively weak ordinal data, gave a value of 0.872, which was highly significant (p<0.0001) and indicates good overall agreement between raters (see Section 3.4.1 for discussion).

Using the author’s ratings as the comparator, there were no statistically significant differences in raters’ assessment of events as either minor or major (p=0.487, p=0.889 and p=0.127 for raters A, B and C respectively) or indeed overall (p=0.321).

### 3.3.2.2 Distribution of severity scoring

Table 3.8 and Figure 3.2 show the data, grouping codes 1-3 together as representing minor or routine interventions, but reporting interventions with severity score 4, 5 and 6 individually.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3</td>
<td>482</td>
<td>377</td>
<td>623</td>
<td>323</td>
<td>462</td>
<td>552</td>
<td>545</td>
<td>806</td>
<td>778</td>
<td>518</td>
</tr>
<tr>
<td>4</td>
<td>115</td>
<td>100</td>
<td>89</td>
<td>91</td>
<td>131</td>
<td>331</td>
<td>317</td>
<td>166</td>
<td>257</td>
<td>235</td>
</tr>
<tr>
<td>5</td>
<td>16</td>
<td>14</td>
<td>26</td>
<td>9</td>
<td>13</td>
<td>23</td>
<td>45</td>
<td>7</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>% 1, 2, 3</td>
<td>78.6</td>
<td>76.6</td>
<td>84.3</td>
<td>76.0</td>
<td>76.0</td>
<td>60.7</td>
<td>59.8</td>
<td>82.2</td>
<td>73.5</td>
<td>66.7</td>
</tr>
</tbody>
</table>
Figure 3.2 Distribution of severity of all interventions per survey

Table 3.9 shows the average severity results for 1999-2001 compared with 2006-2009 and the total number of interventions for 1999-2009

<table>
<thead>
<tr>
<th>Year</th>
<th>1999-2001 (1,2,3)</th>
<th>2006-2009 (4,5,6)</th>
<th>1999-2009 (Totals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3</td>
<td>2267 (78.8%)</td>
<td>3199 (69.0%)</td>
<td>5466 (72.7%)</td>
</tr>
<tr>
<td>4</td>
<td>526 (18.3%)</td>
<td>1306 (28.2%)</td>
<td>1832 (24.4%)</td>
</tr>
<tr>
<td>5</td>
<td>78 (2.7%)</td>
<td>120 (2.6%)</td>
<td>198 (2.6%)</td>
</tr>
<tr>
<td>6</td>
<td>6 (0.2%)</td>
<td>13 (0.3%)</td>
<td>19 (0.3%)</td>
</tr>
</tbody>
</table>

A chi-squared analysis of data derived from the two study periods revealed the difference in distribution of the interventions in terms of severity was highly significant ($X^2=95.06$, df=3, p<0.001) with more interventions being recorded as severe in the 2006-9 period, mainly at level 4 (18.3% vs 28.2%).

3.3.2.3 Further analysis of the serious interventions (4, 5 & 6)

Figures 3.3 and 3.4 show bar charts displaying the serious (severity 4, 5 and 6) intervention data from Table 3.8.
Figure 3.3 Distribution of severity of serious interventions

Figure 3.4 is the same as Figure 3.3 except the Y scale has been truncated to illustrate, more clearly, the score 5 and 6 interventions.

Figure 3.4 Truncated distribution of severity of serious intervention

3.3.2.4 Detailed results for 2001 and 2007

There were two surveys in 2001 and 2007 with detailed and comprehensive data allowing a clear comparison between the early years (1999-2002) and the later years (2006-2009) of the decade. These have been labelled as signal years and have been compared to illustrate the range and type of interventions made. In Table 3.10 and Figure 3.5 the two signal years have been compared.
Table 3.10 Distribution of severity scores for 2001 and 2007

<table>
<thead>
<tr>
<th>Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001 (%)</td>
<td>0</td>
<td>53</td>
<td>409</td>
<td>131</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(8.7)</td>
<td>(67.3)</td>
<td>(21.5)</td>
<td>(2.1)</td>
<td>(0.3)</td>
</tr>
<tr>
<td>2007 (%)</td>
<td>0</td>
<td>87</td>
<td>458</td>
<td>317</td>
<td>45</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(9.5)</td>
<td>(50.2)</td>
<td>(34.8)</td>
<td>(4.9)</td>
<td>(0.5)</td>
</tr>
</tbody>
</table>

Figure 3.5 Percentage distribution of severity scores for 2001 & 2007

An analysis of the distribution of serious (grades 4-6) and non-serious (grades 1-3) interventions between the two study years revealed a highly statistically significant difference ($X^2 = 42.966$, df=1, p<0.001). This indicates a real increase in the proportion of serious interventions made in 2007.

3.3.3 Trends in intervention types

Table 3.11 shows the numbers for the different types of interventions for each of the years 2006-2009. These are then ranked overall in Table 3.12.
Table 3.11 Type of intervention 2006 – 2009

<table>
<thead>
<tr>
<th>Descriptor / Study</th>
<th>Type</th>
<th>2009</th>
<th>2008</th>
<th>2007b</th>
<th>2007a</th>
<th>2006</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation</td>
<td>7</td>
<td>44</td>
<td>100</td>
<td>66</td>
<td>29</td>
<td>48</td>
<td>287</td>
</tr>
<tr>
<td>TTO/IP discrepancy or IP drug omission</td>
<td>8</td>
<td>206</td>
<td>196</td>
<td>283</td>
<td>261</td>
<td>178</td>
<td>1124</td>
</tr>
<tr>
<td>Choice of drug or need for drug</td>
<td>9</td>
<td>160</td>
<td>240</td>
<td>163</td>
<td>151</td>
<td>148</td>
<td>862</td>
</tr>
<tr>
<td>Choice of dose / frequency/timing</td>
<td>10</td>
<td>158</td>
<td>249</td>
<td>222</td>
<td>193</td>
<td>216</td>
<td>1038</td>
</tr>
<tr>
<td>Choice of form/ strength/route</td>
<td>11</td>
<td>51</td>
<td>60</td>
<td>56</td>
<td>51</td>
<td>73</td>
<td>291</td>
</tr>
<tr>
<td>Drug duration</td>
<td>12</td>
<td>23</td>
<td>69</td>
<td>48</td>
<td>52</td>
<td>67</td>
<td>259</td>
</tr>
<tr>
<td>Pharmacokinetics/TDM</td>
<td>13</td>
<td>15</td>
<td>24</td>
<td>24</td>
<td>29</td>
<td>25</td>
<td>117</td>
</tr>
<tr>
<td>Drug admin/incompat/calc</td>
<td>14</td>
<td>14</td>
<td>21</td>
<td>20</td>
<td>28</td>
<td>23</td>
<td>106</td>
</tr>
<tr>
<td>Drug interaction/ADR/SE/monitoring</td>
<td>15</td>
<td>60</td>
<td>45</td>
<td>52</td>
<td>40</td>
<td>85</td>
<td>282</td>
</tr>
<tr>
<td>Drug supply/storage</td>
<td>16</td>
<td>9 (1.2)</td>
<td>13</td>
<td>5</td>
<td>17</td>
<td>15</td>
<td>59</td>
</tr>
<tr>
<td>Other drug information</td>
<td>17</td>
<td>19</td>
<td>25</td>
<td>17</td>
<td>16</td>
<td>20</td>
<td>97</td>
</tr>
<tr>
<td>Nutrition</td>
<td>18</td>
<td>16</td>
<td>3</td>
<td>12</td>
<td>14</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>Therapeutic substitution</td>
<td>19</td>
<td>2 (2.6)</td>
<td>13</td>
<td>13</td>
<td>31</td>
<td>7</td>
<td>66</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td>777</td>
<td>1058</td>
<td>981</td>
<td>912</td>
<td>910</td>
<td>4638</td>
</tr>
</tbody>
</table>

2006-2009 yielded a total of 4638 interventions and a collective pattern shown in the Table 3.12 and Figure 3.6. The code numbers used in Figure 3.6 correspond to those used in Table 3.12. The three most common types of intervention represented 65.2% (3020/4638) of all interventions.
Table 3.12 Ranking and percentage of types of intervention 2006 to 2009

<table>
<thead>
<tr>
<th>Code</th>
<th>Type</th>
<th>Interventions</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>TTO/IP discrepancy or IP drug omission</td>
<td>1124</td>
<td>24.2</td>
</tr>
<tr>
<td>10</td>
<td>Choice of dose/frequency</td>
<td>1038</td>
<td>22.4</td>
</tr>
<tr>
<td>9</td>
<td>Choice of, or need for drug</td>
<td>862</td>
<td>18.6</td>
</tr>
<tr>
<td>11</td>
<td>Choice of form/strength/route</td>
<td>291</td>
<td>6.3</td>
</tr>
<tr>
<td>7</td>
<td>Documentation</td>
<td>287</td>
<td>6.2</td>
</tr>
<tr>
<td>15</td>
<td>Drug interaction/ADR/SE</td>
<td>282</td>
<td>6.1</td>
</tr>
<tr>
<td>12</td>
<td>Drug duration</td>
<td>259</td>
<td>5.6</td>
</tr>
<tr>
<td>13</td>
<td>Pharmacokinetics/TDM</td>
<td>117</td>
<td>2.5</td>
</tr>
<tr>
<td>14</td>
<td>Drug admin/incompatible/calc</td>
<td>106</td>
<td>2.3</td>
</tr>
<tr>
<td>17</td>
<td>Other drug information</td>
<td>97</td>
<td>2.1</td>
</tr>
<tr>
<td>19</td>
<td>Therapeutic substitution</td>
<td>66</td>
<td>1.4</td>
</tr>
<tr>
<td>16</td>
<td>Drug supply/storage</td>
<td>59</td>
<td>1.3</td>
</tr>
<tr>
<td>18</td>
<td>Nutrition</td>
<td>50</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Figure 3.6 Ranking and percentage of types of intervention 2006-9
* see Table 3.12 for code definitions

3.3.3.1 Trends in intervention types for 2001 and 2007
There were a total of 608 interventions in 2001 and 912 interventions in 2007. This represents an increase of 304 or 50% in 6 years.
A specific comparison was made between the results for 2001b and 2007a to see if the data had significantly changed before or after the data gap in 2002-5. In 2005-2007 there was a big increase in the total number of interventions, which coincided with an expansion of the clinical pharmacy service into a new admissions unit. This greater contribution to the admission phase of the hospital episode increased the pharmacists’ interventions on inpatient drug omissions and could have distorted coding for choice, dose/frequency and interaction/side-effects/ADRs.

A Chi-squared test revealed a highly significant difference in the distribution of intervention types in 2007 compared with 2001 (X^2= 101.483, df=12, p<0.0001). The major areas contributing to this difference are shown in bold in Table 3.13.

Table 3.13 A comparison types of intervention in 2001 and 2007.

<table>
<thead>
<tr>
<th>Year / code</th>
<th>2001b (N=608)</th>
<th>2007a (N=912)</th>
<th>2001 %</th>
<th>2007 %</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>176</td>
<td>193</td>
<td>28.9</td>
<td>21.2</td>
<td>Choice of dose/frequency</td>
</tr>
<tr>
<td>9</td>
<td>97</td>
<td>151</td>
<td>16.0</td>
<td>16.6</td>
<td>Choice of, need for drug</td>
</tr>
<tr>
<td>8</td>
<td>78</td>
<td>261</td>
<td>12.8</td>
<td>28.6</td>
<td>TTO/IP discrepancy or IP drug omission</td>
</tr>
<tr>
<td>7</td>
<td>51</td>
<td>29</td>
<td>8.4</td>
<td>3.2</td>
<td>Documentation</td>
</tr>
<tr>
<td>15</td>
<td>51</td>
<td>40</td>
<td>8.4</td>
<td>4.4</td>
<td>Drug interaction/ADR/SE</td>
</tr>
<tr>
<td>12</td>
<td>42</td>
<td>52</td>
<td>6.9</td>
<td>5.7</td>
<td>Drug duration</td>
</tr>
<tr>
<td>11</td>
<td>28</td>
<td>51</td>
<td>4.6</td>
<td>5.6</td>
<td>Choice of form/strength/route</td>
</tr>
<tr>
<td>13</td>
<td>26</td>
<td>29</td>
<td>4.3</td>
<td>3.2</td>
<td>Pharmacokinetics/TDM</td>
</tr>
<tr>
<td>19</td>
<td>9</td>
<td>31</td>
<td>1.5</td>
<td>3.4</td>
<td>Therapeutic substitution</td>
</tr>
<tr>
<td>18</td>
<td>20</td>
<td>14</td>
<td>3.3</td>
<td>1.5</td>
<td>Nutrition</td>
</tr>
<tr>
<td>17</td>
<td>17</td>
<td>16</td>
<td>2.8</td>
<td>1.8</td>
<td>Other drug information</td>
</tr>
<tr>
<td>14</td>
<td>6</td>
<td>28</td>
<td>1.0</td>
<td>3.1</td>
<td>Drug admin/incompatible/calc</td>
</tr>
<tr>
<td>16</td>
<td>7</td>
<td>17</td>
<td>1.2</td>
<td>1.9</td>
<td>Drug supply/storage</td>
</tr>
<tr>
<td>608</td>
<td>912</td>
<td>100</td>
<td>100</td>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

Table 3.13 shows that in 2001, the three most frequently occurring categories were type 10, 9, and 8 which represented 57.7% (351/608) of the total. Table 3.13 also shows that in 2007, the three most frequently occurring categories were type 8, 10, and 9 which represented 66.3% (605/912) of the total.
Table 3.13 shows that in 2001 there were higher proportions for intervention types 10, 7, 15, 12, 18 and 17, and that in 2007 there were higher proportions for intervention types 9, 8, 11, 19, 14 and 16. Data are represented as a bar chart in Figure 3.7.

Figure 3.7 Comparison between 2001 & 2007 of the percentage of different types of intervention. See Table 3.13 for original data and code interpretation.

Table 3.14 shows the size of the changes between 2001 and 2007. It also shows how the ranking of intervention categories changed between these two studies. Data are also displayed as a bar chart in Figure 3.8.
Table 3.14 Number of interventions in 2007 and magnitude of change since 2001.

<table>
<thead>
<tr>
<th>Code</th>
<th>Rank order number of 2007 events</th>
<th>% increased or decreased from 2001 to 2007</th>
<th>Rank order % increase / decrease</th>
<th>Type of intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>10</td>
<td>367</td>
<td>I</td>
<td>Drug admin/incompatible/calc</td>
</tr>
<tr>
<td>19</td>
<td>7</td>
<td>244</td>
<td>II</td>
<td>Therapeutic substitution</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>235</td>
<td>III</td>
<td>TTO/IP discrepancy or IP drug omission</td>
</tr>
<tr>
<td>16</td>
<td>11</td>
<td>143</td>
<td>IV</td>
<td>Drug supply/storage</td>
</tr>
<tr>
<td>11</td>
<td>5</td>
<td>82</td>
<td>V</td>
<td>Choice of form/strength/route</td>
</tr>
<tr>
<td>9</td>
<td>3</td>
<td>56</td>
<td>VI</td>
<td>Choice of drug or need for drug</td>
</tr>
<tr>
<td>12</td>
<td>4</td>
<td>24</td>
<td>VII</td>
<td>Drug duration</td>
</tr>
<tr>
<td>13</td>
<td>9</td>
<td>12</td>
<td>VIII</td>
<td>Pharmacokinetics/TDM</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>10</td>
<td>IX</td>
<td>Choice of dose/frequency</td>
</tr>
<tr>
<td>17</td>
<td>12</td>
<td>-6</td>
<td>X</td>
<td>Other drug information</td>
</tr>
<tr>
<td>15</td>
<td>6</td>
<td>-22</td>
<td>X1</td>
<td>Drug interaction/ADR/SE</td>
</tr>
<tr>
<td>18</td>
<td>13</td>
<td>-30</td>
<td>XII</td>
<td>Nutrition</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>-43</td>
<td>XIII</td>
<td>Documentation</td>
</tr>
</tbody>
</table>

Figure 3.8 Percentage changes from 2001 data to 2007 based on the data in Table 3.13.

The order and identity of types of intervention is taken from Table 3.13. Overall there were 608 interventions in 2001 and 912 in 2007. This represents an increase of 304 or 50% in 6 years shown by the blue line.
3.3.4 Financial motivation

Table 3.15 shows the distribution of the financial motivation of the intervention. Data is incomplete for 1999 but what was available is included.

Table 3.15 Financial motivation of interventions 1999 to 2009

<table>
<thead>
<tr>
<th>Year / Label / Code number</th>
<th>1999 %</th>
<th>2001 (%)</th>
<th>2006 (%)</th>
<th>2007a (%)</th>
<th>2007 b (%)</th>
<th>2008 (%)</th>
<th>2009 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost info</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>0</td>
<td>1 (0.1)</td>
<td>1 (0.1)</td>
<td>2 (0.2)</td>
<td>1 (0.1)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Formulary</td>
<td>21</td>
<td>26 (4.3)</td>
<td>29 (3.1)</td>
<td>56 (6.1)</td>
<td>31 (3.2)</td>
<td>47 (4.4)</td>
<td>18 (2.3)</td>
</tr>
<tr>
<td>Reduce cost</td>
<td>22</td>
<td>44 (7.2)</td>
<td>35 (3.8)</td>
<td>26 (2.9)</td>
<td>25 (2.5)</td>
<td>38 (3.6)</td>
<td>16 (2)</td>
</tr>
<tr>
<td>Financial</td>
<td>20+21</td>
<td>70 (11.5)</td>
<td>65 (7.1)</td>
<td>83 (9.1)</td>
<td>58 (5.9)</td>
<td>86 (8.1)</td>
<td>35 (4.4)</td>
</tr>
<tr>
<td>Non-financial</td>
<td>23</td>
<td>89.0</td>
<td>538 (88.5)</td>
<td>845 (92.9)</td>
<td>829 (90.9)</td>
<td>923 (94.1)</td>
<td>973 (91.9)</td>
</tr>
</tbody>
</table>

Table 3.15 shows that before 2006, the financial interventions contributed about 11%, but after 2006 it was less than 9.1%. In other words, this shows that in 2006 to 2009 over 90% of pharmacists’ interventions were initiated for non-financial reasons.

3.3.5 Outcome of intervention

Table 3.16 shows the distribution of the outcome or acceptance of the intervention. This was what happened subsequently.

Table 3.16 Outcome of interventions

<table>
<thead>
<tr>
<th>Year / Label</th>
<th>Code</th>
<th>1999 (%)</th>
<th>2001 (%)</th>
<th>2006 (%)</th>
<th>2007a (%)</th>
<th>2007 b (%)</th>
<th>2008 (%)</th>
<th>2009 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment altered</td>
<td>24</td>
<td>331 (54)</td>
<td>372 (61.2)</td>
<td>643 (70.7)</td>
<td>379 (42.2)</td>
<td>508 (51.8)</td>
<td>451 (42.6)</td>
<td>529 (68.1)</td>
</tr>
<tr>
<td>Chart altered</td>
<td>25</td>
<td>123 (20)</td>
<td>145 (23.8)</td>
<td>180 (19.8)</td>
<td>336 (37.1)</td>
<td>211 (21.5)</td>
<td>423 (39.9)</td>
<td>156 (20.1)</td>
</tr>
<tr>
<td>Info accepted</td>
<td>26</td>
<td>104 (17)</td>
<td>70 (11.5)</td>
<td>67 (7.4)</td>
<td>177 (19.4)</td>
<td>213 (21.7)</td>
<td>159 (15)</td>
<td>68 (8.7)</td>
</tr>
<tr>
<td>Known</td>
<td>27</td>
<td>37 (6)</td>
<td>12 (2.0)</td>
<td>14 (1.5)</td>
<td>12 (1.3)</td>
<td>33 (3.4)</td>
<td>20 (1.9)</td>
<td>16 (2.1)</td>
</tr>
<tr>
<td>Unaltered</td>
<td>28</td>
<td>18 (3)</td>
<td>9 (1.5)</td>
<td>6 (0.7)</td>
<td>8 (0.9)</td>
<td>15 (1.5)</td>
<td>7 (0.7)</td>
<td>7 (0.9)</td>
</tr>
<tr>
<td>Positive outcome</td>
<td>24+25</td>
<td>558 (91.0)</td>
<td>587 (96.6)</td>
<td>890 (97.8)</td>
<td>900 (98.7)</td>
<td>932 (95.0)</td>
<td>1033 (97.5)</td>
<td>753 (96.9)</td>
</tr>
</tbody>
</table>
Positive outcomes were where the doctor agreed with the pharmacist and either changed the treatment the patient was receiving, altered the chart to make their intentions clearer or accepted the information (when no action was required). Table 3.16 shows that 91.0% to 98.7% of interventions received a positive response.

3.4 Discussion

3.4.1 Validation of the severity rating scale

The rating scale used in the present study has been used by pharmacists to score the severity of medication errors in a variety of settings either as members of a multidisciplinary team, or by a single operator. Dean and Barber judged their system to be reliable, even in the absence of knowledge about specific patient outcomes; however, the mean of at least four judges, scoring each error individually, was required to achieve a reliable score when the judges were drawn from more than one discipline (i.e. pharmacy, medicine and nursing). More recently, Williams and Ashcroft cited inter-professional differences in grading the severity of medication errors reported to the UK National Reporting and Learning System, with nurses and pharmacy technicians assigning higher severity ratings than pharmacists or doctors. In at least one recent study, the judgement of a single, independent senior pharmacist appears to have been acceptable.

The author’s validation study provides evidence that the rating scale, as used by the author, produced similar results to those obtained in the hands of other pharmacists experienced in the use of such rating scales, with at least moderate agreement between them. A high and statistically significant value for Kendall’s coefficient of concordance indicates that there was considerable agreement between users also. This was reflected in the distribution of events into minor or major categories, where differences between raters were insignificant.

The potential severity of an event is frequently open to a degree of personal interpretation, often based on professional experience; but the results do provide evidence that the author was applying the rating scale in a realistic and clinically consistent fashion. Thus the author could conclude that his application of the severity
rating scale was validated. His assessment of every event in the study was likely to have avoided those minor inconsistencies which would have been introduced if multiple single assessors had been used, particularly if they came from disciplines other than pharmacy. Due to the number of events included, the use of a panel to reach consensus was impractical.

3.4.2 Number of interventions

The first thing to discuss is the obvious change in the number of interventions made in the prevalence survey before 2002 and after 2004. In the period 1999-2001 the average number of interventions in each week long survey was 575 (SD=121) and during 2005-9 it was 973 (SD=144). An independent groups t-test revealed a statistically significant difference (t=4.97, df=8, p=0.001, with an estimated difference in means of 398 and a 95% CI of 212.7-581.5). As discussed in Chapter 2, there was a change from inpatient/discharge to an additional focus on admissions and medicines reconciliation. This shows that pharmacists were making a more frequent contribution to patient care in the later stages of the study.

In addition, the author believes that pharmacists started to be more proactive based on their increasing confidence in their knowledge of therapeutics. This was enhanced by the availability of NICE guidance on a range of therapies, for example the prevention of ventilator associated pneumonia\textsuperscript{144} or national service frameworks, guidelines and audit targets such as the myocardial infarction national audit programme.\textsuperscript{145} These specified the treatments recommended by NICE following a diagnosis. At the time, there had been speculation that junior doctor knowledge of therapeutics was imperfect due to a lack of training in clinical pharmacology\textsuperscript{146,147,148}; this opinion has also been expressed more recently.\textsuperscript{149,150} and this increased, and probably still perpetuates, the opportunity for the pharmacist to contribute.

3.4.3 Severity scoring

3.4.3.1 Score 1 Interventions

There were very few interventions that were allocated a severity score of one, perhaps because pharmacists were reluctant to report them. Since the landmark study ‘To err
is human: building a safer healthcare system’ published by the US Institute of Medicine\(^4\) which laid the foundations for interventions aimed at reducing treatment risks for all patients, later publications have indicated a persisting reluctance among healthcare professionals to report negative practice.\(^{151,152}\)

Creating a culture of safety requires changes that carers may perceive as threats to their autonomy and authority. Fear of accusations of malpractice may create an unwillingness to discuss or admit to errors. Anecdotally, from the author’s research, junior pharmacists were reluctant to complete an intervention form for something they thought had ‘gone wrong’ or where they had made a mistake; although each of these events was an opportunity to improve. Where this occurred, the junior should have discussed the scenario with a senior colleague to ensure that they undertook appropriate reading or learning to improve their knowledge. In addition, if their delivery of the message was deficient they needed to improve this by discussion of alternative approaches or phraseology. Where a poor communication, rather than content was identified, a senior pharmacist may have repeated the intervention with a more senior doctor, in order to protect the patient from harm.

In the author’s experience there are occasions where the pharmacist to doctor communication does not work effectively and escalation, in the patient’s interest, is necessary. This might be style of message delivery, or cultural/gender issues, or simply contextual (e.g. it was a bad time to talk to the doctor). These can be very difficult situations but must be managed where patient safety is threatened.

The Code 1 intervention was set up partly for completeness but also in the early days, to uncover those interventions that were inappropriate. For example a pharmacist intervened to get cefuroxime IV converted to an oral cephalosporin such as cephradine or cefalexin. However this was inappropriate as cultures showed the presence of Haemophilus influenza, and cefaclor was the only oral cephalosporin active against this organism. So further information was needed to advise on the most appropriate therapy. This category was a useful learning tool to uncover actions that were pharmaceutically reasonable but clinically inappropriate.
3.4.3.2 Score 2 interventions

Score 2 interventions were those where information was provided to direct questions that did not fit into other categories. These were direct questions of fact unrelated to a particular patient, or questions of policy or procedure. For example, what were the side-effects of a new drug that had not yet been prescribed; i.e. doctor or nurse education. If the drug had been prescribed, the pharmacist might have recommended various biochemical tests to ensure early detection of side-effects. If monitoring had already revealed a side-effect, then the pharmacist might have alerted the doctor to this and recommended changing the drug; but this would then fall in higher score categories.

3.4.3.3 Score 3 interventions

Score 3 interventions formed the bulk of all interventions; they varied from dispensary-style documentation interventions and miss-spelt drug names to enforcing formulary compliance where there was no clinical consequence to the patient. For example, when the doctor prescribed a new sulphonylurea antidiabetic drug glimepiride, which was not on the formulary at Southampton, the pharmacist got this changed to gliclazide, which was on the formulary. Another example was when the prescriber wrote gliclazide 5mg (this could not be administered because the smallest tablets are 80mg). It was not clear initially if this was the wrong dose or the wrong drug; when the pharmacist investigated they found that the drug name was correct but the dose was incorrect. The pharmacist spoke to the doctor who changed the dose to 5mg. The ward did not keep gliclazide as stock so it was unlikely that the patient would have come to any harm.

Score 3 interventions formed the majority of interventions made by junior pharmacists. The author has discussed this with senior pharmacists who anecdotally report that they made these interventions but were less likely to complete an intervention form because they wanted to focus their time on the more serious interventions. These interventions were still important for the smooth running of the drug usage process and may have caused significant delays to medicine supply and administration. Individually they were often easy to resolve but collectively they also
consumed an appreciable amount of time. Some senior pharmacists will have been sufficiently confident about the situation to simply make an annotation to the chart for example amending ‘glipizide 4mg’, when the doctor’s intention was clearly 5mg. A junior pharmacist would have quite rightly, asked the doctor to change the prescription. In the author’s experience, junior pharmacists often took more time to visit a ward because of this, as well as due to their conscientious checking of everything. So in terms of clinical consequence to the patient, these interventions were relatively unimportant, apart from causing delays. However, they were important to the efficient running of the hospital.

Score 3 interventions were often grouped with score 1 and 2 interventions (see Table 3.8) to represent the workload of pharmacists and were an indicator of inefficiency rather than clinical risk. These interventions were the first to be made in a clinical area that was new to a pharmacist. As familiarity and confidence grew then pharmacists made more serious interventions. They could be considered to be an important part of the learning process. The average proportion of severity scores in the 1, 2, 3 group for the period 1999-2009 was 72.7%. In other words, three-quarters of the interventions could be considered to be not very serious.

With reference to Table 3.8, 1999-2001 cohorts’ severity scores 1, 2, and 3 had an average of 78.3% (SD=3.5) and the 2006-9 cohorts had an average of 68.6% (SD=9.4). A t-test showed there was no statistically significant difference (t=2.17, df=5; p=0.082, with an estimated mean difference of 9.7% with a 95% CI of -1.8 to 21.25%). However, the difference in means might reflect a trend not revealed by this particular analysis. A chi-squared analysis of data derived from the two study periods revealed the difference in distribution of the interventions in terms of severity was highly significant (X²=95.06, df=3, p<0.001) with more interventions being recorded as severe in the 2006-9 period, mainly at level 4 (18.3 vs 28.2%).

The 1999-2001 grouping showed little variation around its mean whereas the 2006-9 grouping was more variable, as indicated by the calculated standard deviations. The 2006 and 2007a results showed a higher proportion, 35 to 36%, of severity 4 interventions. Apart from 2009, all other severity 4 results were less than 25%. It was possible that in those two surveys the coding drifted to code 4 where previously they
would have been scored 3. It is also possible that fewer code 3 interventions were reported. The 2007a survey was a week in January and 2006 was a week in May. Junior doctor rotations changed in August and February, so there appears to be no obvious connection with the level of experience of the prescriber in a speciality.

If the group of 1, 2, 3 scores were decreasing with time, this was most likely to be an under-reporting trend. In other words, as the number of interventions increased, pharmacists focussed on reporting the more serious interventions. Alternatively junior doctors might have been making more serious errors or pharmacists were becoming better equipped to detect them.

### 3.4.3.4 Score 4, 5 and 6 interventions

As the percentage 1, 2, 3 scores appear to decrease with time so the serious interventions (those scoring 4, 5, and 6) increased from 21.2% in early years (1999-2001) to 31.0% in later years (2006-9). So not only had the total number of interventions increased but the proportion of high severity scores increased. This then prompts the question: does this mean that the proportion of serious interventions (4, 5, and 6 out of the total) was really increasing or was this because pharmacists were more motivated to report them? Certainly these were the high-impact events that were used to justify the service. In the author’s opinion, as pharmacists gained experience in participating in these surveys they also understood the importance of generating evidence for sustaining the service in a climate of cuts. Although not introduced during the time of the author’s study, it is likely that the adoption of electronic prescribing will eliminate many of the interventions with severity score 3, so the more serious events will increase by proportion in the future.

The interventions that concern the provision of drug information, severity score 2, were important for the education of junior doctors but were less likely to impress managers. Finance managers often viewed education as something that professionals should just do. However whilst some of the drug information was the transmission of facts, some was also to raise awareness of issues that the doctors or nurses had not thought about. For example, doctors and nurse were sometimes unaware that Tazocin needed to be used in reduced dose in a patient with severe renal dysfunction. It is very
difficult for a professional to develop in areas where they are unaware that they lack knowledge. For patient safety, it is important that pharmacists are present, even if electronic prescribing eliminates some of the lower severity interventions. Anecdotally, at an individual level, the junior doctors were highly appreciative of the drug knowledge that pharmacists shared with them.

Table 3.9, in Section 3.3.2, shows that the score 6 interventions increased appreciably between the periods 1999-2001 and 2006-2009 but, it must be remembered that the numbers were very small.

Even so, the data represent the potential for preventing serious harm (score level 5) coming to between nine and 47 patients a week and prevention of death (score level 6) of between one and five patients a week. In terms of patient impact this is very significant. If the data from the weekly snapshots taken in this research were projected over the whole year this would represent a minimum of 50 lives saved each year. In economic terms, prevention of subsequent financial settlements following successful law suits against the Trust might save the costs of the clinical pharmacy service at SUHT (approximately £2million per year) many times over; notwithstanding the human/social cost and risk of adverse publicity and loss of reputation to the Trust.

Table 3.10 shows data for the two signal years (2001 and 2007); the only major differences are a greater proportion of score 3 interventions in 2001 and more score 4s in 2007; the differences were statistically significant. This could represent a shift in coding or more likely a change to reporting more serious interventions in 2007. This is most likely to be due to the impact of more interventions being scored 4 in the admissions environment.

There is further comment on interventions with severity score 5 and 6 in Section 3.4.6.
3.4.4 Type of intervention

The type of intervention will now be discussed in more detail, in the rank order of the frequency in which they have occurred over 2006-2009. This gives a clearer picture of what it was that pharmacists did, and how often they did it.

3.4.4.1 TTO/IP discrepancy or IP drug omission (type 8)

Table 3.12 shows that nearly a quarter (24.2%) of interventions were in this category. TTO/IP discrepancy was where the discharge prescription (TTO) did not match that prescribed for the patient as an inpatient. Some changes on discharge would be normal practice such as changing intravenous antibiotics to oral and these would not be challenged. However where the pharmacist was unable to understand if a change was intentional or accidental, then an intervention was made.

For example, an inpatient prescription for ramipril 2.5mg in the morning was compared to the matching discharge prescription that stated ramipril 2.5mg twice a day. There was often no obvious explanation for this and it is likely to have been a ‘slip of the pen’ mistake. However it could have been a deliberate increase in dose as part of the dose escalation to a target of 10mg per day. The doctor had to be contacted to confirm if this was a deliberate ‘act of commission’ change or an unintended error.

This category also described where a new drug was added on discharge or omitted and the doctor had to be phoned for clarification.

This category of interventions also included where the patient had been consuming a medicine before hospital admission but had never been prescribed it in hospital. Sometimes this would only come to light when the discharge medicines were being prepared and the collection of PODs revealed the additional item. The doctor was then contacted to confirm if the patient was to restart all their own medicines or if an item had been deliberately omitted and the POD item should be removed. An example of this was where the GP had prescribed a proton pump inhibitor for the patient, the admitting doctor had forgotten to prescribe this and the patient had received no ulcer protection during their hospital stay. When the pharmacist found the PPI amongst the
PODs, they contacted the doctor. The doctor confirmed the error and authorised adding the drug to the discharge prescription.

In 1999 this category represented 14% of all interventions and in 2001, Table 3.13 shows that they represented 12.8%. Why has this category increased to 24.2% in 2006 – 2009? Is it because pharmacy is detecting more anomalies or admissions in this category? Or less of the other types? It seems most likely to be an increased focus on this area due to some changes in practice. Patients are now encouraged to bring their own medicines (PODS) into hospital, whereas this was not the case before.

Without the use of PODs in hospital, it would previously have been difficult to detect this error. The NPSA alert on Medicines Reconciliation has also encouraged hospitals to contact general practitioners early in the hospital episode; so the example above would now be avoided. The development of the role of the PODtech and encouraging patients to bring in their own medicines, has revealed that (inpatient) drug omission was a fairly common event varying from between 30 and 70% of admissions.

There was always an ambiguity when the first hospital chart did not contain a medicine consumed prior to admission. It was not clear if the inpatient chart omission was an inadvertent error, or if it was an act of commission, where the doctor had deliberately stopped the medicine for some clinical reason. An example was a patient admitted with bradycardia who was consuming a beta-blocker. To the author it would appear logical that the first prescription chart contained all the medicines that the patient was taking prior to hospital admission. Those that were temporarily unsuitable could then be crossed out with an appropriate entry in the notes. Then if the medicine was to be restarted, all the details would be available. However many of the intervention reports showed that this did not happen; they showed that drugs were omitted in error. This would have been helpful for the clinical team (which may include a different covering doctor) when they reviewed medicines for discharge. A mistake like this would have been translated into poor communication to the general practitioner, which may also have impacted unfavourably on readmission rates.
3.4.4.2 Choice of Dose/frequency (type 10)

Table 3.12 shows that the second most frequent (22.4%) interventions for pharmacists concerned the dose or frequency of medicines. In 2001 this was 28.9% and in 1999 this was 19% when this category (type 10) intervention was the most frequently occurring. So over the 10 years of this study, the top two intervention categories have changed rank positions. In the author’s opinion this represents a rise in type 8 interventions rather than a fall in type 10, but may indicate a need to investigate type 8 interventions in more detail in future research.

This category covers doses that are different from those recommended by the BNF, including doses that are wrong by an order of 10 or more, those that need adjusting due to liver/renal dysfunction and those where the pharmacist is asked for the usual dose of a particular drug. Working in a dispensary makes pharmacists experts at checking doses; this builds an extensive memory of doses for common drugs. In clinical areas pharmacists are often referred to as ‘walking BNFs’.

Knowledge of drug doses was a key descriptor of what pharmacists did, yet we often accepted it as the norm, and assumed it was trivial. In the author’s opinion, most non-pharmacist healthcare professionals struggle to remember this data. So it is noteworthy that pharmacists were a source of this information. The author wonders if electronic prescribing will eliminate questions about normal dose ranges but leave the pharmacists to modify doses in unusual situations.

3.4.4.3 Drug choice, or need for drug (type 9)

The third most frequent intervention (18.6%) was concerned with the choice of drug. Some of these were concerned with the promotion of the hospital formulary and the delayed availability of drugs that were not held routinely in the pharmacy. Doctors were actively persuaded to change non-formulary medicines to those that had been approved by the Drug and Therapeutics Committee and therefore held as stock in the pharmacy. Some of these interventions were concerned with the choice of drug within the formulary for a particular patient. Some were concerned with drugs that had not yet been prescribed, but the patient matched criteria in a local or national guideline.
The formulary choices were made initially on evidence of efficacy and safety. This reduced the range of drugs that the junior doctor had to remember. This was based on the premise that if there was less to remember then recall was likely to be more accurate. The aim of reduced drug choice was to reduce the risk of errors in the drug use process. In addition this reduced the range of medicines held in pharmacy, improved efficiency of ordering and stock rotation and promoted elimination of duplicates or less-safe drugs within a therapeutic group. The medicines on the hospital formulary either intrinsically had lower adverse drug reactions or had been associated with reduced errors in the drug usage process. The cost-effectiveness of medicines was also a significant, but not dominant factor. So pharmacists enforced the adoption of the formulary.

However in formulary management it was not always possible to choose one drug for a whole therapeutic group. For example, the choice of a beta blocker depended on the presence or absence of accompanying pathology, bioavailability and pharmacokinetics. Propranolol is cleared by the liver and is safe in those with renal dysfunction. Atenolol is cleared by the kidney and is safe in liver failure. Metoprolol has a mixed liver and renal clearance and is short acting; it is useful where both liver and kidneys are failing. There are many other beta-blockers but they offer no advantages over the ones mentioned here. Pharmacists had knowledge of the differing properties of a therapeutic group (such as beta-blockers) as well as information about why the different formulary choices were made. Pharmacists therefore increasingly became involved in the choice of drugs within a therapeutic group. This was usually based on the attributes of the specific drug but may be linked to licensed status, range of doses or available formulations.

In the author’s experience, doctors no longer argue about whether a formulary is philosophically advisable or threatens clinical freedom. Non-formulary choices were only supplied by the pharmacist where a particular patient was established on a particular drug and unwilling to change. It was hospital policy that non-formulary supplies should be less than 3% of all issues. New drugs now undergo a strict formulary application process. Choice of drug within the formulary has become a more interesting development for the pharmacists.
As a proportion of all interventions, Table 3.12 shows the 2006-9 cohorts produce an average of 18.6% for drug choice (type 9). In 1999 code 9 interventions were 13% of the total and Table 3.13 shows that in 2001 type 9 interventions were 16%. It could be that this reflects an increase in non-formulary prescribing; but in the author’s opinion a more likely explanation is the increasing role of pharmacists in advising doctors on therapeutic choices, either of therapeutic group, or drugs from within it on the formulary.

In addition during the latter stages of the study, there was an increase in the development of guidelines and care pathways beyond local practice and acceptance of National Service Frameworks, where once a given diagnosis was made the therapeutic pathway was clearly described. Pharmacists were therefore able to justify and communicate both the need for further agents as well as compliance with those described in a care pathway. This has prompted a significant change in practice. Pharmacists used to advise on optimal drug choice compared to what had been prescribed. This might have generated a discussion about local practice and the doctor could have simply disagreed. Now pharmacists can request that new agents are needed to comply with national guidelines. For example the MINAP (Myocardial Infarction National Audit Programme) standards require 90% compliance post-MI with prescribing beta blockers, statins and angiotensin converting enzyme inhibitors or angiotensin receptor blockers. So now it is possible for pharmacists to justify the need for a drug; rather than comment on what has been prescribed. This category of intervention also included interventions where there was an unacceptable deviation from a nationally agreed therapeutic plan.

The top three intervention types (8, 10, and 9) represented 65.2% (3020/4634) of the total. So nearly two thirds of pharmacists’ clinical output appears to have related to choice of drug, dose and frequency, and improving the communication of medicine details at the interface. The transfer of patient care from normal daily living (and primary healthcare) and the secondary care temporary loop was clearly a source of errors.
3.4.4.4 Choice of form/strength/route (type 11)

This was a regular contribution of the pharmacists, who knew what products were available. Table 3.11 shows that this category remained at between 6-8% of all interventions throughout the study period.

Many of these interventions were in clarifying details of a medicine that had been omitted. Today medicines come in multiple formulations partly to extend patent protection. This can make it impossible to complete missing data in order to dispense a drug when there are so many formulations to choose from (e.g. diltiazem). Increasingly, pharmacists were choosing the most appropriate formulation for the patient e.g. liquid or dispersible formulations for patients fed via naso-gastric tube. Examples of changes observed in the research were changes in drug (ferrous sulphate tablets to ferrous fumarate liquid) and formulation (sodium fusidate tablets 500mg to Fucidin suspension 750mg in 15ml).

Details were often omitted and were added by the pharmacist (e.g. ‘N.saline’ was re-written as 0.9% sodium chloride) or clarified (e.g. 10ml magnesium sulphate 10% was more clearly written as 1G/10ml). Simply writing percentages caused frequent problems in subsequent dose calculations.

Route changes such as IV to oral switches were made wherever possible for clinical safety and ease of administration. These were either simple, such as IV ciprofloxacin to oral; or more complex, such as IV cefuroxime to cefaclor (cefuroxime axetil is poorly absorbed and expensive). Route change interventions altered dose (e.g. metronidazole IV 500mg to oral 400mg) or dose and frequency (e.g. ranitidine IV 50mg TDS to oral 150mg BD). Some interventions involved considerations of variations in bioavailability, e.g. phenytoin IV 300mg to 270mg capsules or 45ml suspension.

Increasingly throughout the study the pharmacist prompted changes or annotated the prescription chart to clarify what the doctor intended.
3.4.4.5 Documentation (Type 7)

In 1999 this type of intervention represented 13% out of a total of 613. Table 3.13 shows that in 2001 this type represented 8.4% and Table 3.12 also shows that in 2006 to 2009 this type averaged 6.2%.

So this type of intervention had been decreasing as a proportion of the total number of interventions. The reason for this change is probably that pharmacists increasingly focused (and reported) more on other types of intervention. The author believes that this shows that as clinical practice developed, it moved away from an emphasis on paperwork to a more clinical focus. This was a reflection of a change in practice and different style of thinking in ward pharmacy, from that found in the dispensary.

Documentation referred to those situations where the drug chart was incomplete, such that it was not possible to dispense or administer the medicines because it was not a unique description; for example sodium chloride comes in many strengths and routes of administration – so this had to be explicitly stated.

When a new medicine was produced it was initially available in only one form or strength. However, as usage patterns emerged, more strengths are produced. An example was ciprofloxacin tablets; initially they were launched as 250mg but later 750mg became available. At product launch, ‘one tablet’ could only be interpreted as 250mg, but later this became ambiguous.

A prescription that was illegible meant that the drug name could have been many different things. The perceptions of this varied between those of the dispensary and ward staff because the wards would have been familiar with the one strength they used, but the dispensary had all the strengths used in the hospital. The formulary was designed to limit drug choices and therefore to reduce the risks of having to choose from a larger range. Poorly written prescriptions became ambiguous if patients were transferred to a different ward.

A prescription was ambiguous where a drug name did not match dose or frequency and it was not clear which was correct. It was not possible to decide if the drug name
was wrong, or if the dose was unusual. For example there was often confusion between cephalosporin drugs; a prescription for ‘cefotaxime 1.5G’ could be interpreted as either cefotaxime 2G or cefuroxime 1.5G.

A prescription was illegal if the CD regulations requirements were not completed, e.g. it was not signed or dated.

Within the dispensary, documentation interventions remained at a stable level of 12%. This was because good documentation was important to ensure the right medicine was supplied. Dispensing from the discharge prescription was also one of the final stages before the hospital transferred accountability and the pharmacy staff wanted to ensure clarity and legality in case a complaint arose and the original prescription needed to be referred to. On admission, a previous discharge prescription was one of the useful data sources for reconciliation.

### 3.4.4.6 Drug interaction/ADR/SE (type 15)

Table 3.11 shows that this category represented between 5-9% of all interventions and the rate was stable over the study period. Table 3.12 shows an average over the period 2006 – 2009 of 6.1%.

Pharmacists are known for their extensive knowledge of drug interactions. Interventions in this category were often to alert the prescriber to the existence of an interaction. In early stages of the study, this was accompanied by advice to simply avoid the combination completely. In the latter stages, increased medicine complexity led to an appreciable proportion of interventions in this category being about how an interaction should be managed, rather than avoided. For example digoxin and amiodarone is a common pharmacological combination. The amiodarone gives early conversion to sinus rhythm but has many side-effects long-term. Digoxin is a poor converter but will hold sinus rate once established. Blood level monitoring and regular pulse rate checks allow the combination to be used safely.

This category also included the detection and prevention of adverse drug reactions; for example, being alert to or detecting changes in liver function with rifampicin, or
clindamycin-induced Clostridium difficile infected diarrhoea. Doctors were reminded that Tazocin (piperacillin with tazobactam), Augmentin (amoxicillin with clavulanic acid) and flucloxacillin are penicillins and should not have been used in patients who were allergic to penicillins. Equally a patient was labelled as penicillin allergic and received Tazocin with no symptoms of allergy and the medical records were then amended.

Some side-effects were unwanted, but manageable; such as red man syndrome with vancomycin. This was significantly reduced by a slower rate of infusion.

### 3.4.4.7 Drug duration (type 12)

Table 3.11 shows that this was a relatively small category over the study period, ranging from 3-7%. This category predominantly included pharmacists raising the question of whether a course of antibiotics was complete. However it also encompassed courses of steroids and their phased reduction, antiemetics and opioids. More latterly it also involved treatments with standard durations (e.g. terlipressin or drotrecogin) and cytotoxics with their repeat pulses of treatment.

This category raised the question: ‘Is the drug still needed?’ This is different from needing to initiate a new medicine (code 9). The drug use process is often seen as a having three stages: prescribing, administration and supply; however it has a fourth stage: monitoring the effects of what has been administered. It was important to review whether a therapeutic target had been achieved and if this was at the cost of significant side-effects. This should be part of a continuous review. Drug duration was therefore an important category where the pharmacist asked the doctor if the medicine should be stopped.

### 3.4.4.8 Pharmacokinetics/TDM (type 13)

Table 3.13 shows that in 2001 this type represented 4.3% of interventions and a drop to 3.2% in 2007. Table 3.12 shows that in 2006 to 2009 this type averaged 2.5%.

These interventions involved pharmacokinetic calculations, or the application of pharmacokinetic principles, or the requesting of drug levels or interpretation of
results. Pharmacists had an almost unique understanding of this subject. Most doctors failed to take notice of drug level results or misinterpreted them. There was great misunderstanding of the relationship between the time the sample was taken and the time a dose was given. Over the study period, pharmacist behaviour changed from requesting the test to greater engagement with managing the whole process. This might explain the slight drop in this category of interventions over the study period. The author observed that even pharmacists who were unexcited by this subject contributed to patient care in this area.

A greater presence in clinical areas and participation in clinical decision making processes made this a task that was often undertaken by the pharmacist. Many of the intervention reports showed that the pharmacists were involved in modifying the dosage of vancomycin and organising blood level monitoring. Over the study period, gentamicin started to be prescribed as extended interval dosing: 5-7mg/kg with a different timing of monitoring - 6 to 14 hours post-dose rather than trough levels; this created a number of problems that required intervention by the pharmacist.

3.4.4.9 Drug admin/incompatibility/calc (type 14)

In 1999 this type of intervention represented 2% of the total. Table 3.13 shows that in 2001 this type represented 1.0% of the total; Table 3.12 shows that in 2006 to 2009 this type averaged 2.3%

Pharmacists often answered questions from nurses about how to administer medicines. This frequently followed on from a discussion about changing the route of administration. In addition sick patients presented new challenges where the oral route was unacceptable (especially vomiting or surgery). Pharmacists’ knowledge about what products were available and how to administer them emerged as a unique selling point of their role. In addition, pharmacists initiated supplies of new formulations as appropriate. Many pharmacists clarified intravenous diluents or converted unusual concentrations into something that was easy to prepare or more usually seen. This
standardisation of intravenous therapy was a significant contribution to managing risk.

In general the more complex the activity the greater the risk and the more stages in the process the greater the number of risks. Risk management encompasses a series of activities including risk assessment, learning from mistakes, implementing changes as a result and reporting adverse events. This results in safer practice, enhanced patient care and possibly, reduced litigation. It is known that complex injectable regimens usually are associated with error and the highest consequence for errors reaching the patient. This also reflects an area where pharmacists had growing confidence and the potential to make a real difference.

Many nurses were found to be significantly challenged by mathematics and the pharmacist was a useful resource in checking calculations and altering infusion rates where inaccuracies arose. For example co-trimoxazole for Pneumocystis carinii pneumonia was prescribed as 2640mg to be taken four times a day. This required the nurse to prepare 5.5 x 480mg/5ml amps four times a day. If the total daily dose of 10560 mg was converted into 2 doses of 6 amps (2880mg) and 2 doses of 5 amps (2400mg) this was significantly easier to prepare, with no difference to the patient.

Incompatibility questions were simply what diluent to use, or changing to a lower sodium diluent. They also included advising on a plan of how to avoid two incompatible drugs coming together or something more complex; for example, a complete reworking of how to give 10 drugs through four IV lines. The pharmacists’ knowledge in this area made a large contribution to how medicines were mixed safely. Most doctors claimed no knowledge of drug compatibility. It appears an anomaly of the Medicines Act 1968 that pharmacists cannot directly advise on mixing medicines. All mixing should legally be at the written directions of a prescriber.

Pharmacists are likely to have under-reported in this category because they accepted it as part of their role; it commonly formed part of their daily conversations with nurses. There were small numbers of reports of incompatibility in these surveys and there was large variation between individual studies; but usually they represented 3.5% of intervention reports. The pharmacist’s knowledge of the supply chain, products
available, correct preparation and incompatibility considerations may make this the most significant contribution to avoiding serious harm to patients.

3.4.4.10 Other drug information (type 17)

In 1999 this type of intervention represented 2% of the total. Table 3.13 shows that in 2001 this type represented 1.8% of the total; Table 3.12 shows that in 2006 to 2009 this type averaged 2.1%.

This catch-all category covered a wide range of questions that did not fit into the other types of intervention. It included provision of financial information and analysis, answering questions about policies such as describing the new antibiotic policy, describing first and second line anti-emetics, providing information about a new drug, explaining why liver specialists prescribe pentoxyfylline; or at what level of renal function was the dose of enoxaparin reduced. It also included where a GP had been telephoned to confirm a complex drug history.

3.4.4.11 Therapeutic substitution (type19)

In 1999 this type of intervention represented 3.5% of the total. Table 3.13 shows that in 2001, this type represented 1.5% of the total; Table 3.12 shows that in 2006 to 2009 this type averaged 1.4%.

This was a special category where pharmacists made changes under a trust approved protocol. It took junior doctors time to learn local clinical practice before their rotation changed in 6 months. Consequently many of the pharmacists’ interventions were simple and repeated. These interventions were always accepted by the doctor and could be grouped together as automatic actions. In 1997 the trust empowered pharmacists to follow this procedure. The pharmacist made changes outlined in the policy and the doctor signed the prescription, where appropriate, when they next visited the clinical area. In the last few years this was slowly being replaced by pharmacist prescribing.
For example, magnesium hydroxide was changed to a different time to digoxin, ciprofloxacin or tetracyclines to avoid an interaction and reduced absorption. Where there were obvious gaps in data, such as frequency, these were added. These steps were simple prescribing errors that were safely changed, to avoid harm to patients and reduce interruption and delays to drug administration. They were a recognised expansion of the pharmacist’s role.

### 3.4.4.12 Drug supply/storage (type16)

In 1999 this type of intervention represented 2% of the total. Table 3.13 shows that in 2001 this type represented 1.2% of the total; Table 3.12 shows that in 2006 to 2009 this type averaged 1.3%.

This type of intervention concerned problems where the supply chain was interrupted or there were delays. It was used to convey significant manufacturing problems such as the sudden lack of availability of noradrenaline. It was also used if there was a dispensing error or the medicine had been delivered to the wrong ward causing a dose to be omitted. It was used where drugs had been inadequately stored out of the fridge and the pharmacist was asked if a product was usable.

This type of intervention was the activity that launched pharmacists onto the wards but soon became a very small proportion of the pharmacist’s contribution. It was still an activity undertaken when necessary but probably underreported. The supply chain was reliable compared to other medication related problems. Drug supply was a normal activity that was expected to be perfect and only problems were reported. Anecdotally, pharmacists were more motivated to report the other activities that they contributed to clinical care.

### 3.4.4.13 Nutrition (type 18)

In 1999 this type of intervention represented 3% of the total. Table 3.13 shows that in 2001 this type represented 3.3% of the total; Table 3.12 shows that in 2006 to 2009 this type averaged 1.1%.
Pharmacists have been traditionally involved in advice on food supplements such as vitamins and minerals. So these interventions included ensuring that vitamin B12 had recently been given where folic acid was prescribed, so that a peripheral neuropathy was avoided. It included adding Pabrinex to the prescription of patients at high risk of refeeding syndrome and ensuring that phosphate supplements were prescribed for these patients. This also covered prescribing of parenteral nutrition by pharmacists. Whilst this was a low frequency intervention for most pharmacists, it was an important role.

3.4.5 Comparison of 2001 and 2007

There were more serious interventions made in 2007 both in number of severity 4 and severity 5 interventions. So it appears that pharmacists were either focussing on the more serious interventions, or were able to detect more serious errors. It is also possible that there was reporting bias toward more serious interventions.

A Chi-squared test revealed a highly significant difference in the distribution of intervention types in 2007 compared with 2001 (\( p<0.0001 \)). The major areas contributing to this difference are shown in bold in Table 3.13. Between 2001 and 2007, the top three types of interventions remained the same but the rank order changed. In 2001 the three most frequently occurring categories were type 10, 9, and 8 and in 2007 the order changed to type 8, 10, and 9. In 2007 there was a higher proportion of type 8 (TTO/IP discrepancy or IP drug omission) interventions. This could be explained by the increase in failures to transcribe the discharge prescription from the inpatient chart accurately or an increase in errors of omission from drug history to the inpatient chart. It could also be explained by an increase in patient throughput in the hospital. This would be likely to increase errors in the admission and discharge processes as the time pressures increased.

In 2001 the top 3 types of intervention represented 57.7\% (351/608) of the total. In 2007 the top three types of interventions represented 66.3\% (605/912) of the total. It appears that pharmacists had focussed more on the top three types because they had less time to contribute and record all interventions. Time spent on the wards was not
recorded but the total number of interventions increased from 608 to 912, an increase of 304 or 50.0%.

The biggest increase in type of intervention between 2001 and 2007 was type 14 (Drug admin/incompatible/calc -367%); followed by type 19 (Therapeutic substitution - 244%; then type 8 (TTO/IP discrepancy or IP drug omission -235%). Type 14 and type 19 were a small proportion of the total interventions so the absolute changes were small. However type 8 interventions were the third most frequent intervention type in 2001 and the most frequent in 2007. Thus type 8 interventions showed one of the biggest changes in both percentage and absolute terms.

3.4.6 Financial motivation (20-23)

The data for 1999 was incomplete in that only the percentage of non-financial interventions was retained. Table 3.15 shows that the non-financial category (type 23) in 1999-2001 represented nearly 90% of the interventions made; by 2006-9 this exceeded 90% to a varying degree. This shows that the vast majority of interventions were motivated by a patient benefit agenda rather than for saving money.

This category was concerned with the reason for initiating an intervention. Although not studied in this research, many will have undoubtedly saved money, but the reason for initiation was not financial. It was possible that pharmacists undertook more activities of a financial nature but did not report these as interventions.

The pharmacist was seen as the ‘marketing arm’ of formulary implementation and acceptance. It was certainly true that clinical pharmacists made the formulary work in practice by bringing the evidence into the discussion about alternatives. So pharmacists were also agents of introducing evidence-based medicine.

Hatoum et al. found 58.5% of interventions impacted on quality, 16.1% impacted on cost and 25.6% impacted on both. Savings came from reduced drug costs, reduced laboratory monitoring, reduced complications and therapeutic failures and reduced length of stay in hospital.
However changes made for patient benefit can reduce the cost of patient harm, complaint and litigation. In addition they can avoid unnecessary costs and even save money. So whilst the motivation was non-financial, the effect could have been a substantial saving. Pharmacists did not change medicines to cheaper, inferior products that would decrease the quality of care. Thus the contribution of the pharmacist in making cost saving interventions (category 22) contained a component of improving patient care – the essence of the mantra ‘safe and cost-effective’.

This category also illustrated work that pharmacists undertook away from clinical areas, such as writing and implementing consensus guidelines. This took significant time to prepare and gain agreement. Pharmacists then conducted significant ‘change management’ projects in order to make this work in practice. These projects and interventions were directed at saving money but always had a minimum standard of ‘first do no harm’. The majority of guidelines were still introduced for patient benefit rather than just saving money. Simple standardisation of practice should reduce practitioner error and so avoid patient harm.

Pharmacists also undertook financial analyses and a number of reports (category 21) were prepared for managers who were responsible for drug budgets. It was quite clear that hospital managers were unable to manage these budgets without the contribution of the pharmacist. Whilst it was an everyday reality for pharmacists, many managers struggled with the patterns of drug pricing that often appeared not to withstand logical analysis.

Some pharmacist activities were focussed on saving money but these represent less than 10% of the interventions that were made. The vast majority was focussed on non-financial patient benefit. The pharmacist was the custodian of evidence based practice in the use of medicines. The pharmacist was also a repository of knowledge about safe use of medicines and avoiding practices that were ‘risk laden’.

So whilst pharmacists made interventions for clinical reasons, it was likely that significant savings were made. It has been estimated that pharmacists saved their salaries each year in terms of drug costs and that the avoided costs of litigation were
approximately 50 times larger than the costs of providing the service. This ignores, or did not value the avoidance of patient harm through the work undertaken.

3.4.7 Outcome of intervention (24-28)

When pharmacists first ventured into clinical areas there were many examples of hostility. Nurses were the first to accept the support of pharmacists in facilitating medicines supply and information about drug administration. Doctors were slower to win over. During the study period, many doctors had developed with a pharmacist supporting their practice.

Table 3.16 shows that during 1999 to 2009 on average, 56% of interventions resulted in treatment being altered and 26% produced changes to drug charts. This suggests that pharmacists’ interventions were positively received. It is possible that pharmacists did not report interventions with negative responses or that they only intervened when they were positive about their facts.

‘Treatment altered’ (code 24) was the most positive outcome of the pharmacist intervention because what had been prescribed had clearly changed from something harmful or less ideal. However altering a chart (code 25) to make it safer, clearer or more complete was also positive in that potential harm had been avoided. Providing information that was accepted (code 26) was also a positive outcome in that the answer or information had satisfied the questioner.

The positive outcomes collectively increased from 91% in 1999 to an average of 97.2% in the 2006-9 studies. It appeared that pharmacist interventions were more relevant and readily accepted than in the past. However it is also probable that there was a bias towards reporting the positive events.

‘Information - known/problem not pursued’ (code27) was a neutral outcome in that the pharmacist’s contribution was not accepted, either because the doctor was already aware and it added no value, or the doctor decided not to act on it because it had been included in the decision making process. The incidence of this type of intervention remained very low throughout the study.
‘Treatment unaltered’ (code28) meant that the doctor did not agree with the pharmacist’s concern because it was not relevant for that particular patient. This could be an error of judgement on the pharmacist’s part or that they were not aware of additional clinical information possessed by the doctor. However the lack of negative outcome may have been due to a reluctance to report those interventions where the pharmacist had made a mistake. The negative coding was a reflection of the doctors’ response, which may reflect a personality clash or reluctance to accept that an action (or error) was an unintended event. Again, the reporting in the category remained low throughout the study.

3.4.8 Serious interventions

The severity of an intervention was coded and recorded as the likely clinical consequence if the pharmacist had not intervened. Using the modified Hatoum et al. scoring system, those scoring 4, 5 or 6 were classed as ‘serious’ and the details recorded in a separate report that was sent to the Clinical Risk department of the Trust.

The serious interventions constituted about a fifth of the interventions made. The majority of all interventions were minor, but occurred frequently as new junior doctors were trained in the hospital. Although minor in severity, the quantity of work involved represented a significant contribution to patient safety made by the pharmacy team.

It might be assumed that education would reduce the number of minor interventions and printed cards of guidelines were prepared for the doctors to carry with them. A series of safer prescribing lectures had also been prepared, but their impact was difficult to evaluate. The occurrence of errors is clearly complex and whilst this work has tried to describe and quantify this, there has been no evaluation of why errors occur locally.

The EQUIP study identified the need for just-in-time training - a method of providing training when it is needed. The problem with formal education is that the
learner quickly forgets knowledge that they cannot use immediately after initial training. The study found that doctors considered rewriting drug charts or discharge prescriptions as an automatic processes, requiring little conscious thought. This will be discussed in more detail in Chapter 5 which is specifically focussed on prescribing errors.

This section will look at an analysis of severity score 5&6 that have been reported to the risk management team during 2005-9 in relation to the intervention category codes identified in Table 3.4. The analysis is summarised in Table 3.17. Some of the severity score 5 interventions were not reported to the risk management team, so the overall count is lower than that shown in Table 3.8.

Table 3.17 Cohorts 2005-9, severity score 5 & 6 distribution variation with intervention type.

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>15</th>
<th>7</th>
<th>9</th>
<th>14</th>
<th>10</th>
<th>13</th>
<th>8</th>
<th>18</th>
<th>16</th>
<th>12</th>
<th>Total</th>
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<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>5</td>
<td>17</td>
<td>13</td>
<td>39</td>
<td>1</td>
<td>11</td>
<td>10</td>
<td>9</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>106</td>
</tr>
<tr>
<td>Total 5 &amp; 6 (%)</td>
<td>22</td>
<td>16</td>
<td>41</td>
<td>3</td>
<td>12</td>
<td>10</td>
<td>9</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>119</td>
</tr>
</tbody>
</table>

Table 3.17 shows that more than half (52.9%) of these interventions were represented by type 9 (choice of or need for a drug) and type 15 (interaction/ADR/SE). Incorrect choices of drug, need for drug or combinations and side-effects were likely to be associated with serious consequences.

Type 9 can be further divided as follows: 18/41 (43.9%) involved the need to start a drug, 11/41 (26.8%) involved the need to stop a drug and 12/41 (29.3%) involved poor drug choices for the particular patient (e.g. contra-indications). These represent the most frequently occurring serious medication related consequences to patients.

Poor drug choices for a particular patient were made because of contra-indications or cautions that were not assimilated by the doctor when they made their decision about
what drug to prescribe. This may have been knowledge-based in that they did not know enough about the individual agent or therapeutic group; alternatively it may have been skill based, in that they did not detect the relevant characteristics of the patient. Equally, as the patient’s condition changed it was important to know when to stop a drug and then review frequently to detect relevant changes quickly. The pharmacist had often intervened to ask for monitoring of biochemical signs of toxicity. It appears that delays in stopping medication occurred frequently and could be important. It is often the pharmacist that asks for antibiotics to be stopped even though it is known that extended courses select out resistant bacteria.

Over two fifths of the type 9 serious interventions were the need to start a drug. The author believes this was a relatively new development where the pharmacist understands the therapeutic pathway and is able to prompt initiation of treatment. National guidelines on preventing VAP144 and VTE154 and treatment post myocardial infarction155 are important here.

Type 15 can be further divided into: 9/22 (40.9%) allergy, 7/22 (31.8%) serious side-effect, 5/22 (31.8%) interaction and 1/22 (4.5%) monitoring. These represent the second most frequently occurring serious medication related consequences to patients.

### 3.4.9 Educating healthcare practitioners

Initially when junior pharmacists visit a ward they are accompanied by a senior pharmacist who introduces them to key nursing staff and demonstrates the activities they are to undertake. After a short period they are assessed as competent or further training is undertaken. They have to understand the dynamics of interaction between their roles and the clinical activities of other healthcare professionals and how the ward is managed. This is learnt through observation and discussion with the nurses. After a while they are accepted into the clinical team and nurses ask frequent questions about the medicines being used. They may be asked to give formal lectures, but most education occurs informally as the need arises. The pharmacist is seen as a valued resource to ensure nurses, and other healthcare staff are kept informed about the medicines commonly used on the ward. Clinical pharmacists are highly accessible as they speak to patients and nurses during their daily visits. Whilst the nurses value
the informal education, the pharmacists often see this as a by-product of their clinical activities and not the ‘raison d’être’. Consequently most informal educational answers to questions were not reported on intervention forms. Most interventions by pharmacists were accompanied by an explanation of the reasoning behind the action. This may educate doctors and nurses but it was seen as keeping the team ‘up to date’. It was only specifically reported under ‘other drug information’ where there was no specific intervention involved.

Anecdotally, in the author’s hospital the pharmacist has increasingly been seen primarily as a source of information with medicines supply as a secondary role. The education role has been recognised as important by others.\textsuperscript{156,157}

### 3.5 Conclusions

The interventions that pharmacists made have been recorded and analysed in this chapter. The main conclusions that may be derived from this work appear below.

- In the period 1999-2001 the average number of interventions in each week long survey was 575 and during 2005-9 it was 973. This was a statistically significant increase.

- A chi-squared analysis of data derived from the two study periods revealed the difference in distribution of the interventions in terms of severity was highly significant with more interventions being recorded as severe in the 2006-9 period, mainly at level 4.

- Analysis of the most serious interventions produced small numbers. Even so, the data represent the potential for preventing serious harm (score level 5) coming to between nine and 47 patients a week and prevention of death (score level 6) of between one and five patients a week. In terms of patient impact this is very important.
• If the data from the weekly snapshots taken in this research were projected over the whole year this would represent a minimum of 50 lives saved each year.

• Nearly a quarter (24.2%) of interventions were in the category: TTO/IP discrepancy where the discharge prescription (TTO) did not match that prescribed for the patient as an inpatient, or the first prescription did not match the drug history.

• The second most frequent (22.4%) intervention for pharmacists concern the dose or frequency of medicines.

• The third most frequent intervention (18.6%) was concerned with the choice of drug. Some of these will be concerned with the promotion of the hospital formulary and the delayed availability of drugs that were not held routinely in the pharmacy. Doctors were actively persuaded to change non-formulary medicines to those that had been approved by the Drug and Therapeutics Committee and therefore held as stock in the pharmacy. Some of these interventions were concerned with the choice of drug within the formulary for a particular patient.

• In 1999, interventions on documentation represented 13% out of a total of 613. In 2006 to 2009 this type averaged 4.7%. This shows that this type of intervention had decreased, to be replaced by interventions of a more clinical type.

• Some pharmacist activities were focussed on saving money but these represented less than 10% of the interventions that were made. The vast majority was focussed on non-financial benefits to patients.

• The positive outcomes collectively increased from 91% in 1999 to an average of 97.2% in the 2006-9 studies. It appeared that pharmacist interventions were more relevant and readily accepted than in the past.
• Although numbers were small, an analysis of interventions with severity score 5&6 during 2006-2009 showed that more than half were represented by decisions around choice of, or need for, a drug and drug interactions and side effects. Incorrect choices of drug, need for drug or combinations and side-effects were more likely to be associated with serious consequences. Important interventions, in terms of serious consequences prevented, occurred where there was a need to either start or stop a drug or where the choice of drug for an individual patient was poor, due to unrecognised contraindications. These represented the most frequently occurring serious medication related consequences for patients.

Key finding
Not only has the number of interventions increased, but the severity of potential consequence has also increased (Score 4,5&6 now represent 31% of total). Each week during 2006-9 clinical pharmacists prevented between 9 and 47 highly significant events (Score 5) and between 1 and 5 deaths avoided (Score 6). The interventions related to the most serious consequences avoided (Score 5&6) are related to choice of drug, need for drug or interactions.

Chapter 2 described the range of activities that are encompassed by the term clinical pharmacy. This chapter has reported a detailed analysis of the interventions that pharmacists made. Chapter 4 reports a specific study aimed at characterising the contribution made by a pharmacist to try to decrease the occurrence of prescription anomalies.
Chapter 4 Medication error and adverse events detected in the A&E department.

4.1 Introduction

The third strand of the author’s research was a study of the admission process through the Accident and Emergency (A&E) department prior to admission to a hospital bed. This was to see if a pharmacist could contribute to the admission process, by documenting a medication history and drafting the first inpatient prescription. To complement this research, participants were asked about the medicines they had consumed prior to the hospital episode. This is referred to as the side-study in the following text.

So far, the author has described how the pharmacy had been dispensary-based and focussed on problems arising on discharge. Clinical pharmacy emerged to find out how medicines were used in the clinical areas during the inpatient stage of the hospital episode. In 2001, the author formed an hypothesis that many of the anomalies and errors detected during the inpatient stay may have originated during the admission process. It had not previously been considered feasible for a pharmacist to contribute to the admission phase.

As the lead pharmacist for Critical Care, the author liaised frequently with the A&E department. Many of the doctors worked in intensive care as well as A&E and the author was well known to them. Two specific incidents encouraged the author to consider that maybe involvement of the pharmacist during the admission phase of the hospital episode would be beneficial to patients and this forms the basis for this research. These incidents are described below.

4.1.1 Key incident one

An elderly man had seen his GP who had commenced him on trimethoprim for a suspected urinary tract infection (UTI). Two days later he was admitted to hospital for investigation of his abdominal pain. However his symptoms resolved and he was sent home within 48 hours. On this first hospital admission, no trimethoprim had been
given because it was not part of his usual medication, he did not mention it and he had not brought any medicines with him. When he went home he recommenced his ‘trimethoprim’ 200mg BD. He was also taking digoxin 250 microgrammes and by chance a blood level had been requested.

He was admitted for a second time, after three days with the same abdominal cramps. The doctors investigated to no avail and then paged the author to see if it was medication related. The author investigated the patient’s medication history and examined the medicines he brought in. The author discovered that on his first admission his digoxin level had been high and his creatinine had been raised. Discussion with the doctors was that maybe his UTI had caused deterioration in his renal function and accumulation of his digoxin; therefore his first admission was due to digoxin toxicity. However, it appeared that there had been a mistake at the community pharmacy and the generic digoxin 250 microgrammes had been labelled one to be taken TWICE a day and the generic trimethoprim (in a similar box) ONE in the morning. In hospital the ‘trimethoprim’(digoxin) had not been given and his symptoms resolved. On restarting his home medication he had become digoxin toxic again. This really ignited the author’s interest in admissions subsequent to a medication related adverse reaction (termed AMRARs in the following text).

4.1.2   **Key incident two**

In 2001, the author spent several afternoons in the A&E department following the progress of patients through the system. During that time the doctors frequently asked the author about problems that arose. On one occasion the author was asked about a man who was admitted following a fall. Several days before he had seen his GP who changed his ACEI (angiotensin converting enzyme inhibitor) to doxazocin (an alpha blocker). Whilst ACEIs can produce hypotension with the first dose and are associated with falls, alpha blockers can frequently produce postural hypotension and are associated with falls in the elderly. The patient had obtained his new medicine and taken the first dose that morning at 8.30. On his way to the local shops he collapsed and was brought into hospital by ambulance. The doctors and the author concluded that the alpha blocker had decreased his blood pressure dramatically and caused his collapse. His blood pressure recovered over the next few hours and he was sent home.
on his original ACEI for further review by his GP. This appeared to be an admission associated with a medication-related adverse event (termed AMRAE in the following text).

These two incidents caused the author to wonder how often these events occurred and whether anything could be done to reduce harm to patients and the number of admissions to hospital. There appeared to be two types of medication related admissions, described in the following paragraph.

The admission was medication related due to an adverse reaction (AMRAR). For example a non-steroidal anti-inflammatory drug causing a gastric bleed. The events that caused the admission were linked to a drug effect (AMRAE). For example an alpha blocker causes postural hypotension that then caused a fall and admission for hip fracture.

A meta-analysis published in 1998, found an overall incidence of ADRs in patients being admitted to, or already in hospital of 6.7%. Predictable, Type A reactions represented 76.2%; which implied that good monitoring could possibly prevent them.

The author was also aware that a significant number of medication histories taken by admitting doctors and nurses in the A&E department were limited to drug names without details, suggesting that there may be room to improve the quality of prescription writing and drug history recording in A&E. The pharmacy at Southampton collaborated with the local Drug Safety Research Unit in previous research into surveillance of the otherwise un-trapped (or undetected) drug related adverse events. In addition Wills had studied the incidence of drug related visits to A&E that required follow-up research.

On the admitting ward the first prescription did not include medicines stopped in the A&E Department or withheld temporarily on the admitting ward. This led to the discovery of drug omissions during the checking of discharge prescriptions. Discharge was a time-pressed process and discovery of mistakes caused delays, was inefficient and allowed insufficient time for detailed investigation. If these omissions could have been discovered during the admission process it could have prevented the
admission (as with key incident two – see above) or prevented readmission (as with key incident one). It was also possible that early intervention could have shortened the hospital episode by identifying AMRARs & AMRAEs rather than exploring a new diagnosis.

This study was designed to actively engage with the admission process and assesses the potential for the pharmacist to improve healthcare in this setting.

4.2 **Aim of the study**

The aim of this study was to investigate if a pharmacist could contribute to the admission process, by documenting a medication history and drafting the first inpatient prescription.

4.3 **Objectives**

Initially it was proposed to get a pharmacist to work an eight hour shift matched with an A&E nurse and conduct drug histories on all admissions. However even with randomisation, this was thought to be logistically challenging. So it was decided to recruit all patients, and then eliminate those taking less than three medicines, to produce a manageable workload. It was anticipated that this would halve the anticipated workload and select a cohort where interactions and errors were more likely. The objectives were therefore as follows:

- **A** - to determine the distribution of the number of medicines consumed on admission;
- **B** - to quantify the current rate of medication related admissions at Southampton General hospital;
- **C** - to quantify prescribing anomalies that occurred within the admission process;
- **D** – to determine if drug histories conducted by a pharmacist contain fewer omissions, errors and interactions than those conducted by junior doctors;
- **E** – to assess if the intervention had an impact on the prevalence of adverse events and medication errors after the admission phase of the hospital episode;
• F – to determine if the pharmacist transcribed this data into the first hospital prescription, ready for the doctor to sign; did this reduce medication errors, potential interactions and ‘adverse drug related events’ and facilitate the admission or discharge process?
• G – to examine if it was logistically feasible for a pharmacist working in the A&E department to conduct drug histories;
• H – to explore the patients understanding about the purpose of their medication;
• I - to determine how many patients bring their own medicines(PODS) into hospital; and
• J – to explore the patient’s understanding of adverse effects and allergies.

4.4 Method

This was a medium scale, randomised, prospective UK study of medication review and event resolution by a pharmacist based in A&E. Participants were from a cohort of hospital emergency department admissions who were consuming three or more medications at the time of presentation.

This study was designed to detect errors or miscommunications that occurred from primary to secondary care and particularly during the transition into the hospital system. It was to determine whether subsequent errors were prevented by the pharmacist in A&E transcribing the patient’s current medication on the in-patient prescription chart.

The main project was in three phases and involved three groups of practitioners
• Consent – conducted by two nurses (SJ & KC) who were established members of A&E staff and were trained by the author in the research methodology.
• Capture of drug histories and drafting of first prescriptions – conducted by the research pharmacist (JT).
• Analysis of medical notes for events and errors – conducted by the author.
In addition there was a pilot study to determine the distribution of the number of medicines taken by patients presenting at A&E. There was also a sub-study questionnaire to identify what patients understood about the medicines they were consuming or had taken.

4.4.1 Main study

A protocol was drafted for the main study, by the author and discussed with the research team (consultant nurse in A&E and medical consultant in A&E). It was decided that two nurses who worked in A&E should be used to obtain consent from patients. The protocol is illustrated below in Figure 4.1.

![Diagram of the admission process including additional pharmacist research arm.]

Figure 4.1 The admission process including additional pharmacist research arm.

4.4.1.1 Patient recruitment

When the patient attended A&E, a research nurse ascertained the number of medicines being consumed, and administered a questionnaire about the medicines patients were taking. The nurses also provided an information sheet about the project and obtained patient consent to participate in the study if they were admitted to the hospital. These forms are included in Appendix 3.
If the doctor (in A&E) who saw the patient decided they were to be discharged immediately, the patient was excluded from the study. The A&E nurses routinely asked this doctor if the patient was likely to need admitting. If the patient was expected to be admitted the research nurse then randomly allocated the patient to one of two groups.

4.4.1.2 Inclusions

- All patients admitted to hospital via the Emergency Department, who were seen by the research nurses, who met eligibility criteria
- Participants may have been seen in A&E, minors, majors and attendees who became admissions to the hospital and gave consent to participate in the research project.
- Participants must have been taking 3 medications or more, and latterly in the study, two medications or more.
- Patients presenting between 9am and 5pm whilst the pharmacist was available in A&E.

4.4.1.3 Exclusions

- Spoke insufficient English to understand interview without need (cost) of interpreter.
- Those patients under 16 years of age.
- Unconscious patients (GCS<15) The Glasgow coma score (GCS)\textsuperscript{160} provided an objective measure of consciousness. The patient needed to score 15 out of 15 to have the capacity to consent for a research study. This was used to exclude patients who were unable to participate in the study.
- Those patients who were too unwell to participate. This description referred to patients whose clinical condition meant that, in the opinion of the research nurse, it would have been inappropriate to seek their participation in the research study.
- Patients undergoing emergency resuscitation.
• Patients omitted because research nurses were busy processing other participants.
• Those assessed by research nurses as mentally not competent to consent.
• Those who declined consent for participation.

4.4.1.4 Randomisation
The randomisation was computer generated by an external statistician in blocks of six. Allocation was to either control (normal pathway A) or intervention pathway B (drug history by pharmacist) in equal numbers. See Section 4.4.1.1 for a description of the control and intervention care pathways.

The randomisation schedule was known only to the nurses obtaining the patient consent, who would introduce the pharmacist to the relevant patients. The junior doctors were only told that the pharmacist was asking patients about their knowledge of the medicines they were taking.

The research nurses KC and SJ conducted a structured interview following consent (see Section 4.5 side study). The allocation was not known by either JT or the author. The patients in the control group saw the pharmacist who visited the admitting ward and reviewed their prescription in the normal way. The patients in the intervention cohort saw the research pharmacist as she undertook a drug history and the pharmacists on the admitting ward.

The pharmacists visiting the admitting ward were asked to proceed as normal but would clearly see the prescriptions written by JT (the research pharmacist-see Section 4.4.1.7 for a role description), and those written by the usual junior doctors. The junior doctors on the ward, who would sign the pharmacist’s draft first prescription, were different from those in A&E. So only the junior doctors in A&E were blinded to the pathway allocated to a particular patient. The consultants in the A&E Department and the admitting wards were notified that the research was being conducted and agreed to the process, and the blinding of the junior doctors in A&E. The junior doctors in the A&E department were therefore unaware of the true purpose of the study and to which cohort the patient had been allocated.
4.4.1.5 Control arm of the study

The traditional process of hospital admission was studied in detail and a process map constructed (see Appendix 4). This was then modified to include the consent process and the point at which the pharmacist could conduct drug histories (see Figure 4.1 in Section 4.4.1). The control arm (process A) of the study was the traditional process where the patient would initially encounter a pharmacist on the admitting ward after the first inpatient chart had been written by a doctor. The experimental arm (process B) involved a band 7 pharmacist (JT) determining a drug history and transcribing this onto the first inpatient prescription chart to the ward doctor to check and then sign.

Patients who attended A&E reception were asked some basic identification questions (such as name, date of birth, address and name of GP) before entering a nurse triage system. Here, a basic assessment determined whether patients would go to the ‘minor’ or ‘major’ part of the A&E department.

In the control arm, the patient was attended by a junior hospital doctor in A&E where the first consideration was whether the patient needed to be admitted for inpatient care or whether they could be discharged after treatment in A&E. It was common that patients were discharged following some immediate care or after some simple advice had been given. Local hospital monitoring data showed that only 21% of patients attending the A&E department were actually admitted. In this respect the junior doctor was acting as a gatekeeper to the Trust. It was estimated that if this ratio exceeded 23% of patients, then the hospital would probably exhaust the availability of unfilled beds. Managing the daily bed situation consumed considerable staff resources.

It therefore followed that the A&E doctor had a primary function to assess whether the symptoms described, or identified on examination, represented something that was significant and needed an admission to be evaluated, or was something minor where the patient could be safely discharged.

In addition the A&E department received ‘walking wounded’ from ambulances as well as ‘blue light’ emergencies and road traffic accidents. ‘Walking wounded’
included patients who had suffering a myocardial infarction (MI). Such patients were seen by specialist nurses before being sent directly to the Coronary Care unit.

It was therefore not surprising that junior doctors in A&E provided only an outline of drugs consumed (e.g. therapeutic groups). For those patients who were admitted to hospital the details of medication were initially recorded in the notes by the A&E doctor before the patient was sent to a ward area. On the ward a separate admitting doctor wrote the first prescription chart from the notes made by the doctor in A&E and from their initial interview with the patient. If the patient was unable to give a clear history of medication, the junior doctor could contact the GP surgery for a verbal or faxed list of medications. The focus for the doctor was largely one of ordering tests and establishing a preliminary diagnosis before the medical consultant reviewed the case. A ward pharmacist visited the ward and reviewed the first inpatient prescription. This could be two hours or two days after the patient reached a hospital bed.

4.4.1.6 Experimental arm of the study

In the experimental arm, the A&E doctor recorded the medication as usual, unaware that the pharmacist also interviewed the patient and recorded the drug history. The research nurses paged the pharmacist and introduced them to the patient after the doctor had conducted their initial interview.

The research pharmacist interviewed the patient and discussed the medication taken at that time and any previous medication including non-prescribed, over the counter and herbal medicines. This was then compared with any patient repeat slips from the GP and the PODs. JT recorded the medication details and any problems on a history sheet. If problems were identified the GP surgery was contacted for further clarification. JT then completed an inpatient drug chart and documented any medication related problems.

On the admission ward (a different) junior doctor talked to the patient and signed the prescription chart, drafted by the pharmacist. So the junior doctor working in A&E was unaware of the research pharmacist’s involvement. If they wanted to amend the
details or stop or start medication they could do so. Ward nurses had been instructed not to give any of these medicines until the ward doctor had signed the inpatient prescription. Both control and experimental pathways converged at this point and all patients underwent routine supervision on the consultant ward round at the end of the day of admission.

4.4.1.7 Study personnel

The research pharmacist (JT) covered additional wards as part of her regular employment but on certain shifts could be paged by the research nurses when a suitable patient entered the study. The research pharmacist was a band 7 Pharmacist who had been qualified for four years. She had worked at Southampton for two years as a rotational pharmacist who covered medical, surgical and cardiac wards. The previous year she had joined the critical care team to cover high care areas as a grade D/band 7. She had conducted drug histories as part of her routine clinical activities but received no other training in this role. She was trained in the research methodology of this project but was representative of band 7 pharmacists at Southampton. This was to demonstrate that any findings would be generalisable to all band 7 post holders in UK acute hospitals.

The author provided the additional clinical pharmacy cover to release JT when she was paged by SJ or KC. The author was actively excluded from all recruitment, randomisation and blinding. After the data collection phase, the notes were reviewed by the author to look for incidents and anomalies that occurred in the care of these patients through their secondary care loop, i.e. throughout admission, inpatient and discharge phases.

The research nurses (SK and JC) were seconded part-time to this project. The remainder of their time was allocated to routine A&E shifts. They had previously worked in A&E for at least two years each.

4.4.1.8 Ethics

The initial proposal was refined and formed the basis of the Ethics submission. At that time the author was a member of the NHS Local Research Ethics Committee (LREC).
The LREC was just changing from a paper based local system to a centralised electronic format. This research project was to be one of the first cohorts reviewed by the committee to detect problems in the ethics process. This delayed the Ethics submission process and made it more complex.

One of the requirements of LREC was that when recruiting for a study, the patient should be given sufficient time to read and reflect on the patient information leaflet, provided before giving informed consent. This was to avoid any coercion or bias in obtaining consent. This was difficult in the A&E department where staff were also trying to process patients within four hours to meet the government target. To overcome this, posters were placed in the patient triage waiting areas where the junior doctors in A&E would not be present.

This was because in this study, junior doctors needed to be unaware that the study was being undertaken. This was one of the reasons why the research nurses were regular employees in the A&E department and not noticeably different from other nurses working in A&E.

The LREC considered the application 293/03/t and gave a favourable opinion on 19th November 2003. The author provided additional information to the committee about the study as would any other researcher; but was excluded from the decision making process. The University of Portsmouth Biosciences Research Ethics Committee also gave approval on 3rd February 2004.

Following the one-month (May 2004) data collation and analysis, it was clear the project would recruit insufficient patients for the statistical power calculation. So a modified application was made to the LREC to recruit patients consuming two or more medications. On 5th July 2004 the project received ethics approval to amend the protocol to two drugs or more.

4.4.1.9 Statistical calculations
The statistical power calculation to determine sample size, assumed a continuous normal distribution of medication errors, and using data from a pilot study of clinical
pharmacy interventions on wards. A two-group continuity Chi squared test with a 0.05 two-sided significance level was envisaged. This would have 80% power to detect the difference between the groups when the sample size in each group was 151. This gave a sample size of around 300 which would take approximately 4 months to collect.

Results from both studies were analysed using mainly descriptive statistics. Where data from the control and intervention arms of the study were compared, the Chi-squared test was employed for nominal data. A level of statistical significance of \( p < 0.05 \) was accepted.

4.4.2 **A&E side-study Questionnaire**

In addition to the main study, the author decided to add a side- or sub-study where the research nurses administered a questionnaire to patients who met the inclusion criteria, immediately after the consent process and before randomisation for the main study.

The questionnaire (see Appendix 5) was designed to obtain data concerned with what participants knew about their medicines and understood about allergies and adverse effects. It also quantified how many patients brought PODS into hospital and verified the number of medicines being consumed.

The questionnaire was discussed with and managed by the research nurses. There was no pilot and interpretation was decided collaboratively with the nurses. It was semi-structured in that the nurses asked the patient the questions and recorded their answers on the questionnaire. Most of the questions were open as the author wanted narrative of patients’ understanding. The questionnaire was brief containing only 12 questions on one side of A4 paper.

4.4.2.1 **Justification for the side-study**

The side-study formed part of the submission to the local research ethics committee.
Part of the justification for the side-study was to ensure that those patients who gave consent for the research would contribute or gain information even if they were allocated to the control arm of the main study.

There was concern in the A&E department that patients avoided taking pain killers, before hospital admission because they were frightened that it might confuse the diagnostic process or cause the doctor to dismiss their symptoms as minor and discharge them, when they needed to be admitted. It was hoped that the answers would enable an appropriate information sheet to be produced.

Some of the errors and anomalies were likely to be associated with adverse effects and allergies. It was possible that the patient’s understanding and explanations of these would be different from those of healthcare professionals. This might have caused confusion in communicating true allergy status. Patients have received medicines, such as antibiotics, when they have a documented allergy to them (see Chapter 3). However this did not always produce anaphylaxis. Therefore there is likely to have been a mis-understanding about adverse and allergic reactions. If this could be understood it may have been possible to produce an information sheet about this whilst the patient was waiting to see a doctor, and therefore improve the quality of documentation connected with allergies and adverse effects.

The patient’s recollection of the number, name and purpose of the medication they consumed was important in obtaining an accurate drug history. This could be verified if they actually brought in their PODs. This was important to medicines reconciliation with the first inpatient drug chart. The questions might have identified why patients did not bring in their own medicines to hospital. This information might have highlighted different types of errors or verified the data on the number of medicines consumed.

4.5 Results
In the following sections, the results of the side-study are discussed first, followed by the results of the main study. This order has been chosen because some of the findings of the side-study provide useful explanations of the main study. Also the side-study
fills some of the gaps in the main study concerned with the number of medicines being consumed prior to admission.

4.5.1 Results from the side-study questionnaire

One hundred and seventy-seven patients were recruited to this study whereas only 115 were recruited into the main study. The difference of 62 comprises patients who were either not admitted or those who were missed by the pharmacist.

The results of the side-study are presented in the same order as the questions appeared in the questionnaire.

Question 1

A: How many different prescribed/non-prescribed medicines do you take?

177/177 (100%) patients responded to this question, but 6 were unable to give an exact number. Table 4.1 shows the distribution of the number of medicines consumed, and Figure 4.2 illustrates the data as a bar-chart. Excluding those who were unsure; 161/171 (90.0%) were taking three or more medicines and 76/171 (42.9%) were taking six or more and 113/171 (66.1%) were taking five or more.

<table>
<thead>
<tr>
<th>Number</th>
<th>unsure</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>6</td>
<td>10</td>
<td>19</td>
<td>29</td>
<td>37</td>
<td>16</td>
<td>18</td>
<td>14</td>
<td>12</td>
<td>6</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4.1 shows that the mode was 5 medicines and a total of 1000 medicines consumed. These were consumed by 171 patients so this gives a mean of 1000/171 (5.8 medicines per patient).
B- How many different tablets do you take each day?

All patients responded to this question, but 28 were unable to give an exact number. Table 4.2 shows the distribution of the number of medicines consumed, and Figure 4.3 illustrates the data as a bar-chart. The answers show at least 1327 tablets (doses) were taken in total by 177 patients. Excluding those who were unsure; nearly half 638/1327 (48.1%) were taking eleven or more tablets and 1162/1327 (87.6%) were taking six or more tablets per day.

Table 4.2- Frequency distribution of number of tablets (doses) taken each day in side-study

<table>
<thead>
<tr>
<th>Number</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsure</td>
<td>28</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>13</td>
<td>2</td>
</tr>
</tbody>
</table>
**Question 2**

*At what times do you find it easier to take medicines?*

All patients responded to the question; it was not clear how many answered a different question of when they actually took them, rather than expressing a preference. The five most popular responses were morning; morning and evening; morning lunch and evening; night-time and as prescribed.

**Question 3**

*Which medicines, if any, do you most frequently forget to take?*
All patients responded and Table 4.3 shows the answers to this question. However, only 9% identified a particular tablet and only 3.4% identified a time of day.

**Table 4.3 Answers to question 3, most frequently forgotten medicines**

<table>
<thead>
<tr>
<th>None</th>
<th>Carer gives</th>
<th>Named tablet</th>
<th>Time of day</th>
<th>Occasionally</th>
<th>Yes all tabs</th>
</tr>
</thead>
<tbody>
<tr>
<td>127</td>
<td>12</td>
<td>16</td>
<td>6</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>71.8%</td>
<td>6.8</td>
<td>9.0</td>
<td>3.4</td>
<td>6.2</td>
<td>2.8</td>
</tr>
</tbody>
</table>

**Question 4**

*Does taking medicines disrupt your daily routine?*

All patients responded and Table 4.4 shows that 88.1% gave a simple negative response.

**Table 4.4 Answers to question 4, disruption to daily routine**

<table>
<thead>
<tr>
<th>No</th>
<th>sometimes</th>
<th>Part of routine</th>
<th>Only if on holiday</th>
<th>side effect</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>156</td>
<td>2</td>
<td>8</td>
<td>1</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>88.1%</td>
<td>1.1</td>
<td>4.5</td>
<td>0.6</td>
<td>1.7</td>
<td>4.0</td>
</tr>
</tbody>
</table>

**Question 5**

*Can you remember the names of any prescribed medication that you take?*

The response was 174/177 (98.4%) and Table 4.5 shows that 69.5% were able to name some. Where names could be provided these have been quantified in Table 4.6.

**Table 4.5 Answers to question 5, names of prescribed medicines**

<table>
<thead>
<tr>
<th>Cant recall</th>
<th>All on a list</th>
<th>Only what they were for</th>
<th>All in pill box</th>
<th>All on a prescription</th>
<th>Only by colour</th>
<th>No all new</th>
<th>Able to name some</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>121</td>
</tr>
<tr>
<td>20.7</td>
<td>4.6%</td>
<td>1.7</td>
<td>1.1</td>
<td>1.1</td>
<td>0.6</td>
<td>0.6</td>
<td>69.5</td>
</tr>
</tbody>
</table>

A total of 520 could be named. This is 520/1327 (39.2%) of that found in question 1. This data is illustrated by a bar-chart in Figure 4.4
Table 4.6 Answers to question 5, where the respondent could provide names

<table>
<thead>
<tr>
<th>Number of named medicines</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>10</td>
<td>18</td>
<td>22</td>
<td>22</td>
<td>19</td>
<td>13</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Percentage N=121</td>
<td>8.3</td>
<td>14.0</td>
<td>18.2</td>
<td>18.2</td>
<td>15.2</td>
<td>10.7</td>
<td>5.8</td>
<td>1.7</td>
<td>1.7</td>
<td>3.3</td>
<td>0.8</td>
<td>0.8</td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.4 Frequency distribution of medicines named in side-study

**Question 6**

_Do you know what they are for?_

All patients responded and Table 4.7 shows that 9/177 (5.1%) could not recall what their medicines were for. 91.0% could name the condition or describe the part of the body that was affected and the responses are shown in Table 4.8

Table 4.7 Answers to question 6, did patients know what their medicines were for

<table>
<thead>
<tr>
<th>Response</th>
<th>no</th>
<th>Have a list</th>
<th>Cant recall</th>
<th>Yes</th>
<th>Named conditions or parts of body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>7</td>
<td>161</td>
</tr>
<tr>
<td>Percentage</td>
<td>2.3</td>
<td>0.6</td>
<td>2.3</td>
<td>4.0</td>
<td>91.0</td>
</tr>
</tbody>
</table>
Table 4.8 Answers to question 6 where a condition was named

<table>
<thead>
<tr>
<th>Number of conditions named</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>24</td>
<td>46</td>
<td>40</td>
<td>51</td>
</tr>
<tr>
<td>Percentage (N=161)</td>
<td>14.9</td>
<td>28.6</td>
<td>24.8</td>
<td>31.7</td>
</tr>
</tbody>
</table>

**Question 7**

*Have you taken any medication such as painkillers before coming here today (particularly if injury related)?*

All patients responded with 50/177 (28.2%) responding in the affirmative. Table 4.9 shows the distribution of reasons given for patients who did not take any painkillers.

It was not ascertained how many patients had pain as part of their presenting symptoms although 12 actively declared this

Table 4.9 Answers to question 7 where patients did not take painkillers

<table>
<thead>
<tr>
<th>Category</th>
<th>Not relevant</th>
<th>Reluctant</th>
<th>Didn’t think</th>
<th>Felt sick</th>
<th>Came in sudden</th>
<th>Named a drug</th>
<th>Usual meds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>12</td>
<td>5</td>
<td>7</td>
<td>7</td>
<td>15</td>
<td>36</td>
<td>45</td>
</tr>
<tr>
<td>% N=127</td>
<td>9.4</td>
<td>3.9</td>
<td>5.5</td>
<td>5.5</td>
<td>11.8</td>
<td>28.3</td>
<td>35.4</td>
</tr>
</tbody>
</table>

The ‘not relevant’ category refers to patients who did not come to hospital with pain as one of their symptoms. The reluctant category refers to those patients who thought that they should not take pain killers because it would confuse the doctor working out what was wrong with them. The ‘felt sick’ category refers to those patients who were nauseous. The ‘came in sudden’ category refers to those patients who were rapidly admitted and did not have access to pain killers before they came to hospital. The ‘named a drug’ category refers to those patients who specified the pain killer taken and the ‘usual meds’ category refers to patients who replied that thy only took their usual medication; it is not clear how many of these included pain killers.

**Question 8**

*Do you have any allergies to drugs?*
All patients responded and Table 4.10 shows that 74.6% did not have allergies to drugs. It was not possible to validate this with the notes because the questionnaire was not designed to do this; so identifiers were not correlated.

### Table 4.10 Answers to question 8 – allergies to drugs

<table>
<thead>
<tr>
<th>Q8</th>
<th>No</th>
<th>Yes</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>177</td>
<td>132</td>
<td>41</td>
<td>4</td>
</tr>
<tr>
<td>100%</td>
<td>74.6%</td>
<td>23.2%</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

Table 4.11 shows the descriptions of reactions given by the 45 patients who declared they were allergic or were unsure whether the reaction was true allergy.

### Table 4.11 Answers to question 8 descriptions of possible allergic reactions

<table>
<thead>
<tr>
<th>Allergy descriptor</th>
<th>Symptoms of illness</th>
<th>Side-effect of drug</th>
<th>Named a drug or told allergic without description</th>
<th>Allergic symptoms described</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>3</td>
<td>14</td>
<td>17</td>
<td>11</td>
</tr>
<tr>
<td>% N=45</td>
<td>6.7</td>
<td>31.1</td>
<td>37.8</td>
<td>24.4</td>
</tr>
</tbody>
</table>

The ‘symptoms of illness’ category refers to patients who described the illness that the drug was being used to treat rather than descriptors of allergy; for example ‘iodine causes pus in wounds’. The ‘side-effect of drug’ category refers to descriptions of drug side-effects rather than descriptors of allergy; for example aspirin produces ‘funny tummy’. The ‘named a drug’ category refers to patients who were told they were allergic to a drug but could not remember or were not given a description of their allergy symptoms.

### Question 9

*If you have taken antibiotics before, have you ever had any form of reaction to them?*

All patients responded and Table 4.12 shows that 82.5% had not had reactions to antibiotics before; 28/31 (90.3%) supplied further information and these answers are shown in Table 4.13. The responses are classified in the same way as Table 4.11.
Table 4.12 Answers to question 9, reactions to antibiotics

<table>
<thead>
<tr>
<th>Q9</th>
<th>No</th>
<th>Yes</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>177</td>
<td>146</td>
<td>28</td>
<td>3</td>
</tr>
<tr>
<td>100%</td>
<td>82.5</td>
<td>15.8</td>
<td>1.7</td>
</tr>
</tbody>
</table>

Table 4.13 Answers to question 9 where further information was supplied

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Symptoms of illness</th>
<th>Described side-effect of drug</th>
<th>Named a drug or told allergic without description</th>
<th>Allergic symptoms described</th>
<th>Unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>1</td>
<td>4</td>
<td>12</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>% N=25</td>
<td>4.0</td>
<td>16.0</td>
<td>48.0</td>
<td>20.0</td>
<td>12.0</td>
</tr>
</tbody>
</table>

**Question 10**

*Do you often take antibiotics?*

All patients responded and Table 4.14 shows that 80.2% did not often take antibiotics. Table 4.15 shows the reasons why antibiotics are often taken in the 31 patients who supplied further information.

Table 4.14 Answers to question 10, taking antibiotics often

<table>
<thead>
<tr>
<th>Q10</th>
<th>No</th>
<th>Yes</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>177</td>
<td>142</td>
<td>31</td>
<td>4</td>
</tr>
<tr>
<td>100%</td>
<td>80.2%</td>
<td>17.5%</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

Table 4.15 reasons why patients often took antibiotics

<table>
<thead>
<tr>
<th>Q10b</th>
<th>Chest infections</th>
<th>Recurrent infections</th>
<th>UTI</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>18</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>100%</td>
<td>58.1%</td>
<td>29%</td>
<td>12.9%</td>
</tr>
</tbody>
</table>
**Question 11**

*If you take medication regularly have you brought them with you?*

All patients responded and Table 4.16 shows that 39% did not bring any of their own medicines with them, and 42.9% brought all of them.

**Table 4.16 Answers to question 11, did patients bring their own medicines into hospital.**

<table>
<thead>
<tr>
<th>Q11</th>
<th>No</th>
<th>Only some</th>
<th>No run out</th>
<th>No but list</th>
<th>Out of house</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>177</td>
<td>69</td>
<td>6</td>
<td>1</td>
<td>22</td>
<td>3</td>
<td>76</td>
</tr>
<tr>
<td>100%</td>
<td>39%</td>
<td>3.4%</td>
<td>0.6%</td>
<td>12.4%</td>
<td>1.7%</td>
<td>42.9%</td>
</tr>
</tbody>
</table>

**Question 12**

*Have you ever used somebody else's prescribed medication because you have a similar problem?*

All patients responded and Table 4.17 shows that 93.8% had not used somebody else's prescribed medication.

**Table 4.17 Answers to question 12, use of someone else’s medicines**

<table>
<thead>
<tr>
<th>Q12</th>
<th>No</th>
<th>Yes same meds</th>
<th>Yes same symptoms</th>
<th>Yes but problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>177</td>
<td>166</td>
<td>5</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>100%</td>
<td>93.8%</td>
<td>2.8%</td>
<td>2.8%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>
4.5.2 Results from randomised study

4.5.2.1 Recruitment to pilot study to determine the distribution of the number of medicines taken by patients presenting at A&E.

Objective A - To determine the distribution of the number of medicines consumed on admission

Table 4.18 shows that 346 patients were admitted between 5th and 27th of May 2004, on the days worked by the research nurses.

<table>
<thead>
<tr>
<th>Total</th>
<th>Resuscitation</th>
<th>Missed</th>
<th>3 or more meds</th>
<th>Less than 3 meds</th>
</tr>
</thead>
<tbody>
<tr>
<td>346</td>
<td>33</td>
<td>22</td>
<td>125</td>
<td>166</td>
</tr>
</tbody>
</table>

Twenty-two patients were missed because the research nurses were occupied processing other participants and 33 went straight into A&E emergency resuscitation - a separated area of the A&E department. When occupied, the access to this area is restricted to essential personnel only. Thus 55 were unable to be considered for consent. Out of the 291 remaining, 43% were consuming three or more medicines.

Table 4.19 shows the distribution pattern for patients entering the consent process from the 125 patients who were consuming three or more medicines.

<table>
<thead>
<tr>
<th>Total</th>
<th>GCS*&lt;15</th>
<th>Too unwell</th>
<th>Declined</th>
<th>Missed</th>
<th>Recruited</th>
</tr>
</thead>
<tbody>
<tr>
<td>125</td>
<td>36</td>
<td>27</td>
<td>29</td>
<td>9</td>
<td>24</td>
</tr>
</tbody>
</table>

*GCS - Glasgow coma score

‘Declined’ means those patients who refused to consent to participate in the study. ‘Missed’ means patients who were discharged or admitted before the pharmacist could attend A&E.

So from 125 patients who were eligible to enter the consent process, in only 24 was consent obtained. Although only 29 patients actually declined consent for the study, this means that out of 346 patients per month presenting, only 24 per month could be
recruited for the main study. This means that the original target of 300 patients would have taken 12.5 months to recruit compared to the initial projection of 4 months. However the pharmacist may not have been able to see all 24 because of logistics of rotas and time taken to interview patients.

The funding for the nurses would have run out by the end of August, so it was decided to seek an amendment to the study from the LREC. On 5\textsuperscript{th} July 2004 the Ethics Committee approved an amendment to change the protocol to two or more medicines.

4.5.2.2 Patients with and without events, results from randomised study

The remainder of the results refer to participants recruited on three or more medicines from May to July, and on two or more medicines from July to September; this only recruited an additional 10 patients. Over 4-5 months of research, 151 patients were recruited to the project and randomised for the main study. Thirty-six out of the 151 who were planned for admission were then discharged without actually being admitted to a ward. This left 115 for analysis. Randomisation produced 76 patients allocated to the control arm (doctors only), and 75 patients allocated to intervention arm (pharmacist obtaining drug histories and writing first prescriptions), as shown in Table 4.20.

| Doctor history i.e. control | 76 | 17 | 59 |
| Pharmacist history i.e. Intervention | 75 | 19 | 56 |
| Totals | 151 | 36 | 115 |

Nineteen patients were randomised but not admitted; this included 13 who went to the ward before the research pharmacist (JT) was able to take a drug history, leaving 115 to be analysed. Three patients were seen twice on separate admissions and were treated independently.
Table 4.21 shows the numbers of patients who had a medicine related event at some stage in their hospital visit. In terms of patients, the difference was not statistically significant.

Table 4.21 Patients with or without events throughout hospital episode

<table>
<thead>
<tr>
<th>Patients</th>
<th>Analysed</th>
<th>Patients with no events</th>
<th>Patients with events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor history</td>
<td>59</td>
<td>25</td>
<td>34</td>
</tr>
<tr>
<td>Pharmacist history</td>
<td>56</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>Totals</td>
<td>115</td>
<td>56 (48.7%)</td>
<td>59 (51.3%)</td>
</tr>
</tbody>
</table>

Chi-squared=1.939, DF=1, p=0.164 (so no sig. diff. between pharmacists and docs)

The 34 patients who had events in the doctor history cohort had a total of 58 events. The 25 patients who had events in the pharmacist history cohort had a total of 32 events.

4.5.2.3 Medication related admissions (MRAs)

**Objective B- To quantify the current rate of medication related admissions at Southampton General hospital**

There were 11 patients in the control arm who had 13 events where medication was possibly linked to reason for admission. There were 14 patients in the intervention arm who had 14 events where medication was possibly linked to reason for admission. In terms of patients, there was no statistically significant difference between the two groups (Chi-Sq = 0.105, DF = 1, p = 0.745).

This gives a total of 25/115 (21.7%) patients where 27 medication related events were possibly linked to the reason for admission. These events are listed in Table 4.22 with an explanation linking the side-effect of the drug with an event that caused the patient to be admitted.
Table 4.22 Medication anomalies detected that may be related to the reason for admission (27 events in total).

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Reason for admission</th>
<th>Drug</th>
<th>Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr*</td>
<td>Admission with suspected head injury or stroke.</td>
<td>captopril</td>
<td>Captopril has side-effect of postural hypotension that may have led to a fall and head injury.</td>
</tr>
<tr>
<td>Dr</td>
<td>Admission due to acute left ventricular heart failure.</td>
<td>atenolol</td>
<td>Atenolol may have accumulated and decreased heart rate and cardiac output, so worsening heart failure.</td>
</tr>
<tr>
<td>Dr</td>
<td>Admission with shortness of breath (SOB), confirmed as active Non-ST elevation myocardial infarction (NSTEMI).</td>
<td>nifedipine</td>
<td>Nifedipine stopped on admission as it produces vasodilatation and low blood pressure that may decrease coronary perfusion during heart attack.</td>
</tr>
<tr>
<td>Dr</td>
<td>Admission with symptoms of increasing heart failure.</td>
<td>ibuprofen</td>
<td>Addition of ibuprofen four months previously may have contributed to altered cardiac output. Doctors added ACEI and calcium channel blockers on this admission.</td>
</tr>
<tr>
<td>Dr</td>
<td>Admission with weakness and fatigue attributed to low sodium and hypokalaemia.</td>
<td>celecoxib</td>
<td>Celecoxib is known to increase risk of heart failure and MI.</td>
</tr>
<tr>
<td>Dr</td>
<td>Admission with dehydration, constipation and abdominal pain. Unable to pass urine due to abdominal distension.</td>
<td>bendroflumethiazide</td>
<td>Bendrofluazide is a diuretic that may decrease sodium and potassium.</td>
</tr>
<tr>
<td>Dr</td>
<td>Admission with dehydration, constipation and abdominal pain. Unable to pass urine due to abdominal distension.</td>
<td>frusemide</td>
<td>Frusemide can produce dehydration, constipation and abdominal pain.</td>
</tr>
<tr>
<td>Dr</td>
<td>Diabetic patient with problems controlling blood sugar.</td>
<td>Mixtard insulin</td>
<td>Recent change in Mixtard insulin dose from 38 to 50 units BD.</td>
</tr>
<tr>
<td>Dr</td>
<td>Epileptic patient with increased seizure activity.</td>
<td>sodium valproate</td>
<td>Sodium valproate 400mg BD changed to 400mg mane and 600mg nocte.</td>
</tr>
<tr>
<td>Dr</td>
<td>Asthmatic patient admitted with SOB and wheeze.</td>
<td>asthmatic inhaler</td>
<td>Patient ran out of inhalers so unable to control symptoms.</td>
</tr>
<tr>
<td>Dr</td>
<td>Epileptic patient with possible fit leading to collapse and causing fractured neck of femur.</td>
<td>carbamazepine</td>
<td>Patient ran out of medicines and had not taken carbamazepine for four days.</td>
</tr>
<tr>
<td>Dr</td>
<td>Admission with SOB and wheeze.</td>
<td>ibuprofen</td>
<td>Patient ha recently taken ibuprofen 400mg TDS. Ibuprofen is known to worsen asthma in some patients.</td>
</tr>
<tr>
<td>Dr</td>
<td>Patient collapsed with</td>
<td>ramipril</td>
<td>Ramipril can cause postural</td>
</tr>
</tbody>
</table>

177
<table>
<thead>
<tr>
<th>Patient</th>
<th>Condition</th>
<th>Medication</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ph</strong></td>
<td>Possible postural hypotension.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>Diabetic ketoacidosis caused by insulin problem.</td>
<td>insulin</td>
<td>Poor control of blood sugars with insulin can cause diabetic ketoacidosis.</td>
</tr>
<tr>
<td><strong>Ph</strong></td>
<td>Patient with worsening heart failure, possible following myocardial infarction.</td>
<td>digoxin</td>
<td>Digoxin started five months prior, but stopped this admission. Digoxin accumulation or poor response.</td>
</tr>
<tr>
<td>Patient</td>
<td>Collapsed with loss of consciousness, possibly secondary to dehydration.</td>
<td>diuretics and nitrates</td>
<td>Diuretics and nitrates stopped on admission because diuretics can cause dehydration and nitrates can cause low blood pressure.</td>
</tr>
<tr>
<td><strong>Ph</strong></td>
<td>Admission with SOB, raised blood pressure and recently treated bradyarrhythmias. Thyroxine recently reduced.</td>
<td>diclofenac and digoxin</td>
<td>Hypothyroidism can cause bradycardia. Diclofenac can cause water retention; SOB and raised BP. Digoxin can accumulate with water retention causing bradyarrhythmias.</td>
</tr>
<tr>
<td>Patient</td>
<td>Admission with vision problems and muscle and ligament pain.</td>
<td>amiodarone and simvastatin</td>
<td>Amiodarone can cause corneal deposits. Simvastatin and amiodarone interact with increased risk of muscle and ligament pain. Patient also taking bezafibrate.</td>
</tr>
<tr>
<td><strong>Ph</strong></td>
<td>Admission with dizziness, visual disturbance, chest pain haematuria, hypertension and anxiety.</td>
<td>fluoxetine and nifedipine</td>
<td>Recently started fluoxetine can cause visual disturbance. Dizziness could be related to nifedipine.</td>
</tr>
<tr>
<td>Patient</td>
<td>Admission with chest pain and possible heart attack.</td>
<td>celecoxib</td>
<td>Celecoxib can cause water retention and MI.</td>
</tr>
<tr>
<td><strong>Ph</strong></td>
<td>Patient with urinary tract infection, confusion, decreased urine output, and collapse (also possible septic dilatation)</td>
<td>atenolol</td>
<td>Atenolol can accumulate in renal dysfunction causing bradycardia and heart failure.</td>
</tr>
<tr>
<td>Patient</td>
<td>Admitted and died of heart failure. GP increased ramipril from 5mg to 10mg but patient said made feel worse so only took 5mg</td>
<td>ramipril</td>
<td>The increased dose of ramipril may have decrease blood pressure and made patient feel weak. Reducing dose back from 10mg could decrease cardiac output.</td>
</tr>
<tr>
<td><strong>Ph</strong></td>
<td>Doctor rewrote chart. Pharmacist noted increase in MTX toxicity. Readmitted three weeks later with NSTEMI.</td>
<td>celecoxib</td>
<td>Possibly extra doses of methotrexate. Celecoxib can cause heart failure.</td>
</tr>
<tr>
<td>Patient</td>
<td>Admitted following fall, maybe caused by dehydration or change in cardiac output.</td>
<td>allopurinol and amlodipine</td>
<td>Diuretics can cause dehydration and renal dysfunction. No dose reduction for allopurinol despite raised creatinine. Atenolol and</td>
</tr>
</tbody>
</table>
enalapril replaced by amlodipine could change cardiac and renal function.

Osteoporotic patient with recent manipulation by osteopath, admitted following a fall. Co-proxamol and amitriptyline. Co-proxamol can cause dizziness and confusion. Amitriptyline is associated with falls. Manipulation may have affected gait.

Previous admission with hypoglycaemia. Glipizide stopped on discharge. Patient re-admitted after a fall. Metformin taken twice a day at home but doctor prescribed daily on first chart. Glipizide and metformin. Fall possibly related to blood sugar control. Metformin first prescription error.

Problems with gait leading to a fall. Compliance. Compliance history and gait may contribute to fall.

*Dr – doctor; Ph - pharmacist
Table 4.23 summarises the 27 medication-related admissions in five categories and identifies those events that were potentially avoidable.

Table 4.23 Distribution of medication-related admissions by type

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Avoidable</th>
<th>Side effect</th>
<th>Cardiac</th>
<th>Dose change</th>
<th>Fall</th>
<th>Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8</td>
<td>5</td>
<td>9</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

The ‘side-effect’ category refers to a patient who was consuming a medicine with a recognised side-effect that matched their presenting complaint. For example, a patient admitted with weakness and fatigue attributed to hyponatraemia and hypokalaemia who was consuming bendroflumethiazide. The ‘cardiac’ category refers to the patient’s presenting complaint that could have been caused or worsened by a drug. This could be a sub group of the side-effect category. For example a patient admitted with worsening anginal pain was consuming celicoxib, which can cause water retention and precipitate myocardial infarction.

The ‘fall’ category refers to a patient admitted after a fall that could have been caused by a drug. An example was a patient admitted following a fall, who was consuming captopril that is associated with postural hypotension. The ‘dose change’ category was where symptom control was lost following a dose change or corrected by a change in...
dose of their medication. For example a diabetic patient admitted because of problems controlling their blood sugar following a recent change in Mixtard insulin dose from 38 to 50 units twice daily.

A patient may be admitted with worsening symptoms of a pre-existing condition for which they had been prescribed medication, but had not taken them because they had not collected further supplies. For example, an asthmatic was admitted with shortness of breath and wheeze that the patient had previously controlled with inhalers, but they had emptied and not replaced them.

4.5.2.4 Events during the admission phase

Objective C - To quantify prescribing anomalies that occurred within the admission process.

During the admission process there were 13 patients in the control arm who had 22 events, and four patients in the intervention arm who had seven events. Table 4.24 lists the 29 events that occurred (some patients had more than one event). The difference between groups in terms of events was not statistically significant (Chi-Sq = 0.518, DF = 1, p = 0.472). In terms of patients, the difference was significant (Chi-sq = 10.006, DF = 1, p = 0.002).

Table 4.24 Patients experiencing events detected during the admission process

<table>
<thead>
<tr>
<th>Pt.</th>
<th>Cohort</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Dr*</td>
<td>Patient on cruise admitted with confusion due to UTI, now treated with trimethoprim. Also leg swelling &amp; Shortness of breath, possible congestive cardiac failure. Drug history on quetiapine but not on clerking nor first chart.</td>
</tr>
<tr>
<td>I</td>
<td>Dr</td>
<td>Patient on cruise admitted with confusion due to UTI, now treated with trimethoprim. Also leg swelling &amp; Shortness of breath, possible congestive cardiac failure. Confusion over Sinemet dose and Entacapone dose.</td>
</tr>
<tr>
<td>II</td>
<td>Dr</td>
<td>Glipizide on TTO but not given during 5 day inpatient stay</td>
</tr>
<tr>
<td>III</td>
<td>Dr</td>
<td>Seretide omitted on admission clerking added two weeks later as patient using own without doctors being aware.</td>
</tr>
<tr>
<td>IV</td>
<td>Dr</td>
<td>Patient with stroke and epilepsy admitted following fall. Transferred to orthopaedics. Alendronate in drug history but not on drug chart so added by pharmacist.</td>
</tr>
<tr>
<td>V</td>
<td>Dr</td>
<td>Patient admitted with suspected stroke. PODs revealed</td>
</tr>
<tr>
<td>Dr</td>
<td>V</td>
<td>Patient admitted with suspected stroke. PODs revealed</td>
</tr>
<tr>
<td>Dr</td>
<td>V</td>
<td>Patient admitted with suspected stroke. PODs revealed</td>
</tr>
<tr>
<td>Dr</td>
<td>VI</td>
<td>Montelukast omitted from the inpatient chart so they were</td>
</tr>
<tr>
<td>Dr</td>
<td>VI</td>
<td>Seretide omitted from the inpatient chart so they were</td>
</tr>
<tr>
<td>Dr</td>
<td>VI</td>
<td>Omeprazole omitted from the inpatient chart so they were</td>
</tr>
<tr>
<td>Dr</td>
<td>VII</td>
<td>Sulfasalazine prescribed on inpatient chart but enteric coated</td>
</tr>
<tr>
<td>Dr</td>
<td>VII</td>
<td>Methotrexate prescribed as weekly. Pharmacist discovered</td>
</tr>
<tr>
<td>Dr</td>
<td>VII</td>
<td>Patient prescribed Hydroxychloroquine BD but pharmacist</td>
</tr>
<tr>
<td>Dr</td>
<td>VIII</td>
<td>Salbutamol prescribed as metered dose inhaler but the patient</td>
</tr>
<tr>
<td>Dr</td>
<td>VIII</td>
<td>Beclomethasone inhaler prescribed without a strength. The</td>
</tr>
<tr>
<td>Dr</td>
<td>IX</td>
<td>Candesartan prescribed as 8mg but POD was for 16mg. The</td>
</tr>
<tr>
<td>Dr</td>
<td>IX</td>
<td>Simvastatin prescribed in the morning. However it is more</td>
</tr>
<tr>
<td>Dr</td>
<td>X</td>
<td>Diltiazem MR 90mg prescribed as BD but patient usually</td>
</tr>
<tr>
<td>Dr</td>
<td>XI</td>
<td>Ezetimibe was stopped 3 weeks prior to operation but</td>
</tr>
<tr>
<td>Dr</td>
<td>XII</td>
<td>Patient was admitted on warfarin and co-proxamol. The Co-</td>
</tr>
<tr>
<td>Dr</td>
<td>XIII</td>
<td>Allopurinol changed from 300mg to 100 due to acute renal</td>
</tr>
<tr>
<td>Ph</td>
<td>XIV</td>
<td>Patient prescribed diltiazem on inpatient chart. Pharmacist</td>
</tr>
<tr>
<td>Ph</td>
<td>XIV</td>
<td>A patient on warfarin reported to the pharmacist that they</td>
</tr>
</tbody>
</table>
Doctor ignored pharmacist’s chart and wrote a new prescription chart but omitted diazepam. This was added at a later date by another doctor.

Doctor ignored the pharmacist’s chart and wrote a new prescription chart but regular paracetamol that the patient was taking. This was added at a later date by another doctor.

Doctor ignored the pharmacist’s chart and wrote a new prescription chart but omitted timolol eyes drops. This was added at a later date by another doctor.

Pharmacist added that patient takes alendronate on Mondays.

On the previous admission the pharmacist had made lots of changes on the discharge prescription. On the previous admission the patient was taking sodium valproate 400mg in the morning and 600mg at night. However on this admission they were prescribed 400 BD. There was no documented record of a change in dose.

*Dr= doctor; Ph = pharmacist

**Objective D – To determine and quantify if drug histories conducted by a pharmacist contain fewer omissions, errors and interactions than those conducted by junior doctors.**

A total of 17 patients had 29 events occur during their admission process. These events have been categorised in Table 4.25.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Prescribing errors on admission</th>
<th>Clerking drug omission</th>
<th>Error of detail</th>
<th>Inappropriate drug choice</th>
<th>Dose adjust for renal dysfunc.</th>
<th>Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor history</td>
<td>22 (75.9%)</td>
<td>10</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Pharmacist history</td>
<td>7 (24.1%)</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Totals</td>
<td>29</td>
<td>14</td>
<td>11</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

The ‘clerking drug omission’ category means that the first inpatient chart had a whole drug omitted, when compared to the drug history. The ‘error of detail’ category means that a detail of prescribing (dose, frequency, timing, route or formulation) did not match the drug history. The ‘inappropriate drug choice’ category means the drug was contraindicated or otherwise unsuitable for an individual patient. The ‘dose adjust for renal dysfunc.’ category means that the dose or frequency of the medication had not been adjusted for level of the renal dysfunction.
**Objective E – To assess if the intervention had an impact on the prevalence of adverse events and medication errors after the admission phase of the hospital episode.**

This objective examined the inpatient and discharge phases of the hospital episode to see if there is a connection with the intervention made during the admission phase.

### 4.5.2.5 Events during the inpatient phase

Eight patients had nine events during the inpatient phase of the hospital episode. They were all from the doctor cohort and are listed in Table 4.26. The inpatient events have been categorised in Table 4.27.

**Table 4.26 Events detected during the inpatient phase**

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr</td>
<td>The conversion of IV metronidazole to oral, except the IV dose is 500mg TDS and the oral is 400mg TDS. The doctor prescribed oral 500mg TDS so the ward pharmacist changed to 400mg</td>
</tr>
<tr>
<td>Dr</td>
<td>An alcoholic was prescribed IV Pabrinex, but could have taken oral medication because they were already on a reducing dose of chlordiazepoxide. After 48 hours the ward pharmacist got the doctor to change to oral thiamine 100mg daily</td>
</tr>
<tr>
<td>Dr</td>
<td>Patient with oesophageal varices and history of gastric bleeding was prescribed diclofenac. The ward pharmacist cautioned against this because diclofenac can cause gastric bleeding</td>
</tr>
<tr>
<td>Dr</td>
<td>A patient on meloxicam was prescribed aspirin for cardiac protection. This would negate the selective effect of the low dose aspirin</td>
</tr>
<tr>
<td>Dr</td>
<td>Co proxamol changed to codydramol in a patient with uncontrolled pain</td>
</tr>
<tr>
<td>Dr</td>
<td>Patient presented with shortness of breath, confirmed as NSTEMI. Enoxaparin prescribed 1mg/kg BD pharmacist changed to 70mg to ensure that something was administered</td>
</tr>
<tr>
<td>Dr</td>
<td>Clexane 1mg/Kg clarified to 80mg dose by pharmacist</td>
</tr>
<tr>
<td>Dr</td>
<td>Chest pain Clexane 1mg/kg BD changed to 80mg by pharmacist</td>
</tr>
<tr>
<td>Dr</td>
<td>Patient developed rash after three doses of Augmentin. There were no previously documented events</td>
</tr>
</tbody>
</table>
Table 4.27 Distribution of inpatient anomalies in control group

<table>
<thead>
<tr>
<th>Inpatient anomalies</th>
<th>Details</th>
<th>Drug appropriate</th>
<th>Procedure</th>
<th>ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

The ‘details’ category refers to dose, frequency, or route that did not match those listed in the BNF for a particular drug. The ‘drug appropriate’ category refers to the selection of a drug that is either sub-optimal or harmful for a particular patient. The ‘procedure’ category refers to poor completion or lack of adherence to a Trust recognised procedure.

4.5.2.6 Events during the discharge phase

Ten patients in the control (doctor) cohort had 14 events during the discharge phase and eight patients in the intervention (pharmacist) cohort had 11 events on discharge with the pharmacist; these events are listed in Table 4.28. The discharge phase contributed 25/45 (55%) of all the events in the hospital episode. The difference between groups was statistically significant in terms of events (Chi-Sq = 4.834, DF = 1, p = 0.028).

These 18 patients had 25 events that are summarised in Table 4.29. Some patients in the main study had more than one event; this is illustrated in Table 4.32.

Table 4.28 Events detected during the discharge process

<table>
<thead>
<tr>
<th>Pt</th>
<th>Cohort</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Dr</td>
<td>Admission with SOB confirmed as NSTEMI. Clopidogrel started on inpatient chart but omitted from discharge prescription (TTO).</td>
</tr>
<tr>
<td>II</td>
<td>Dr</td>
<td>Admission with suspected stroke. Simvastatin prescribed daily on TTO but pharmacist changed to at night to improve efficacy.</td>
</tr>
<tr>
<td>II</td>
<td>Dr</td>
<td>Citalopram started on inpatient chart but omitted from TTO.</td>
</tr>
<tr>
<td>III</td>
<td>Dr</td>
<td>An admission with alcoholic liver disease, cirrhosis, jaundiced, and very unwell was prescribed vitamin K on the TTO. This would imply phytomenadione that requires bile salt secretion for its absorption. The pharmacist changed the prescription to menadiol, which is more water soluble and has good absorption even with cholestasis.</td>
</tr>
<tr>
<td>IV</td>
<td>Dr</td>
<td>Folic acid prescribed on the inpatient chart but omitted from TTO.</td>
</tr>
<tr>
<td>IV</td>
<td>Dr</td>
<td>Tiaprofenic acid prescribed BD on admission but unintentionally changed to daily on discharge.</td>
</tr>
<tr>
<td>V</td>
<td>Dr</td>
<td>Dihydrocodeine 30mg QDS prescribed on inpatient chart but 6mg QDS on TTO.</td>
</tr>
<tr>
<td>---</td>
<td>----</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>V</td>
<td>Dr</td>
<td>Diclofenac MR BD prescribed on inpatient chart but plain tablets prescribed daily on TTO.</td>
</tr>
<tr>
<td>VI</td>
<td>Dr</td>
<td>A steroid reducing schedule was prescribed ambiguously on the TTO, so the pharmacist clarified the details with the doctor.</td>
</tr>
<tr>
<td>VII</td>
<td>Dr</td>
<td>A patient with a history of deep vein thrombosis was admitted on a Friday ready for bladder tumour resection and removal of bladder polyp and stones on the next Monday. On the Friday they were started on both enoxaparin and warfarin. The INR was due to be checked on Monday morning following three loading doses of warfarin. The patient would require therapeutic enoxaparin (1.5mg/kg) until the INR was 2 to 3. However the patient had to be urgently discharged on the Saturday and was only prescribed 40mg enoxaparin on the TTO. After discussion with the pharmacist the junior doctor changed the dose back to the 120mg that had been given on the Friday.</td>
</tr>
<tr>
<td>VIII</td>
<td>Dr</td>
<td>Patient was using their own Flixonase nasal spray on the ward but omitted from TTO.</td>
</tr>
<tr>
<td>VIII</td>
<td>Dr</td>
<td>Patient was using their own Otrivine nasal spray on the ward but omitted from TTO.</td>
</tr>
<tr>
<td>IX</td>
<td>Dr</td>
<td>Lansoprazole prescribed as 2mg daily on the TTO.</td>
</tr>
<tr>
<td>X</td>
<td>Dr</td>
<td>Amiodarone was prescribed TDS on the inpatient chart but daily on the TTO. The pharmacist changed to BD for 1 week, then daily in accordance with usual dosing schedule.</td>
</tr>
<tr>
<td>XI</td>
<td>Ph</td>
<td>Isosorbide mononitrate dose ambiguous so clarified by pharmacist.</td>
</tr>
<tr>
<td>XI</td>
<td>Ph</td>
<td>Antibiotic course prescribed for 28 days was confirmed with doctor that only two days were required to complete the course. Patient was readmission within 2 days of discharge and subsequently died of congestive heart failure and atrial fibrillation. There was no clear link to any medication.</td>
</tr>
<tr>
<td>XII</td>
<td>Ph</td>
<td>Patient was prescribed QVAR for regular use, said he only used it when required. The pharmacist counselled the patient and wrote a compliance chart. Subsequently the pharmacist screened the TTO that stated that Becotide was required; because the pharmacist knew the patient they changed the TTO to QVAR.</td>
</tr>
<tr>
<td>XIII</td>
<td>Ph</td>
<td>Patient was taking diltiazem on a previous admission, when it was stopped. However on this admission it was prescribed on TTO. Doctor confirmed this was unintended.</td>
</tr>
<tr>
<td>XIV</td>
<td>Ph</td>
<td>Ranitidine prescribed as 200mg at night on TTO so pharmacist changed to usual dose of 300mg.</td>
</tr>
<tr>
<td>XIV</td>
<td>Ph</td>
<td>A patient was admitted for surgery taking warfarin. In accordance with normal practice this was changed to therapeutic doses of enoxaparin around the time of the operation. However on discharge there was no warfarin prescribed on the TTO, so the pharmacist wrote that the GP could restart anticoagulation when wound drains had been removed (in accordance with instructions on the operation note.</td>
</tr>
<tr>
<td>XV</td>
<td>Ph</td>
<td>Nicorandil prescribed as 20mg BD on the inpatient chart but on the</td>
</tr>
</tbody>
</table>
TTO it was written as 30mg BD. The pharmacist confirmed this was an unintended change.

XVI Ph A patient was taking zolpidem when required at night. However the TTO stated that it should be taken regularly, every night.

XVI Ph A patient was prescribed simvastatin 60mg at night on the inpatient chart, but 600mg on the TTO.

XVII Ph A salbutamol inhaler was prescribed in a dose of 2.5mg (nebuliser dose) on the TTO. The pharmacist changed this to the usual 100 microgram inhaler dose.

XVIII Ph A patient was admitted to intensive care with a respiratory tract infection. They were started on steroids and a proton pump inhibitor. On the ward the steroids were reduced progressively. On the TTO the steroid reduction was continued without a clear indication to stop either steroids or proton pump inhibitor.

### Table 4.29 Summarised events detected during the discharge phase

<table>
<thead>
<tr>
<th>Details</th>
<th>Drug omission</th>
<th>Failure to finish procedure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>5</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Intervention</td>
<td>0</td>
<td>1</td>
<td>11</td>
</tr>
</tbody>
</table>

**4.5.2.7 Patients with multiple events**

### Table 4.30 Distribution of patients throughout main study with number of events

<table>
<thead>
<tr>
<th>Patients</th>
<th>Analysed</th>
<th>pts with 1 events</th>
<th>pts with 2 events</th>
<th>pts with 3 events</th>
<th>pts with 4 events</th>
<th>pts with 5 events</th>
<th>Total pts with events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor history</td>
<td>59</td>
<td>22</td>
<td>8</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>34</td>
</tr>
<tr>
<td>Pharmacist history</td>
<td>56</td>
<td>19</td>
<td>5</td>
<td>1</td>
<td></td>
<td></td>
<td>25</td>
</tr>
<tr>
<td>Totals (%)</td>
<td>115</td>
<td>(35.6)</td>
<td>(11.3%)</td>
<td>(2.6)</td>
<td>(0.9)</td>
<td>(0.9)</td>
<td>(51.3)</td>
</tr>
</tbody>
</table>

Just over half, (59/115; 51.3%) had events in the main study (MRAs and events in hospital); 41/115 (35.6%) patients had one event; 13/115 (11.3%) patients had two events and 5/115 (4.3%) patients had more than two events. However because only 115 patients could be analysed, this study is underpowered to prove a statistically significant difference. The small difference gives chi-squared = 1.939, DF=1, p=0.164. These results therefore do not show a statistically significant difference –
although there is a trend. The study power is only 0.23 and to show a statistically
significant difference would have required recruitment of 231 subjects in both arms of
the study. If the medication related admissions are disregarded this leaves just events
that occurred within the hospital processes (representing $37/115 = 32\%$ of patients).
To show the numbers of patients with multiple events Table 4.30 becomes Table 4.31.

Table 4.31 Distribution of patients with multiple events within the hospital
episode.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Total Patients Analysed</th>
<th>pts with 1 events</th>
<th>Pts with 2 events</th>
<th>Pts with 3 events</th>
<th>Pts with 4 events</th>
<th>pts with 5 events</th>
<th>Total pts with events (corrected for duplicates)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor history</td>
<td>59</td>
<td>21</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>31 (25)</td>
</tr>
<tr>
<td>Pharmacist history</td>
<td>56</td>
<td>7</td>
<td>4</td>
<td>1*</td>
<td></td>
<td></td>
<td>12 (12)</td>
</tr>
<tr>
<td>N (%)</td>
<td>115</td>
<td>28 (24.3)</td>
<td>12 (10.4)</td>
<td>2 (1.7)</td>
<td>0</td>
<td>1</td>
<td>43 (37)</td>
</tr>
</tbody>
</table>

* This event was because the doctor rewrote the pharmacist’s chart; the pharmacist’s
chart did not contain these events.

4.5.2.8 All events within hospital processes

*Objective F – To determine if the pharmacist transcribed this data into
the first hospital prescription, ready for the doctor to sign, does this
reduce medication errors, potential interactions and ‘adverse drug
related events’ and facilitate the admission or discharge process.*

Table 4.32 summarises all 63 events that occurred in hospital across the admission,
inpatient and discharge phases. Some patients had events in more than one phase of
the hospital episode or journey that causes some double counting. Within one phase,
some patients had more than one event.

Table 4.32 Summary of events during the complete hospital episode

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Prescribing events on admission</th>
<th>Prescribing events as inpatient</th>
<th>Prescribing events on discharge</th>
<th>Total events within hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor (control)</td>
<td>Patient</td>
<td>13</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Event</td>
<td>22</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>Pharmacist (Intervention)</td>
<td>Patient</td>
<td>4</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Event</td>
<td>7</td>
<td>0</td>
<td>11</td>
</tr>
</tbody>
</table>
A total of 63 events occurred within hospital processes and 45/63 (71.4%) occurred within the control cohort. Seventeen patients had 29 events during the admission phase with 22/29 (75.9%) events occurring in the control cohort. Eight patients had nine events during the inpatient phase with all events in the control. Eighteen patients had 25 events during the discharge phase with 14/25 (56%) events occurring in the control cohort. In the control arm 22/45 (48.9%) prescribing errors occurred on admission, 9/45 (20.0%) during the inpatient phase and 14/45 (31.1%) during discharge. In the intervention arm 7/18 (38.9%) prescribing errors occurred on admission and 11/18 (61.1%) during discharge. There were no anomalies during the inpatient phase.

Table 4.33 shows a summary of events that occurred before and during the hospital episode and Table 4.34, the events occurring throughout the whole hospital process, including discharge.

### Table 4.33 Summary of events that occurred before and during the hospital episode.

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Medication related admissions</th>
<th>Events within hospital</th>
<th>Total (corrected for double counting)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (doctor)</td>
<td>Patients 11</td>
<td>31</td>
<td>42 (34)</td>
</tr>
<tr>
<td></td>
<td>Events 13</td>
<td>45</td>
<td>58</td>
</tr>
<tr>
<td>Intervention (pharmacist)</td>
<td>Patients 14</td>
<td>12</td>
<td>26 (25)</td>
</tr>
<tr>
<td></td>
<td>Events 14</td>
<td>18</td>
<td>32</td>
</tr>
</tbody>
</table>

Almost three quarters of patients (31/42; 73.8%) in the control arm had events that occurred within the hospital processes, but the double counting of patients introduces a notable discrepancy; 12/26 (46.2%) patients in the intervention arm had events that occurred within hospital processes. The majority of events (45/63; 71%) that occurred within the hospital process occurred in the control (doctor) pathway.

### Table 4.34 Summary of events that occurred within hospital processes.

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Total events during hospital episode</th>
<th>No events during hospital process</th>
<th>Number of patients in cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Patients 25</td>
<td>34</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>Events 45</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>Patients 12</td>
<td>44</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>Events 18</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>
There was a statistically significant difference between the control and intervention cohorts in terms of patients affected (Chi-sq.=5.775, DF=1, p=0.016).

4.6 Discussion

4.6.1 Part 1 - side-study questionnaire

The recruitment to this side-study (177) is greater than the main study (151) because it was conducted immediately after consent to participate in research; 26 patients were not admitted or missed by the pharmacist. The frequency distribution gives an interesting insight into the distribution of the number of medicines consumed in the main study – although the total numbers do not match. Firstly, increasing the recruitment to those taking 2 medicines or more only added a maximum of 10 patients. So this does not explain the lower than expected recruitment rate in the main study. It may be that the rate of recruitment increased as the researchers became more familiar with the routine.

The range of medicines taken by the subjects in this study varied from two to 14. It was interesting how many medicines were consumed; half the patients were consuming 5 or more and a quarter, 7 or more.

Question 1 (see Appendix 5 for questions)

This question was divided into two parts: part A asked about the number of medicines and part B asked about the number of tablets. Part B was to review how patients often describe the number of tablets taken and to correlate to part A. It was hoped that by asking the question in two different ways an internal correlation could be achieved and still achieve the goals of brevity and clarity.\textsuperscript{161,162} However it revealed a deficiency in the question, which should have read: ‘how many doses per day?’. Some patients included inhalers and creams, some did not. Some patients in their answers showed that they thought of medicines as mixtures and different from tablets. GTN spray and inhalers also caused confusion. The nurses recorded more detail as the study progressed and they learnt a simple number was inadequate. So it is not possible
to analyse this rationally. Suffice it to say that many patients were taking a lot of medicines and a lot of doses. It is hardly surprising that medication errors occurred.

**Question 2**
This did not reveal the most convenient time of day to take a medicine. The question was deficient, or too complex.

**Question 3**
This found that 127/177 (71.8%) stated they never forgot a medicine, but this could have been to try to say what they thought the nurse wanted to hear. Twelve said their carer ensured they did not forget, increasing the alleged compliance to 139 /177(78.5%). Table 4.3 shows that the remaining 38 (21.5%) admitted to frequently forgetting their medicines. The 38 patients gave a variety of answers, from forgetting ‘all of them’, ‘just occasionally’, ‘those at a particular time of day’, or named a particular tablet. There were also those who took a specifically missed tablet later in the day.

**Question 4**
This gives some insight into how patients perceived medicine taking, but it is really only hypothesis generating, like much of the data from this questionnaire.156/177 (88.2%) stated that it did not disrupt their daily routine and a further 8 stated it was part of the routine.

**Question 7**
This originated from a perception that patients who consumed pain killers would not be admitted because the doctor would be misled by their level of pain. The answers showed only five patients who expressed this concern. It is not clear out of the 127 (who had taken no pain killers), how many were not in any pain. However a more conditional question (like question 10) demonstrated that patients had difficulty understanding a more complex question. Forty-five patients just took their normal medication but it was not always clear in how many cases this included an analgesic.
**Questions 8 and 9**

These questions explored the complex subject of intolerance due to side effects and perceptions of allergy. Question 8 asked about allergies to all drugs and 74.6% said they did not have any and 2.3% were unsure. Out of the 45 patients who provided further information (following an affirmative answer) three described symptoms of illness and 14 described a side-effect of the drug to which they were ‘allergic’. In the author’s opinion, this can be interpreted as 14/177 (7.9%) were intolerant. If the unsure and uninformed were included, then it could be assumed that 10% of patients might benefit from a medication review, prior to classification as having a drug allergy.

Seventeen patients stated that they were allergic but were unable to describe the symptoms. Some were told by the anaesthetist that they had an allergic reaction, but they were otherwise unaware. Others accepted a statement by a healthcare professional that they were allergic to a particular drug without asking for details; 28/177 (15.8%) said they were truly allergic to a medicine they have been given. This shows the importance of this question when taking a medication history.

**Question 9**

Nearly all patients had had antibiotics and 82.5% (146/177) had had no adverse reaction. Out of the 25 who had, 8/25 (32%) were either unclear, described symptoms of illness or side effect of a drug i.e. intolerance; and 17/25(68%) described allergic symptoms or stated they were allergic. In other words 17/177 (9.6%) appeared to be truly allergic to an antibiotic they had taken.

**Question 10**

This looked at those patients who were regularly or frequently prescribed antibiotics; 31/177 (17.5%) fell into this category. The three main indications were 18/31 (58.1%) chest infections (particularly in winter), 9/31(29.0%) recurrent infections (notably oncology patients) and 4/31 (12.9%) urinary tract infections. 4/177 (2.3%) were unclear how to respond because they had been prescribed antibiotics for gut decolonisation or splenectomy prophylaxis. The majority (142/177; 80.2%) did not take regular antibiotics.
Question 11
This was asked to explore how many patients brought in their medicines to aid the admission history taking process; 42% brought in their medicines and a further 12.4% only brought in a written list. The 39% who brought in nothing gave no reason and it is not clear if they were told not to, or simply forgot. This presents a challenge to the A&E department; a decade ago, hospitals wanted patients to either not bring in their medicines or return the medicines to home within 24 hours. Anecdotally many medicines were mislaid as patients transferred between wards and the pharmacy has to re-dispense them. In the author’s opinion, many hospitals now use PODS wherever possible; but previous hospital experience may make patients reluctant to bring in their medicines.

Question 12
The author initially expected all patients to deny taking someone else’s medicines; but only 166/177 (93.8%) did this; 11/177 (6.2%) of patients declared they took someone else’s medicines and volunteered their justification for this.

4.6.2  Part 2- main study

4.6.2.1  Randomisation & exclusion
The nature of this project in the A&E department produced anticipation that there would be a large drop out rate due to attendee patients being very ill and unable to consent to a research project. However the size of the other exclusion categories was somewhat surprising.

Twenty-two patients were missed before the research nurses could discuss the study. This was despite the fact that the nurses were familiar with the flow of patients. They were missed because the nurses were obtaining consent from other patients. This demonstrates the rapid throughput of patients in the A&E department and the difficulties of conducting research in this area. The total number of patients possible for recruitment (the denominator) was obtained from a booking record for the hours that the nurses were working. So an initial screening loss of 55 patients out of a possible 346 represents unavoidable 16% omissions to recruitment.
The project design was a compromise between analysing all patients, and the workload involved. A previous project in Portsmouth Hospital had suggested that half the patients attending A&E were taking two or less medicines. So in this study three or more medicines were chosen as the cohort most likely to have problems of prescribing, interactions and polypharmacy.

### 4.6.2.2 Objective A - To determine the distribution of the number of medicines consumed on admission.

In May 2004, 291 patients (346-55) were recruited and 43% (125/291) were consuming three or more medicines. Out of the 125 captured, a further 9 were missed by the pharmacist, and 61 excluded (according to criteria) because they were too unwell. Only 29 declined consent and 24 were recruited to the study. This gives an elimination of 81% (101/125). This high a proportion would be of concern in a normal randomised controlled trial of an investigational medicinal product. However there is no reason to presume that the exclusion was other than by the initial criteria set. It would therefore form a standard error or proportion each month. This demonstrates the difficulty of running a research project in the A&E and impacts on the number of pharmacists that would be needed to conduct a drug history service for all patients admitted during daylight hours of weekdays.

The level of three medicines or more was chosen to optimise capture of drug interactions and polypharmacy. It could be argued that patients could have an AMRAE or AMRAR from one drug alone. However right from the start if a pharmacist intervention service were to be provided, it would be likely to focus on those taking multiple medicines. This criterion of recruitment is likely therefore, to under-estimate the true incidence of medicine related admissions.

An analysis of the results in May indicated that the researcher would be unable to recruit a sufficient number of patients to satisfy initial power calculations before funding for the research nurses was exhausted. In hindsight, the constraint on recruitment was the time of the nurses as they filtered out the patients. To conduct this again it would probably be necessary to increase the number of nurses to at least
three. At the time, there were no funds to do this. It had proven difficult to obtain funding of any sort. The nurses’ start date could have been delayed, but planning and ethics applications had to coincide with the availability of two nurses who could be recruited to do this work.

This also had to be matched with the logistical availability of the research pharmacist JT and her ability to conduct drug histories. Although the allocated pharmacist time was underused, recruitment could only have been increased by two pharmacists working on drug histories at the same time. This is because there were times when several patients were recruited and ready but the pharmacist was already occupied conducting a drug history with the first patient. This was a feature of the research methodology in that patients were not recruited in an even pattern and some clustering was inevitable. This would have introduced a new variable into the conduct of the drug history that is crucial to the consistency of this research. A key feature of this research is that one pharmacist was conducting the intervention (JT) and a different single pharmacist (the author) was searching the notes, to give consistency and reliability.

The end result of this was that after 5 months of patient recruitment, only 151 patients had completed randomisation and consent. From this, 36 were lost because they were discharged before being admitted to a ward. Often this was discovered when the medical notes were retrieved and reviewed and there was no entry of an admission clerking or no first hospital prescription. This left 115 patients for analysis. At inception, this project was known to be ambitious; however it was not anticipated that such a high rate of attrition would occur.

The randomisation produced a balanced allocation to each arm of the study. 76 participants were allocated to the control pathway (doctors making their traditional notes of the medicines consumed) and 75 allocated to the intervention pathway (pharmacist conducting detailed drug history).

After randomisation there were 36 patients who were not admitted. This comprised 17 in the control cohort and 19 (includes 3 missed by the pharmacist) in the intervention cohort. This left a total of 115 patients where the notes could be analysed: 57 in
doctor cohort and 56 in pharmacist cohort. The ‘not admitted’ category is part supposition, in that the notes were reviewed but no entry nor prescription chart could be found for these dates; so it can only be assumed that they were discharged before they were admitted.

4.6.2.3 **Objective B - To quantify the current rate of medication related admissions at Southampton General hospital.**

Table 4.22 (Section 4.5.2.3) lists the medication related events that may have contributed to the patient being admitted.

The results (Section 4.5.2.3) show that there were 25 patients (11+14) who had events or symptoms that contributed to the admission that could be explained by the medicines they were consuming. This means that 25/115 (21.71%) of admissions were medication related. They were approximately evenly divided between the control (11) and intervention (14) cohort. The difference was not statistically significant. This was not surprising, because no intervention had been made at this point; the control and intervention cohorts were effectively the same group. Some patients had more than one event; two patients in the control cohort had two events.

A review of publications from 1966-2001 showed that 28% of emergency department visits (attendees) were drug related and 70% were preventable yet 24% produced hospital admissions. The data were captured either by recording the admission as ‘medication related’ or following a review of the charts. One study in the review attributed non-compliance as representing 58% of cases. Up to 70% of drug-related visits to A&E were deemed preventable. Recommendations included involving pharmacists to help identify and resolve drug-related problems and prevent recurrence.

A Dutch study in 1997 showed that 102 admissions of over 70 years of age were consuming an average of 5.9 drugs; 24% of the admissions had severe ADRs. A UK study in 2004 in a medical admissions unit, showed that 8-18% of admissions were medication related. It also showed that 39% of GP letters contained
inaccuracies in drug histories. The pharmacists in MAU made 150 interventions per week of which 42% were highly significant.

The author’s finding is higher than the 5-7% reported by other workers.\textsuperscript{163} This might be because the author was drawing this conclusion independent of the admission process. Many studies have used either preliminary screening by a nurse, or a consensus panel. Many studies have entered into an evaluation after the doctor has eliminated other possible diagnoses. The 22% found in this study illustrates that the presenting complaint could have been explained by drug effects. Clearly the patient’s condition could have deteriorated independently of the drugs being consumed. Alternatively, inadequate dosing may produce symptoms that are undertreated (unlikely to be detected in this study). This was underestimated, apart from the two patients who ran out of the medicines they normally consumed.

Table 4.23 (Section 4.5.2.3) summarises the medication related admissions (MRAs) and estimates those that were potentially avoidable. The ‘avoidable’ row in Table 4.23 refers to events that in the author’s opinion, could have been avoided by not taking one of their medicines, with more careful monitoring or maintaining a supply of the medicine. For example a patient admitted with dehydration, constipation, abdominal pain and an inability to pass urine was taking furosemide, which can produce dehydration, constipation and abdominal pain. Better advice about side-effects and more frequent monitoring by the GP could have prevented this admission, although it may have required more participation from the patient. In total 14/25 (56%) events may have been avoidable. This is comparable to the 70% found in other studies.\textsuperscript{163}

From a total of 31 drugs implicated in admissions, the most frequent therapeutic groups were non steroidal anti-inflammatory agents (six cases) and diuretics (4 cases). These are common culprits in other studies and could perhaps be categories to which particular attention is paid when taking a drug history and quizzing the patient about side-effects.
4.6.2.4 **Objective C - To quantify prescribing anomalies that occurred within the admission process.**

Table 4.24 (Section 4.5.2.4) lists the events that occurred during the admission phase. Table 4.25 shows the total numbers of events during the admission process and the number of patients involved and seeks to classify the events.

The control cohort contained 14 out of 59 patients (23.7%) who had 22 prescribing anomalies in the admission phase. The intervention cohort contained 4 out of 56 patients (7.1%) who had 7 prescribing anomalies in the admission phase; 22/29 (75.9%) of all the prescribing anomalies occurring during the admission phase were in the control cohort.

The control group had more patients (14 *versus* 4) who experienced prescribing anomalies during the admission phase compared to the intervention cohort. The control group experienced more prescribing anomalies (22 vs. 7) during the admission phase compared to the intervention cohort. The intervention produced fewer anomalies in terms of events, but the difference in numbers of patients affected was not statistically significant.

4.6.2.5 **Objective D - To determine if drug histories conducted by a pharmacist contain fewer omissions and errors than those conducted by junior doctors**

Table 4.25 shows the events during admission sorted into five categories.

The control (doctor only) cohort contained six patients who had 10 drugs omitted. One patient had ibuprofen, Fybogel and hypromellose omitted. Another patient had Seretide, omeprazole and montelukast omitted. The remainder had single drugs omitted, which were alendronate, Seretide, glipizide and quetiapine. All of these omissions could be classified as important; they would score 4 as interventions (see Table 3.3, Section 3.2.3.1).
The control cohort had five patients who had nine anomalies of prescribing details, such as omitting enteric coating where there was a choice of product, or confusion over the precise dose needed. There were two inappropriate drugs prescribed: atorvastatin instead of ezetimibe, and co-dydramol instead of co-proxamol. There was one inappropriate dose: allopurinol 300mg in a patient with acute renal failure.

The intervention (pharmacist) cohort contained two patients where the independent doctor clerking in A&E omitted 3 drugs (diazepam, paracetamol timolol eye drops) in one patient compared to the pharmacist’s drug history. In a further patient, whilst both doctor and pharmacist noted that the patient had been consuming diltiazem, the pharmacist noted that the patient had recently stopped taking this medicine. These events have been counted as they occurred within this cohort. However the pharmacist history noted the diazepam, paracetamol and timolol and the doctor did not. The doctor on the ward ignored the pharmacist’s prescription and wrote a new chart, omitting these three drugs. In the second case, the doctor added the diltiazem to the pharmacist’s first prescription. It could be argued that these were not omissions attributed to the pharmacist’s drug history.

Both doctor and pharmacist noted that the patient taking alendronate was on a weekly rather than a daily dose. However the pharmacist also recorded the day of the week to increase the chance that this cycle would be continued and blocked off the days when the medicine would not be taken to lessen the risk of a mistake being made. As above, this was counted in the cohort but could be seen as non-attributable to the accuracy of the pharmacist’s drug history.

One patient was taking sodium valproate 400mg BD but at the last discharge, the dose had been increased to 400mg *mane* and 600mg *nocte*; but the patient had not been taking this new dose. This was a genuine event, and not detected by either pharmacist or A&E doctor.

One patient was taking an inappropriate over-the-counter medicine that interacted with the warfarin they were taking.
It can be seen that most of the events in the pharmacist cohort were not the result of the intervention. The diltiazem event was noted and the other drugs omitted were because the doctor rewrote the chart written by the pharmacist. The interaction was discovered by the pharmacist and the detail was an addition rather than something incomplete. So the pharmacist cohort could reduce to one interaction and one detail.

The pharmacists drug histories and first prescriptions contained fewer medication anomalies than the doctors’. However the study was underpowered to demonstrate if this was statistically significantly different. This study also showed that the admission phase is an important source of errors.

4.6.2.6 Objective E – To assess if the intervention had an impact on the prevalence of adverse events and medication errors after the admission phase of the hospital episode.

The inpatient events (Section 4.5.2.5) are listed in Table 4.26 and are summarised in Table 4.27. These show that during the inpatient phase, the control cohort produced a further nine prescribing errors whilst the intervention cohort had none. These nine events did not relate to previous medication history; so although the accurate drug history on admission was associated with reduced medication anomalies throughout the patient journey, this was an association by chance and not causal.

The discharge events (Section 4.5.2.6) are listed in Table 4.28 and summarised in Table 4.29. These data show that on discharge, in the control cohort 10 patients had 14 events. Four patients had five drugs omitted including two for the whole inpatient episode, i.e. only discovered during discharge. There were seven patients who had eight details that were incorrect (including two who had omitted drugs). There was one failure to complete procedure that concerned warfarin management. This looks like 12 patients due to an apparent double counting (see discussion of Table 4.31).

On discharge, in the intervention cohort there were eight patients who had 11 events.
Eight patients had 10 incorrect details and one patient had an additional failure to complete procedure. The procedural event was a failure to re-prescribe warfarin after an operation. It is not clear whether the fact that this cohort had no drug omissions was chance or linked in some way to the clearer drug history.

4.6.2.7 **Objective F - Does the pharmacist writing the first prescription reduce adverse events and medication errors on the patient’s journey through the hospital?**

Table 4.25 (Section 4.5.2.4) shows that the admission phase produced 22/45 (48.9%) of all the anomalies found in the control cohort during their hospital episode and 7/18 (38.0%) of all the anomalies found in the intervention cohort; 29/63 (46%) events occurred in the admission phase of the hospital episode. The control group experienced a greater percentage of their prescribing anomalies (48.9% vs. 38.0%) during the admission phase of their hospital episode compared to the intervention cohort. The control group contributed 22/29 (75.9%) of the errors during the admission phase. Table 4.34 shows that the difference between the two groups was statistically significant.

The author has shown in Section 4.5.2.4, objectives C and D, that the pharmacist taking a drug history in A&E and drafting the first drug chart will reduce omissions and anomalies in prescribing during the admission phase. However does this have an impact on the remainder of the patient journey?

In this research, the notes of patients were inspected to look for anomalies throughout the hospital journey (admission, inpatient and discharge). However in conducting this research it was noticeable that pharmacists did not appear to write in the notes. Most of the pharmacist’s input, if recorded, was written on the drug chart. Notation in green pen was the only indication that some events had occurred. However it was evident from the changes made to the drug charts that the pharmacist had made interventions to correct anomalies. Why do pharmacists not write in the notes? Do pharmacists not want to be seen to criticise the doctor? Surely entries could be made in the notes that could positively describe the action and input made without criticism.
Table 4.30 (Section 4.5.2.7) shows the distribution of patients who had multiple events throughout the main study. In the control cohort, 34 patients had up to 5 events and in the intervention arm, 25 patients had up to 3 events. Some patients were admitted because of medication related events and went on to experience further events at different phases of their admission. This might be because they were on complex medicines, but the patient who had five events had one drug omission error (minor), three minor details and one important detail. The patient who had three events in the intervention cohort did not have these events introduced by the pharmacist. They occurred because the doctor ignored the chart written by the pharmacist and the doctor rewrote a new chart.

Table 4.30 includes MRAs and events in hospital. However the MRAs would not be influenced by the intervention made. Therefore, Table 4.30 has been reconstructed with the MRAs removed to produce Table 4.31. This table shows a similar pattern to Table 4.30 but the double counting in the control cohort is more pronounced. Patients who had events in more than one phase of their hospital episode produced a total of 31 events in the control cohort. However, correction of double counting reduces this to only 25.

Table 4.32 (Section 4.5.2.8) summarises the events that occurred during hospital processes. It combines data from Tables 4.25, 4.27 and 4.29 to show that in the control cohort, a total of 45 events occurred within hospital processes and in the intervention cohort, there were 18 events. However, some patients had multiple events within one phase and between phases. This introduces the double counting illustrated in Table 4.31.

Table 4.33 summarises all the events that occurred during the main study. It combines data from Tables 4.21 and 4.30 with data about the MRAs. This table shows that the double counting in the control cohort appears as 42 patients but is in fact only 34. That is, 11 patients had MRAs and 25 patients had events within hospital processes. In the control cohort, two patients had two MRAs and two patients with MRAs had further events. This double counting reduces the apparent 36 (11+25) to a figure of 34 patients.
Table 4.33 also shows the double counting; the total in the intervention cohort appears as 26 patients but is in fact only 25. That is 14 patients had MRAs and 12 patients had events within hospital processes. In the intervention cohort one patient with an MRA had further events. This double counting reduces the apparent 26 (14+12) to 25 patients.

One of the objectives of this research was to determine if the pharmacist transcription of the first hospital prescription, ready for the doctor to sign, reduced medication errors, potential interactions and adverse drug related events early in the admission process, as well as throughout the patient journey.

It is not clear if this objective has been achieved since none of the inpatient anomalies related to a prior drug history. However there were fewer anomalies in the intervention cohort on admission, inpatient and discharge phases of the hospital episode. Tables 4.32 and 4.33 (Section 4.5.2.8) show a total of 45 events in the control group and only 18 in the intervention group.

Table 4.34 (Section 4.5.2.8) makes this clearer as it summarises all the patients who experienced events within the hospital processes and accounts for the double counting. It shows that out of 59 patients in the control cohort, 25 experienced events from within hospital processes and 34 had no events. The corresponding figures for the intervention group were 12 and 44 – a statistically significant difference.

4.6.2.8 **Objective G – To examine if it is logistically feasible for a pharmacist working in the A&E department to conduct drug histories.**

Within the constraints of this research, it has been shown that some patients could have drug histories taken by a pharmacist. In the author’s opinion, if this was a funded service it would be significantly easier to achieve. However to do this for all patients would require more pharmacists and 24/7 cover. This is unlikely to be achievable.

The data capture period for this research ended in September 2004. In 2007 the hospital developed an initial assessment area and funded two pharmacists to provide a
clinical pharmacy service in this area. These pharmacists work an early or a late shift. They participate in the post-take ward round where many interventions are made.

The first prescription written should contain the totality of medication that the patient is consuming on admission. Subsequently changes are made to reflect treatment of new symptoms, a new diagnosis or discontinuing medications that are no longer needed or causing further problems.

However in reviewing the charts and notes, it appears that doctors did not prescribe medication that they consider no longer necessary without making clear notes to describe their actions. It is therefore not possible to determine if a drug was actively omitted or changed (an act of commission) or inadvertently omitted (an act of omission).

During the inpatient stay or on discharge, it may be appropriate to re-commence the initial medications. Without an accurate initial drug history, this is not possible and causes delays and errors in the discharge communication with the ongoing care of the patient. The recording of an accurate drug history and comparison with the first prescription is now called medication reconciliation and forms part of an NPSA alert. Anecdotal feedback from the ward doctors was that they liked the pharmacist drafting the first prescription, as it helped their workload. However it was noticeable that many of the ward doctors rewrote the drug charts after the pharmacist had written it. No data were collected on this and it is not clear why this happened; it was probably lack of information about the process. If this was a service being implemented, much more support would be provided and this problem would be removed. Anecdotally, ward pharmacists remarked that it was easier to read the pharmacist’s prescriptions and deliberate pausing or stopping of medicines was more clearly indicated.

No data were collected on whether the nurses also found the pharmacist first prescription useful or if this reduced administration errors.
4.7 Study critique

This was a single site study that had to be completed within four months. Initial estimates suggested that this would easily recruit over 300 participants. However in practice only 151 were recruited and only 115 could be analysed. This means that the numbers for detailed analysis are small. The differences across the whole hospital episode were statistically significant different. However the study was under-powered to determine this for each phase of admission, inpatient and discharge.

Pharmacists do not record their actions in the medical notes, so more events may have occurred but were not detectable by the time the notes were reviewed. Doctors do not always record why changes are made on drug charts, so more events could have occurred than were detected.

4.8 Suggestions for future research

It would be interesting to quantify more accurately the number of medicines consumed on admission to hospital. This would include details of those taking less than three medicines and would in turn need clearer definitions or explanation about what counts as a medicine, given the confusion discovered with author’s questionnaire.

Medicines reconciliation is facilitated if patients bring their own medicines into hospital. It is possible that positive encouragement is required from general practitioners and ambulance crew to increase the proportion of patients with PODs. A study could be conducted where a lecture, or other awareness intervention could be used to attempt to increase the number of PODs brought into hospital.

Hospital pharmacists have tried to contribute to a review of medication prescribed as patients move from admission to hospital discharge. This is independent of the primary reason (e.g. surgery) for the hospital episode. Community pharmacists have been commissioned to conduct medication usage reviews and pass their recommendations on to the patient and general practitioner. It would be interesting to examine if this has an impact on hospital admissions.
To provide a useful service, the pharmacist must conduct the drug history and attend a post-take ward round (often within 24 hours of admission). It is also likely that a pre-admission clinical MUR would detect MRAs. Pharmacists contributing to pre-admission clinics have now been shown to produce positive benefits.\textsuperscript{166}

Some future work could analyse what pharmacists write in the medical notes and make recommendations about what should be written. This could be undertaken by asking the pharmacists to submit date and patient details when they write in the notes and then get someone to photocopy and analyse all the entries.

## 4.9 Conclusions

### 4.9.1 Questionnaire sub-study

The questionnaire results provided useful information about the frequency distribution of patients entering the main study and A&E in general. There was some information about compliance and perceptions of medicines but although the nurses administered the questionnaire personally, there was still some ambiguity.

- From the questionnaire study it can be seen that many patients were ill informed and lacked knowledge about the medicines they had taken.
- Just over half (54\%) facilitated medication history taking by bringing in their medicines or a written list.
- Many patients entered hospital on multiple medications; in the preliminary survey, almost two thirds (64\%) reported taking five or more medicines from a range of two to 14 medicines.
- Almost half (42.9\%) of the patients taking six or more tablets were consuming nearly nine-tenths (87.6\%) of all the tablets.
- In May 2004, 291 patients were recruited as potential admissions through the Emergency Department and 43\% (125/291) were consuming more than three medicines.
- 38/177(21.5\%) admitted to frequently forgetting their medicines.
• 121/177 (68.4%) were able to name some of their medicines. However, in total only 520 (39.2%) out of a total of 1327 could actually be named.
• 161/177 (91.0%) knew the name of the condition their medicine was treating or described the part of the body that was affected. Up to four conditions could be named.
• 50/177 (28.2%) patients took painkillers before coming to hospital, although it was not clear how many had pain as a symptom of their presenting complaint.
• 132/177 (74.6%) of patients declared they did not have allergies to drugs. However some of the ‘allergic’ symptoms described drug side-effects or symptoms of their illness.
• 15% claimed to have experienced true drug allergies and should have had good documentation of this on their records.
• 146/177 (82.5%) declared that they had not had reactions to antibiotics before. Only 17/177 (9.6%) described allergic symptoms or were told they were allergic.
• 31/177 (17.5%) took antibiotics frequently, more than half (58.1%) were for chest infections.
• 69/177 (39%) did not bring any of their own medicines with them, and 76/177 (42.9%) brought all of them.
• 11/177 (6.2%) admitted they had used somebody else's prescribed medication.

4.9.2 Main Study

• The randomisation achieved the desired balance between control and intervention cohorts.
• 25 out of 115 (21.7%) admissions were medication related. In other words 25 patients had events or symptoms that contributed to the admission that could be explained by the medicines they were consuming. They were fairly evenly divided between the control (11) and intervention (14) cohort. Some patients had prescription charts with more than one anomaly.
• In addition to any medication related events, during the admission phase alone the control (or traditional) cohort revealed 14 out of 59 patients (23.7%) who
had 22 prescribing anomalies. This represented 22/45 (49%) of anomalies found in this cohort as they completed their hospital journey.

- During the admission process, the pharmacist (intervention) cohort revealed 4 out of 56 patients (7.1%) who had 7 prescribing anomalies in the admission phase. This represents 7/18 (38.9%) anomalies found in this cohort as they completed their journey through hospital. Therefore drug histories conducted by a pharmacist contained fewer omissions and errors than those conducted by junior doctors and this was a statistically significant reduction.

- During all three phases of the hospital episode (admission, inpatient and discharge) 34 patients in the control (doctor) cohort of 59 patients experienced a total of 45 medication anomalies.

- During all three phases of the hospital episode, 25 patients in the intervention (pharmacist) cohort of 56 patients experienced a total of 18 medication anomalies during their hospital stay. The reduction seen in the intervention cohort reached statistical significance in terms of patients affected, but recruitment numbers were low.

- Involving a pharmacist in the admission process was associated with reduced medication risks to patients – a significant difference was noted, in terms of patients affected.

- The intervention included not just taking a drug history but also getting the pharmacist to transcribe this data onto the first hospital prescription, ready for the doctor to sign. This reduced errors in the admission process and was associated with reduced medication errors. However it is not clear if there was a causal relationship since none of the inpatient nor discharge anomalies related to a prior drug history.

- It was logistically feasible for a pharmacist working in the A&E department to conduct drug histories. However it would require more than one pharmacist to provide sufficient input to review the majority of patients admitted.

**Key finding**

This research has focussed on patients who are admitted on weekdays between 9am and 5pm, through A&E, who are over age of 16, who are consuming three or more medicines. If a pharmacist conducts a medication history and drafts the first hospital
inpatient chart, this produces a statistically significant reduction in the number of patients who experience adverse drug related events or errors. Although the numbers were low (115) the implication for clinical practice is that hospitals that adopt this innovation and employ pharmacists to write the first hospital prescription should see a reduction in errors generated throughout the hospital episode. This has implications for process efficiency, will decrease junior doctors hours allocated to this task and reduce risks to patients that should in turn impact on complications, complaints, litigation and the costs associated with this.
Chapter 5 - Prescribing errors and interventions

5.1 Introduction

A hospital prescription is a primary communication device that translates the prescriber’s thoughts into what they want the pharmacist to supply and what they want the nurse to administer. Pharmacists look at prescriptions whether on the wards or in the dispensary; they do not routinely observe what nurses administer; their focus is on what has or will be supplied and what the doctor’s intention was when they wrote the prescription. Experience shows that in many cases, what was intended is not exactly what was written; this is called a technical prescribing error. However if the doctor’s choice of treatment was inappropriate, or did not take account of all relevant clinical information this would be a clinical prescribing error.

5.1.1 Nature and classification of prescribing errors

Technical prescribing errors are failures to execute a plan. These are often acts of omission; for example, the prescriber forgot to sign or date the chart. However they can also be acts of commission, such as prescribing the wrong drug completely (e.g. amiloride instead of amlodipine) or miss-spelling a drug name such as to introduce ambiguity (e.g. disopyramide instead of dipyridamole).

A clinical prescribing error is a planning failure. It could be prescribing a drug that is licensed for the patient’s condition but contra-indicated for that particular patient (e.g. an antibiotic to which the patient is allergic); or prescribing slow sodium to a patient with heart failure and hyponatraemia, where the problem is more likely to be water excess (needing a diuretic) rather than salt deficit. These are acts of commission; in other words, something is prescribed but it is inappropriate for some reason. Planning errors can also be acts of omission where the prescriber fails to undertake an action described in a national or local guideline. In general, clinical prescribing errors are more difficult to detect than technical prescribing errors.

These are fundamental problems that arise in the dispensary. Detection in the dispensary is largely limited to technical prescribing errors. In the clinical areas,
because of greater access to data, it is possible to detect clinical prescribing errors. Pharmacist interventions prevent prescribing errors (PEs) reaching the patient. They act as a filter or barrier to prevent PEs translating into patient harm. So it is possible that recorded pharmacist interventions may be a data source for PEs. In this case PEs were a subset of interventions. Clearly there will be other PEs not detected (or not reported) as pharmacist interventions. For example it is likely that nurses also detect PEs and they are corrected before administration of medicines can proceed. Medical consultants supervise junior doctors in their team and will detect clinical PEs through clinical supervision.

Several authors have raised the issue of inadequate training of junior doctors on pharmacology and therapeutics as a reason why PEs occurred. However we shall see data in this chapter that suggest that this is only part of the problem.

In 2007, the General Medical Council (GMC) offered funding support for research into PEs. In Southampton University the Dean of the School of Medicine was interested in pharmacists’ reporting of PEs in order to improve teaching. The clinical supervisors of junior doctors at Southampton General Hospital were interested in pharmacists reporting individual poor prescribers to improve performance of junior doctors in practice. The author and the pharmacy risk lead worked collaboratively with the Associate Dean and lead clinical supervisor to produce a bid to conduct a research project to capture PEs using the same systems used for pharmacist interventions. In practice this meant conducting an intervention study but coding those interventions that were the end of a process that was initiated by PEs.

This was different from the methodology defined in Chapter 3 (intervention data) because it focused specifically on PEs and excluded interventions that were not PEs. Definitions of non-prescribing errors (NPEs) are given in Appendix 6, but include mainly the following:

1. When the prescription is safe, but not in accordance with hospital policy or formulary e.g. Gaviscon instead of Gaviscon Advance;
2. When the doctor seeks advice about how to do something before initiating the process;

3. When a prescription is intrinsically safe but the pharmacist makes it safer (IV to oral conversion or adding a maximum dose) or more effective (statins at night) or cheaper (esmolol to labetolol), or easier to administer (changing from oral tablets to liquids). Where a pharmacist makes a prescription or treatment safer, more cost-effective or easier to administer, it is termed optimisation; or

4. When there is detection of a nurse administration error.

5.1.2 Objectives of the study

The study reported in this chapter had the following objectives.

- To determine what proportion of interventions are related to prescribing errors (PEs).
- To determine what proportion of prescribing errors were acts of omission (omission prescribing errors or OPEs) or commission (commission prescribing errors or CPEs).
- To discover what proportion of OPEs and CPEs occurred on admission, discharge or inpatient phases of the patient journey through hospital.
- To describe how the intervention data were changed when PEs were eliminated and what was left of interventions that were not PEs.

5.2 Method

The project had two parts: firstly a specific analysis of the 2007 interventions conducted in anticipation of winning the GMC research funding referred to in section 5.1. The second part of this study was a collective review of the 2005-9 interventions that were coded as PEs.
5.2.1 Method (part 1) 2007 Project

The intervention study scheduled for June 2007 was set up prospectively to capture data that would enable analysis of PEs. Data fields were added to the intervention form (see Appendix 7) to aid the identification of prescribers (recording pagers and GMC number), grade of doctor, patient hospital number and an indication of PE or NPE. The Dean and clinical tutors instructed all junior doctors to sign prescriptions and add GMC and bleep numbers.

Each intervention form (primary data) from June 2007 was analysed and coded as PE or NPE. If it was a PE it was sorted into errors of omission (OPEs) or commission (CPEs). Non-compliance with the hospital formulary was considered not to be a prescribing error (NPE). The prescribing errors were further sorted into those that occurred on admission, during the inpatient episode or on discharge.

Each category (OPE or CPE) and phase of hospital episode (admission, inpatient, discharge) were then sorted into categories relevant to prescribing. For example, categories such as failure to follow/finish procedure, failure to review, or dealing with thromboprophylaxis, whole drug omissions, or details (e.g. dose, frequency, and route). Different categories naturally emerged from the different phases of hospital episode e.g. on discharge, unclear indication of treatment course completion, or addition of a new drug.

The main descriptors for various categories of prescribing errors are shown in Table 5.1.

The data collection forms were then summarised into a matrix (Table 5.2, section 5.3.1.1) with three columns: admission, inpatient and discharge; and three rows: CPE, OPE and NPE.
<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>POD whole drug</td>
<td>This is where The PODtechs discovered that the PODS include a medicine that the doctor had completely omitted from the first prescription.</td>
</tr>
<tr>
<td>Inpatient dose/freq or detail mismatch</td>
<td>Where the dose, or frequency or other detail did not match the previous data (e.g. TTO did not match that prescribed as an inpatient).</td>
</tr>
<tr>
<td>Ph drug or combo incorrect/inappropriate</td>
<td>Where the pharmacist had identified that the drug was incorrectly prescribed, or inappropriate in the particular patient. It also referred to where a combination of drugs might be inappropriate when combined.</td>
</tr>
<tr>
<td>Renal or liver or TDM</td>
<td>Where a drug dose had not been adjusted or discontinued in renal or liver dysfunction. It also referred to dose adjustments following therapeutic drug level monitoring.</td>
</tr>
<tr>
<td>Prophylactic</td>
<td>Where prophylactic agents recommended in guidelines had been omitted or prescribed incorrectly. E.g. anticoagulants in atrial fibrillation or to prevent harm from blood clots or stress ulcers or peri-operative infections.</td>
</tr>
<tr>
<td>Dose outside normal range</td>
<td>A dose was too high or low, compared to that recommended in standard text (e.g. BNF) or local and national guidelines.</td>
</tr>
<tr>
<td>Pt/chart/drug details wrong</td>
<td>Where there were inaccuracies in the documentation, such as prescribing a drug on another patient’s drug chart. Alternatively where the dose did not match the route prescribed.</td>
</tr>
<tr>
<td>Failure to follow plan or finish procedure</td>
<td>A procedure/policy/guideline existed but had been executed incorrectly or not completed. E.g. not prescribing antiplatelet drugs following cardiac stenting.</td>
</tr>
<tr>
<td>Failure to review</td>
<td>As the patient’s condition changed medication had not been adjusted. For example failure to discontinue potassium supplements despite a normal serum level.</td>
</tr>
<tr>
<td>Allergy</td>
<td>Failure to record a penicillin allergy; or prescribing a statin when a patient had been noted to be allergic. Some of these may have been false label, but some could be very significant anaphylactoid reactions.</td>
</tr>
<tr>
<td>Unusual drug selection / combination</td>
<td>Where the drug choice in a particular patient was inappropriate or outside the usual pattern. Drug combinations may also have been unusual.</td>
</tr>
</tbody>
</table>
5.2.2 Method (part 2) 2001-2009 Project

This was a retrospective re-coding of intervention forms. The forms from 2001 to 2009 were retrieved from storage. Intervention forms where a PE had not occurred (NPE), were then excluded. The PEs were sorted into those that were an act of commission (CPE) and those that were an act of omission (OPE).

The prescribing errors were then further sorted into a number of categories in the same way as the June 2007 data (see Section 5.2.1 Table 5.1). This was summarised as findings over the 9 years (8 studies) as a collective view. The results were presented as CPE and OPE as well as analysed by phase of hospital episode (admission, inpatient, discharge). The errors were described as technical prescription writing errors or clinical choice/judgement prescribing errors.

5.3 Results

5.3.1 Results for 2007 Project (part 1)

The doctors were poor at recording their identifiers (GMC and pager numbers) on the prescription charts, but that was not crucial to this analysis. One week in June 2007 the pharmacists reviewed charts from 2,050 patients involving over 17,000 items and produced 996 intervention report forms. This was one intervention per 5.7% items or one every 4.8 patients. These are summarised in Table 5.2.

<table>
<thead>
<tr>
<th>Table 5.2 Summary of interventions and errors in June 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients reviewed</td>
</tr>
<tr>
<td>Number of newly prescribed items</td>
</tr>
<tr>
<td>Number of interventions</td>
</tr>
<tr>
<td>Number of errors</td>
</tr>
<tr>
<td>Ratio of errors to interventions</td>
</tr>
<tr>
<td>Error rate</td>
</tr>
<tr>
<td>Number errors with severity score &gt;4*</td>
</tr>
</tbody>
</table>

*Severity scores are described in Table 3.3, Chapter 3

In 2007, prescribing errors represented just over half (53.1%) of the forms submitted and 45.0% (238/529) of prescribing error forms related to the initial inpatient drug chart. Almost one quarter (22.3%; 118/529) of the prescribing error forms related to
where the dose or frequency did not match that normally consumed by the patient, or was outside BNF recommendations.

### 5.3.1.1 Recalibration

After reflection about the conduct and preliminary review of study results, the author decided a recalibration was required. All of the intervention data were based on the number of forms. Often a form for an admission intervention would cover several items that had been omitted. However for the patient, each item that was incorrect or omitted was important to them. So in this chapter, all of the prescribing error data were based on the number of items that were incorrect, rather than the number of forms. This recalibration for prescribing errors changed the data; each item omitted was considered to be a prescribing error that could harm the patient. The results of recalibration are shown in Table 5.3

**Table 5.3 Distribution of PEs vs. hospital phase after recallibration**

<table>
<thead>
<tr>
<th>Type of error/hospital phase</th>
<th>Admission</th>
<th>Inpatient</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPE</td>
<td>46 (8.6%)</td>
<td>275 (42.6%)</td>
<td>20 (16.9%)</td>
</tr>
<tr>
<td>PE</td>
<td>492 (91.4%)</td>
<td>370 (57.4%)</td>
<td>98 (83.1%)</td>
</tr>
<tr>
<td>Total errors</td>
<td>538</td>
<td>645</td>
<td>118</td>
</tr>
</tbody>
</table>

A statistical analysis of the differences between the proportions of NPEs and PEs in the three different phases showed a statistically significant difference (Chi-squared = 181.96, DF=2, p<0.001). This was largely accounted for by the greater proportions of prescribing errors occurring during the admission and discharge phases (see Table 5.3). The recalibrated prescribing error rate from the number of items prescribed was 5.5% (960/17313). On average, this represented 2.1(2050/960) patients per prescribing error. Alternatively, this represented an average of a prescribing error every other patient.

The recalibrated events totalled 1301. This changed the 2007 data so that prescribing errors represented 73.8% (960/1301) of the events that were reported; 538/1301 (41.3%) of all events occurred during the admission phase. There were a total of 960 prescribing errors consisting of 292 CPEs and 668 OPEs. A small majority of PEs (51.3%; 492/960), occurred during admission; 370/960 (38.5%) prescribing errors
occurred during the inpatient phase and 98/960 (10.2%) occurred during discharge.
These data are summarised in Table 5.4.

Table 5.4 Distribution of type of prescribing error across phase of hospital episode.

<table>
<thead>
<tr>
<th>Type of prescribing error / hospital phase</th>
<th>Admission</th>
<th>Inpatient</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPE</td>
<td>110 (37.7%)</td>
<td>145 (49.6%)</td>
<td>37 (12.7%)</td>
</tr>
<tr>
<td>OPE</td>
<td>382 (57.2%)</td>
<td>225 (33.7%)</td>
<td>61 (9.1%)</td>
</tr>
<tr>
<td>Total PE</td>
<td>492</td>
<td>370</td>
<td>98</td>
</tr>
</tbody>
</table>

Most prescribing errors of commission occurred during the inpatient phase, whilst most errors of omission occurred during the admission phase. This produced a significant statistical difference ($X^2=31.04$, df=2, $p<0.001$).

5.3.2 Results for 2001-2009 Project (Part 2)

5.3.2.1 All prescribing errors collectively

Over the period 2001 and 2009, eight studies were evaluated. The PEs represented an average of 73.9% (5151/6966) of all interventions. Tables 5.5, 5.6 and 5.7 show a breakdown of PEs into subgroups (OPE and CPE) and phases of hospital episode. Table 5.5 shows the distribution of all prescribing errors across admission, inpatient and discharge phases.

Table 5.5 Distribution of all prescribing error across phase of hospital episode

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Inpatient</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total PE</td>
<td>2334</td>
<td>2207</td>
<td>610</td>
</tr>
<tr>
<td>%</td>
<td>45.3</td>
<td>42.8</td>
<td>11.8</td>
</tr>
</tbody>
</table>

Table 5.6 shows how the division of prescribing errors into OPEs and CPEs. Approximately two thirds of all PEs are OPEs.

Table 5.6 Distribution of all prescribing errors between those of omission and commission

<table>
<thead>
<tr>
<th></th>
<th>Number of PEs</th>
<th>% of all PEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPEs</td>
<td>3457</td>
<td>67.1</td>
</tr>
<tr>
<td>CPEs</td>
<td>1694</td>
<td>32.9</td>
</tr>
</tbody>
</table>
Table 5.7 categorises the PEs using the descriptors from Table 5.1 with a sub-categorisation of technical, clinical or technical/clinical.

**Table 5.7 Distribution of type of prescribing errors across phase of hospital episode**

<table>
<thead>
<tr>
<th>PE descriptor</th>
<th>Admission* (% column)</th>
<th>IP (%)</th>
<th>TTO (%)</th>
<th>Total (%)</th>
<th>Type PE†</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>POD whole drug</td>
<td>572 (24.5)</td>
<td>0</td>
<td>207 (33.9)</td>
<td>779 (15.1)</td>
<td>Technical</td>
<td></td>
</tr>
<tr>
<td>IP dose/freq or detail mismatch</td>
<td>651 (27.9)</td>
<td>0</td>
<td>152 (24.9)</td>
<td>803 (15.6)</td>
<td>Technical</td>
<td>2666 (51.8)</td>
</tr>
<tr>
<td>Dose abnormal</td>
<td>27 (1.2)</td>
<td>289 (13.1)</td>
<td>39 (6.4)</td>
<td>355 (6.9)</td>
<td>Technical</td>
<td></td>
</tr>
<tr>
<td>Details incorrect</td>
<td>0</td>
<td>614 (27.8)</td>
<td>115 (18.9)</td>
<td>729 (14.2)</td>
<td>Technical</td>
<td></td>
</tr>
<tr>
<td>Ph Drug or combo incorrect/inappropriate</td>
<td>946 (40.5)</td>
<td>176 (8.0)</td>
<td>46 (7.5)</td>
<td>1168 (22.7)</td>
<td>Technical &amp; clinical</td>
<td>1168 (22.7)</td>
</tr>
<tr>
<td>Interaction</td>
<td>8 (0.3)</td>
<td>87 (3.9)</td>
<td>1 (0.2)</td>
<td>96 (1.9)</td>
<td>Clinical</td>
<td></td>
</tr>
<tr>
<td>Fail to follow plan, finish procedure or review</td>
<td>86 (3.7)</td>
<td>717 (32.5)</td>
<td>47 (7.7)</td>
<td>850 (16.5)</td>
<td>Clinical</td>
<td>1317 (25.6)</td>
</tr>
<tr>
<td>Renal or liver or TDM</td>
<td>24 (1.0)</td>
<td>137 (6.2)</td>
<td>0</td>
<td>161 (3.1)</td>
<td>Clinical</td>
<td></td>
</tr>
<tr>
<td>Prophylactic</td>
<td>20 (0.9)</td>
<td>187 (8.5)</td>
<td>3 (0.5)</td>
<td>210 (4.1)</td>
<td>Clinical</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2334</td>
<td>2207</td>
<td>610</td>
<td>5151</td>
<td></td>
<td>5151</td>
</tr>
</tbody>
</table>

*Admission refers to the first hospital prescription; IP = inpatient drug chart; TTO = discharge prescription.

†The division of all prescribing errors into either clinical or technical errors was incomplete because some errors were a combination of both types.

A technical prescribing error was a failure to correctly execute the writing of a prescription. This was an incomplete, illegible or illegal prescription. It also referred to omitted or miss-spelt drug names or inappropriate combinations of route, frequency and dose. A clinical prescribing error was a planning failure where the drug or detail was inappropriate for an individual patient. This was often a failure to review the treatment as the patient’s condition changed, but also included prescribing a drug that was contra-indicated in a particular patient.
Table 5.8 shows how a breakdown of types of prescribing errors was distributed between prescribing errors of omission and those of commission. It shows that about a third (36.6%) of prescribing errors were connected with details and about a third (32.0%) were the omission of regular medicines. However the largest category (47.7%) of OPEs was drug omissions. The largest category (70.4%) of CPEs was incorrect details.

Table 5.8 Detailed distribution of prescribing errors into those of commission and those of omission

<table>
<thead>
<tr>
<th>PE category</th>
<th>Total (%)</th>
<th>OPE (%)</th>
<th>CPE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular meds omitted</td>
<td>1649 (32.0)</td>
<td>1649 (47.7)</td>
<td>0</td>
</tr>
<tr>
<td>Details (inc dose/freq) mismatch or inappropriate</td>
<td>1887 (36.6)</td>
<td>695 (20.1)</td>
<td>1192 (70.4)</td>
</tr>
<tr>
<td>Drug or combo incorrect, inappropriate, or interaction</td>
<td>394 (7.6)</td>
<td>17 (0.5)</td>
<td>377 (22.3)</td>
</tr>
<tr>
<td>Fail to follow plan, finish procedure, or review</td>
<td>850 (16.5)</td>
<td>808 (23.4)</td>
<td>42 (2.5)</td>
</tr>
<tr>
<td>Renal or liver adjustment or TDM</td>
<td>161 (3.1)</td>
<td>126 (3.6)</td>
<td>35 (2.1)</td>
</tr>
<tr>
<td>Prophylactic</td>
<td>210 (4.1)</td>
<td>162 (4.7)</td>
<td>48 (2.8)</td>
</tr>
<tr>
<td>Total PE</td>
<td>5151</td>
<td>3457</td>
<td>1694</td>
</tr>
</tbody>
</table>
5.3.2.2  Prescribing errors of Commission (CPE)

Tables 5.9, 5.10, 5.11 and 5.12 show the distribution of 1694 CPEs across the admission, inpatient and discharge phases of the hospital episode:

Table 5.9 CPE distribution across phases of hospital episode

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Inpatient</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total CPE</td>
<td>557</td>
<td>916</td>
<td>221</td>
</tr>
<tr>
<td>100%</td>
<td>32.9</td>
<td>54.1</td>
<td>13.0</td>
</tr>
</tbody>
</table>

Table 5.10 CPEs during the admission phase sorted into 7 categories

<table>
<thead>
<tr>
<th>Prescribing errors of commission</th>
<th>Events</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission categories</td>
<td>557</td>
<td>100.0</td>
</tr>
<tr>
<td>admission IP dose or freq or details mismatch</td>
<td>405</td>
<td>72.7</td>
</tr>
<tr>
<td>Drug or combo incorrect or inappropriate</td>
<td>76</td>
<td>13.6</td>
</tr>
<tr>
<td>dose outside normal range</td>
<td>27</td>
<td>4.8</td>
</tr>
<tr>
<td>pt/chart/drug details wrong</td>
<td>22</td>
<td>4.0</td>
</tr>
<tr>
<td>renal or liver or TDM</td>
<td>12</td>
<td>2.2</td>
</tr>
<tr>
<td>Allergy</td>
<td>8</td>
<td>1.4</td>
</tr>
<tr>
<td>fail to follow plan or finish procedure</td>
<td>7</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Table 5.11 CPEs during the inpatient phase was sorted into 9 categories

<table>
<thead>
<tr>
<th>Prescribing errors of commission</th>
<th>Events</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient categories</td>
<td>916</td>
<td></td>
</tr>
<tr>
<td>dose/freq unknown inappropriate</td>
<td>280</td>
<td>30.6</td>
</tr>
<tr>
<td>Details of route, formulation etc</td>
<td>274</td>
<td>29.9</td>
</tr>
<tr>
<td>Drug or combo inappropriate</td>
<td>163</td>
<td>17.8</td>
</tr>
<tr>
<td>Interactions</td>
<td>85</td>
<td>9.3</td>
</tr>
<tr>
<td>DVT prophylaxis</td>
<td>48</td>
<td>5.2</td>
</tr>
<tr>
<td>fail to follow plan or finish procedure</td>
<td>24</td>
<td>2.6</td>
</tr>
<tr>
<td>renal or liver or TDM</td>
<td>23</td>
<td>2.5</td>
</tr>
<tr>
<td>fail to review</td>
<td>11</td>
<td>1.2</td>
</tr>
<tr>
<td>Allergy</td>
<td>8</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Table 5.12 CPEs during the discharge phase was sorted into 8 categories

<table>
<thead>
<tr>
<th>Prescribing errors of commission</th>
<th>Events</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge categories</td>
<td>221</td>
<td></td>
</tr>
<tr>
<td>IP/TTO dose mismatch</td>
<td>91</td>
<td>41.2</td>
</tr>
<tr>
<td>unusual drug selection/ combination</td>
<td>36</td>
<td>16.3</td>
</tr>
<tr>
<td>unusual or mismatched frequency</td>
<td>23</td>
<td>10.4</td>
</tr>
<tr>
<td>Duration</td>
<td>23</td>
<td>10.4</td>
</tr>
<tr>
<td>CD</td>
<td>18</td>
<td>8.1</td>
</tr>
<tr>
<td>dose outside normal range</td>
<td>16</td>
<td>7.2</td>
</tr>
<tr>
<td>incorrect route or formulation</td>
<td>13</td>
<td>5.9</td>
</tr>
<tr>
<td>Interaction</td>
<td>1</td>
<td>0.5</td>
</tr>
</tbody>
</table>
5.3.2.3 Prescribing errors of Omission (OPEs)

Tables 5.13, 5.14, 5.15 and 5.16 show how the 3457 OPEs were distributed across admission, inpatient and discharge phases of the hospital episode.

Table 5.13 OPE distribution across phases of hospital episode

<table>
<thead>
<tr>
<th>Type</th>
<th>Admission</th>
<th>Inpatient</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total OPES</td>
<td>1777</td>
<td>1291</td>
<td>389</td>
</tr>
<tr>
<td>100%</td>
<td>51.4</td>
<td>37.3</td>
<td>11.3</td>
</tr>
</tbody>
</table>

Table 5.14 OPEs during the admission phase categorised as to type.

<table>
<thead>
<tr>
<th>Type</th>
<th>Events</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total OPEs in this phase</td>
<td>1777</td>
<td></td>
</tr>
<tr>
<td>Ph whole drug incorrect or inappropriate.</td>
<td>870</td>
<td>48.9</td>
</tr>
<tr>
<td>POD whole drug</td>
<td>572</td>
<td>32.2</td>
</tr>
<tr>
<td>Admission IP dose or freq or details mismatch</td>
<td>224</td>
<td>12.6</td>
</tr>
<tr>
<td>Fail to follow plan or finish procedure</td>
<td>46</td>
<td>2.6</td>
</tr>
<tr>
<td>Fail to review</td>
<td>30</td>
<td>1.7</td>
</tr>
<tr>
<td>Thrombo-prophylactic</td>
<td>19</td>
<td>1.0</td>
</tr>
<tr>
<td>Renal or liver or TDM</td>
<td>12</td>
<td>0.7</td>
</tr>
<tr>
<td>Wrong plan</td>
<td>3</td>
<td>0.2</td>
</tr>
<tr>
<td>Prophylactic</td>
<td>1</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Table 5.15 OPEs during the inpatient phase categorised as to type.

<table>
<thead>
<tr>
<th>Type</th>
<th>Events</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total OPEs in this phase</td>
<td>1291</td>
<td></td>
</tr>
<tr>
<td>fail to review</td>
<td>559</td>
<td>43.3</td>
</tr>
<tr>
<td>Details</td>
<td>340</td>
<td>26.3</td>
</tr>
<tr>
<td>fail to follow plan or finish procedure</td>
<td>123</td>
<td>9.5</td>
</tr>
<tr>
<td>renal/liver or TDM</td>
<td>114</td>
<td>8.8</td>
</tr>
<tr>
<td>thrombo-prophylactic</td>
<td>109</td>
<td>8.5</td>
</tr>
<tr>
<td>Prophylactic</td>
<td>30</td>
<td>2.3</td>
</tr>
<tr>
<td>dose unknown inappropriate</td>
<td>9</td>
<td>0.7</td>
</tr>
<tr>
<td>Drug or combo inappropriate</td>
<td>5</td>
<td>0.4</td>
</tr>
<tr>
<td>Inter- action</td>
<td>2</td>
<td>0.2</td>
</tr>
</tbody>
</table>
Table 5.16 OPEs during the discharge phase categorised as to type

<table>
<thead>
<tr>
<th>Type</th>
<th>Events</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total OPEs in this phase</td>
<td>389</td>
<td></td>
</tr>
<tr>
<td>Regular meds omitted</td>
<td>207</td>
<td>53.2</td>
</tr>
<tr>
<td>IP/TTO dose mismatch</td>
<td>61</td>
<td>15.7</td>
</tr>
<tr>
<td>Duration</td>
<td>43</td>
<td>11.1</td>
</tr>
<tr>
<td>fail to review</td>
<td>27</td>
<td>6.9</td>
</tr>
<tr>
<td>fail to follow plan or finish procedure</td>
<td>20</td>
<td>5.1</td>
</tr>
<tr>
<td>Details</td>
<td>18</td>
<td>4.6</td>
</tr>
<tr>
<td>new drug or unusual selection/ combination</td>
<td>10</td>
<td>2.6</td>
</tr>
<tr>
<td>thrombo-prophylactic</td>
<td>3</td>
<td>0.8</td>
</tr>
</tbody>
</table>

5.3.2.4 Non-prescribing errors (NPEs)

When prescribing errors were removed from the intervention database there were 1,849 non-prescribing errors. These are categorised by type in Table 5.17.

Table 5.17 remaining NPEs categorised by type.

<table>
<thead>
<tr>
<th>NPE type</th>
<th>Events</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choice or need for drug or regimen</td>
<td>578</td>
<td>31.3</td>
</tr>
<tr>
<td>Choice of dose/freq/timing</td>
<td>359</td>
<td>19.4</td>
</tr>
<tr>
<td>Interaction or SE or ADR or monitoring</td>
<td>159</td>
<td>8.6</td>
</tr>
<tr>
<td>Admin or calc or compatibility</td>
<td>128</td>
<td>6.9</td>
</tr>
<tr>
<td>Choice of form or strength or route</td>
<td>119</td>
<td>6.4</td>
</tr>
<tr>
<td>Documentation</td>
<td>101</td>
<td>5.5</td>
</tr>
<tr>
<td>Pharmacokinetic or TDM</td>
<td>101</td>
<td>5.5</td>
</tr>
<tr>
<td>Drug Duration</td>
<td>80</td>
<td>4.3</td>
</tr>
<tr>
<td>Nutrition</td>
<td>79</td>
<td>4.3</td>
</tr>
<tr>
<td>Supply or storage</td>
<td>74</td>
<td>4</td>
</tr>
<tr>
<td>Other DI</td>
<td>71</td>
<td>3.8</td>
</tr>
</tbody>
</table>

5.4 Discussion

5.4.1 Discussion (part 1) 2007 Project

From the counting of forms it can be seen that 53% (529/996) of the interventions were classified as PEs. From the counting of items we find that 73.8% (960/1301) of the interventions were classified as PEs. This shows that however the tallying is done, PEs represented more than half of all interventions made. This reflects the fact that
pharmacists tend to focus on prescription forms rather than administration errors; they are often not in a position to detect the latter anyway.

From the counting of forms we find that 3% (529/17313) of the total items prescribed were classified as PEs. From the more informative counting of items it can be seen that 5.5% (960/17313) of the total items were classified as PEs.

About one fifth (21%; 112/529) had a severity score of four or more in terms of consequence to the patient. This shows that the bulk of the errors were minor in likely consequence. There is a perception that it is unlikely that a nurse would give a grossly inaccurate dose or that minor dosage errors are unlikely to cause patient harm. This also contributes to the culture of errors being ubiquitous but not harmful to patients, thus trivialising errors and building an acceptance that they will always occur no matter what is done to try and prevent them.

In terms of hospital phase, total events were distributed into 41.3% admission, 49.6% inpatient and 9.6% discharge whereas PEs were distributed as 51.3% admission, 38.5% inpatient, 10.2% discharge. This suggests that a greater proportion of PEs occur on admission to hospital whereas NPE interventions occur later in the patient journey. Alternatively the pharmacists who work in admission areas were so busy correcting prescribing errors they had relatively less time to make NPE interventions. It might be argued that NPE interventions require a more reflective process to detect that takes time and is therefore more likely to occur later. This also suggests that if PEs could be decreased, the pharmacist could be involved in more optimisation throughout the hospital journey.

A research study could investigate if additional pharmacist time in A&E or admissions wards would increases the NPE interventions to optimise therapy rather than just correct PEs. Alternatively, as budgets get squeezed and pharmacists’ time on the wards reduces, the number of interventions in total will decrease and the NPEs should reduce until all interventions are just prescribing errors. A third option might be the introduction of electronic prescribing. If electronic prescribing reduces the documentation errors (often severity 3) this should release more time for the higher level NPE interventions.
What is apparent is that most inpatient activity is invisible to the dispensary. The dispensary staff only saw charts sent to them for non-stock supplies. One of the reasons why pharmacists emerged from the dispensary into clinical areas was to reduce problems and delays on discharge. Yet this is now a small proportion of the PEs seen.

Clinical pharmacy has increased the detection of clinical rather than technical errors and the inpatient phase has progressively grown. More recently PEs on admission have emerged as the most significant phase of the hospital episode.\(^70, 121, 167\)

**5.4.2 Discussion (part 2) 2001-2009 project**

Moving to the broader historical data, we see that PEs represented 73.9 % (5151/6966) of all interventions. Again this reflects the pharmacists’ focus on anomalies in prescriptions themselves. Nurse administration errors are reported in the adverse event forms that are sent to the NPSA, but these are not observed by pharmacists. Over 5,000 (5,151) PEs errors required pharmacist intervention over 8 study periods of one week. This is an average of 644 PE per week, or 2,576 per month. There are some data variations, but the last four studies (2006-9) gave an average of 10,400 items per week, or a prescribing error rate of 6.2 % (644/10391).

These were still large numbers of events, occurring on a regular basis.

In comparison, Table 5.18 shows the annual number of the medication related adverse event forms submitted to the NPSA from Southampton University Hospitals NHS Trust, divided on the basis of health care profession.
Table 5.18 Medication adverse event forms from SUHT submitted each year to NPSA, by healthcare profession.

<table>
<thead>
<tr>
<th>Job Title / year</th>
<th>2004 (%)</th>
<th>2005 (%)</th>
<th>2006 (%)</th>
<th>2007 (%)</th>
<th>2008 (%)</th>
<th>2009 (%)</th>
<th>2004-9 total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>779 (65.9)</td>
<td>547 (57.3)</td>
<td>517 (51.6)</td>
<td>600 (76.2)</td>
<td>445 (65.5)</td>
<td>601 (66.5)</td>
<td>3336 (61.1)</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>32 (2.7)</td>
<td>34 (3.6)</td>
<td>82 (8.2)</td>
<td>96 (12.2)</td>
<td>87 (12.8)</td>
<td>87 (9.6)</td>
<td>843 (15.4)</td>
</tr>
<tr>
<td>Other</td>
<td>300 (25.4)</td>
<td>240 (25.1)</td>
<td>111 (11.1)</td>
<td>21 (2.7)</td>
<td>25 (3.7)</td>
<td>22 (2.4)</td>
<td>267 (4.9)</td>
</tr>
<tr>
<td>Doctor</td>
<td>3 (0.3)</td>
<td>4 (0.4)</td>
<td>3 (0.3)</td>
<td>10 (1.3)</td>
<td>22 (3.2)</td>
<td>20 (2.2)</td>
<td>108 (2.0)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>68 (5.8)</td>
<td>130 (13.6)</td>
<td>288 (28.8)</td>
<td>60 (7.6)</td>
<td>100 (14.7)</td>
<td>174 (19.2)</td>
<td>908 (16.6)</td>
</tr>
<tr>
<td>Total</td>
<td>1182</td>
<td>955</td>
<td>1001</td>
<td>787</td>
<td>679</td>
<td>904</td>
<td>5462</td>
</tr>
</tbody>
</table>

This shows that over the six years 2004-2009, nurses completed the majority (61.1%) of the reports. There were 908 forms where the reporter did not declare their professional group. Apart from the unknown reporter category, pharmacists were the next most frequent reporter. Although the average number of total reports per year (918) is about the same as the number of interventions reported in the annual pharmacy survey, it is clear that pharmacists reported appreciably less often than this to the NPSA.

### 5.4.2.1 Phase of the hospital episode

Table 5.5 shows a breakdown of the types of PE that occurred during the three phases of the hospital episode. Overall the largest portion 45.3% (2334/5151) of PEs occurred during the admission phase of the hospital episode. This is interesting because prior to 2005, most of PE detection was during the inpatient (2207, 42.8%) and discharge (610, 11.8%) phases. So by adding in the detection of PEs during admission, the pharmacists had nearly doubled (2817 to 5151) the number of detected PEs.

Table 5.6 shows that 67.1% of all PEs related to something that had not been done (OPE). How can the pharmacist detect these errors? The active collection of drug histories and the availability of national and local guidelines are probably important and will be further explored later in this section.
Table 5.7 shows the distribution of all PEs across the different phases of the hospital episode. This table also shows a crude division of PEs into those that related to the technical aspects of writing a prescription and those that related to clinical decisions about what to prescribe. Over half (2,666/5151; 51.8%) were technical - a failure to prescribe completely and accurately from the data available; 1317/5151 (25.6%) were clinical - a failure to follow a clinical guideline or review medication consistent with the changing clinical status of the patient; 85.6% (1128/1317) occurred during the inpatient phase; 1168/5151 (22.7%) were a combination of the two types. Junior doctors were still in training and needed to learn the clinical guidelines (i.e. the therapeutic plan) and practise skills in prescribing safely whilst at the same time learning how to diagnose. Pharmacists who were allocated to a ward area were first instructed in the relevant therapeutics so that they understood what should happen following a given diagnosis.

5.4.2.2 Technical prescribing errors
In section 5.3.2 Table 5.7, technical errors were described by five categories: ‘POD whole drug’, ‘IP dose/freq or detail mismatch’, ‘dose abnormal’, ‘detail incorrect’, and an ambiguous portion of ‘Ph Drug or combo incorrect/inappropriate’. The first four categories represented 2666/5151 (51.8%) of the total PEs, so technical prescribing errors contributed to more than half of all PEs.

A proportion (15.1%; 779/5151) of all PEs was categorised under ‘POD whole drug’. This was where the POD technician found that the patient had brought in their own drugs but they did not match what was written on the first hospital prescription (admission phase) or on the discharge (TTO) prescription; 572/779 (73.4%) of these related to an incomplete transfer of data from drug history to first prescription. It is unclear why the doctor did not do this, then cross out those drugs that were to be temporarily withheld or changed with an explanation in the notes. The POD technician could detect the anomaly but was unable to judge if this was deliberately omitted or not. Where there was uncertainty, the POD tech informed the pharmacist. If the pharmacist intervened, this would be categorised under ‘Ph Drug or combo
incorrect/inappropriate’. In many cases it was an error. In those cases where it was a deliberate deletion it is likely that no intervention record was made. In the author’s opinion, pharmacists have for many years detected a failure to accurately transfer medication from the inpatient chart to the discharge prescription.

A proportion (15.6%; 803/5151) of all PEs were where dose or frequency (and related details) on the inpatient chart did not match what was taken before admission or on discharge; 651/803 (81.1%) occurred on admission. These were usually simple transcription errors, but the consequence for patients varied from the trivial to very serious.

A small proportion of PEs (6.9%; 355/5151) were where the dose was outside the normal range; 289/355 (81.4%) occurred during the inpatient phase of the hospital episode. This included doses that did not match the drug and doses that were just outside the BNF range. For example cefuroxime 2G (products available as 750mg or 1.5G); it included greater than 10 fold errors, such as digoxin 0.625milligramme rather than 62.5microgramme.

A proportion of PEs labelled as ‘details incorrect’ (14.2%; 729/5151) were where the route, rate, concentration or formulation were impossible to achieve, did not match dose or drug, or were simply incorrect. They were also omitted details that were essential. A large proportion (84.2%; 614/729) occurred during the inpatient phase, because this was where new medication was added to the regimen.

From Table 5.7 the technical prescribing errors can be divided into those that represented failures to transcribe from a previous prescription (1582) and failures to include relevant details or check parameters in a reference text such as the BNF (1084).

The transcription errors comprised 779 errors detected by POD technicians where the whole drug was omitted and 803 where details (such as dose and frequency) did not match. There were also the ‘whole drug omission’ errors found by the pharmacist. The 1084 errors of inaccurate details comprised 729 ‘failure to check details’ and 355 doses outside the normal range. Transcription failures were 30.7% (1582/5151) of all
PEs; 21% (1084/5151) of the prescribing errors were represented by poor attention to detail

Transcription errors occurred on admission or discharge whereas ‘failure to check dose or details’ occurred mainly during the inpatient phase. This reflects poor attention to detail in transcription. It appears that when new drugs were added, PEs occurred where the doctor prescribed a medicine but guessed details such as dose, or recalled from memory rather than checking it in the BNF. In the author’s opinion, doctors and pharmacists approach prescribing from different philosophical perspectives. Doctors work under an expectation that they should know how to prescribe (despite little formal training) and pharmacists are taught to check details if there is any doubt.

The next category was a combination of technical and clinical prescribing errors; 22.7%(1168/5151) of these were where the pharmacist detected a drug discrepancy (on admission or discharge) or where the drug or combination chosen was inappropriate for a particular patient (caution or contra-indication). This was the largest category of all PEs and 81%(946/1168) occurred during admission.

5.4.2.3 Clinical prescribing errors
A small proportion of clinical prescribing errors (1.9 %; 96/5151) were drug interactions and could be combined with the previous category of drug combinations that were inappropriate. They have been separately identified because, in the author’s experience, doctors are often unaware of interactions whereas pharmacists often detect them and advise on how to manage the situations that arise. A large proportion of these (87/96; 90.6%) occurred during the inpatient phase where new drugs were added.

A larger proportion of PEs (16.5%; 850/5151) were failures to complete a clinical guideline or procedure, or review progress when the condition changed; for example, dose escalation of beta blockers and ACE inhibitors post-MI. In the author’s opinion this could have reflected a lack of time but often it appeared to be a lack of knowledge about when a review was appropriate, or what patient parameters were relevant to
particular drugs; 717/850 (84.3%) of these occurred during the inpatient phase. It could be that better access to guidelines or training on their use would decrease these errors

Just 3.1% (161/5151) of clinical prescribing errors related to adjusting doses due to renal or liver dysfunction. It also included organising the appropriate timing of blood samples and interpreting the results for drugs that required TDM). A large proportion 137/161 (85.1%) occurred during the inpatient phase. This was not only where new medicines were added but also where the patient’s condition may have been rapidly changing due to the nature of the disease or the result of surgery or treatments. Changes could be negative, as the condition deteriorated, or positive, as the patient recovered. In the author’s opinion, this appears to be knowledge that the pharmacist possessed but the doctor often lacked. An example was an omission to change allopurinol dosage in response to changing renal function.

A small proportion of events (4.1%; 210/5151) related to the prescribing of prophylactic agents (including prevention of venous thromboembolism). These guidelines are now widely available; however during 2001 to 2005 this may not have been the case. Venous thromboembolism guidelines were significantly developed during 2005 and 2006. It also related to peri-operative antibiotics and stress ulcer prophylaxis. It is not surprising that 187/210 (89.0%) occurred during the inpatient phase.

Summarising, this analysis has shown when, during the hospital episode, the different prescribing errors occurred. It offers some insight into both technical and clinical prescribing errors.

5.4.2.4 Errors of omission and commission
Prescribing errors were largely 67.1% (3457/5151) errors of omission (OPEs); things that had not been done; 81% (1442/1777) of all OPEs that occurred during the admission phase, were the omission of regular medication producing incomplete first prescriptions.
In terms of clinical errors, this reflects a lack of completion of tasks or finishing a process. It was things that should have happened rather than things that were actively done incorrectly. This also shows that pharmacists had an enhanced understanding of what should happen to patients and their medicines, and a comprehension of therapeutics not just pharmacology. Is this something that just pharmacists have seen or do medical consultants also observe this? If consultants also correct these OPEs, the incidence could be much greater than that found by the author. Alternatively it may be that pharmacists’ knowledge of therapeutics enables them to make more pro-active interventions to correct these omissions before a medical consultant ward round occurs. This is something that merits further study.

Errors of commission occurred mainly during the inpatient phase whereas errors of omission occurred during the admission phase. To understand this we need to examine in more detail a breakdown of CPEs and OPEs; this is done in Sections 5.4.2.5 and 5.4.2.6.

5.4.2.5 Prescribing errors of commission (CPEs)
Over half (54.1%; 916/1694) of CPEs occurred during the inpatient phase of the hospital episode. This shows that active prescribing errors (doing something wrong) occurred more frequently after admission and before discharge.

Inpatient CPEs were further sorted into nine categories; the top three representing 78.3% (717/916) of the total derived from:

- dose or frequency inappropriate;
- route or formulation incorrect; or
- drug choice or combination inappropriate or risk of drug interactions.

These are active errors rather than things that have not been done. This suggests that doctors prescribed a dose that was wrong (or a dose that did not match the drug) without checking it or they prescribed a route or formulation that was inappropriate (without checking in the BNF) or they prescribed a drug, inappropriate combination or interaction, without checking for a problem. This was a combination of technical and clinical prescribing errors (the proportion could not be determined).
It is not clear why this situation would arise. Was this over-confidence on their accuracy, or was the reference text inaccessible or did the doctors lack the volition to check their work? Maybe they viewed prescribing as a minor task and allocated insufficient time and attention to it. Perhaps doctors were unaware of the consequences of an error in their prescribing or assumed they did not make errors.

The high proportion of these errors (30.6%; 280/916) suggests that the pharmacist focussed on dosage as an expert in posology. It also reflects a failure of doctors to retrieve doses from the BNF, preferring to recall them from memory. Does this reflect a poor layout of the BNF or a more generalised poor access to dosing information or preference of doctors for memory recall rather than checking doses in reference texts? The present study could not answer this, but illustrates that every effort must be made to make dosing data readily available to minimise risk. Further research might investigate doctor’s preferred methods for retrieving dose information and once known, pharmacy may play a part in optimising these methods. Pharmacists are trained to check doses in the BNF rather than guess.

Over one quarter (29.9%; 274/916) of inpatient CPEs concerned incorrect route or formulation. These were where the drug or dose was correct but the further details were inconsistent; for example, metronidazole IV is 500mg whereas the oral dose is 400mg (either the dose or the route were incorrect). These were not a desire to give a licensed drug via an unlicensed route (e.g. Tazocin orally was not the intention). They were a very concerning group of active prescribing errors. So, Adalat was prescribed as a special slow release formulation for administration down a nasogastric tube, by a route that was not safe. Is it that the doctors did not understand that the LA suffix denotes ‘long acting’ or did they consider that slow release products were suitable by this route? Electronic prescribing will force the correct route, which will be good for the Tazocin example. However with the metronidazole case, was the oral route or the IV 500mg the intention? Pharmacists will not be prompted to challenge these with electronic prescribing, to determine the true intention.

A proportion (17.8%; 163/916) of inpatient CPEs concerned choice of drug or choice of drug combination. These were challenged by the pharmacist because they were clinical or planning errors. This means the doctor actively chose a contra-indicated or
sub-optimal wrong drug for a particular patient. These were about optimising drug choice within a therapeutic group. These were not interactions, because straight interactions were coded separately. These were drug choices and combinations of a therapeutic nature. Some of these errors were difficult to evaluate. For example, prescribing a beta blocker and salbutamol seems intrinsically wrong. However there was a case where bisoprolol was prescribed in a patient with cardiac wheeze. This was to determine if the problem was pulmonary oedema (caused by cardiac failure) or respiratory wheeze caused by lung inflammation. However most of these CPEs were choosing a drug that was contraindicated or cautioned in a particular patient. This was a failure to check details or the details unavailable when the prescription was written.

CPEs during the admission phase represented a third (32.9%) of the total PEs made. The predominant error (72.7%) was writing the wrong dose or frequency (or other detail) which did not match what the patient was consuming prior to admission. The wrong drug was less frequently prescribed but the details written were often wrong. To the author, it appears that the doctor thought that the task was complete when the drug name was recorded and further details were unimportant. However to the pharmacist and nurse, these details must be correct for them to act appropriately. For effective patient care all these details are important. It must be remembered that an act of commission means these errors are actively undertaken even though they are wrong.

CPEs were least likely to arise during the discharge phase, representing only 13% of the total. These CPEs were mainly dose mismatches between the inpatient chart and the discharge prescription; the next most significant category was an unusual drug selection. All of these CPEs involved incorrect details that, whilst seemingly trivial to the prescriber, could be very important for effective patient care. Without the pharmacist’s investigation and correction, communication with the general practitioner and future care could be compromised.

Anecdotally, this correction process adds significantly to the delay of discharges and therefore by inference, the availability of beds for new admissions. Pharmacists have focussed on getting the discharge correct, but it may be that a bigger impact could be made by getting the admission process right first time.
5.4.2.6 Prescribing errors of omission (OPEs)

OPEs represented 67.1% (3457/5151) of all prescribing errors detected. The proportion varied between phases: 76.1% (1777/2334) on admission, 58.5% (1291/2207) as inpatients, and 63.8% (389/610) on discharge.

Just over half (51.4%;1777/3457) of OPEs occurred during the admission phase of the hospital episode. This differs from CPEs where the most frequent occurrence was during the inpatient phase; intuitively, this would be expected; but what was not expected was the magnitude of these errors.

The main categories where admission OPEs occurred were: 81.1% (1442/1777) of admission OPEs were the complete omission of a drug; 48.9% (870/1777) were detected and corrected by the pharmacist and 32.2% (572/1777) were detected by a pharmacy technician who reported this to the pharmacist for correction or subsequent dialogue with the doctor. A further 12.6% (224/1777) was where the admission dose, frequency or details did not match what was written on the first prescription.

So altogether 93.8% (1666/1777) of admission OPEs were a failure to get the first hospital prescription correct. This could represent a potentially important contribution for the pharmacist if they could write the first prescription themselves with perhaps greater attention to detail.

The main category where inpatient OPEs occurred was a failure to review medication (43.3%; 559/1291). This category related to the doctor omitting to return to the patient and review their medication as the hospital journey progressed. Examples were, adjusting the allopurinol dose post-operation, when the renal function had deteriorated, or not changing from intravenous flucloxacillin to oral when the patient could eat normally; or stopping Augmentin when a seven day course was complete.

A proportion of OPEs (26.3%; 340/1291) were omitted details in the inpatient phase; these were mainly technical prescribing errors. Many of these would have caused significant delays or gaps in therapy until they were added; for example, an omitted prescribed dose was a 'show stopper' until it was added. A second example was...
enoxaparin prescribed as 1mg/kg BD, which could not be given until the patient was weighed and the dose written in milligrams on the chart. This was for acute coronary syndrome where delays were critical. These errors were common. Alternatively it could be an omitted date and signature, which, whilst legal requirements, may not delay therapy to the patient. However it would put the administering nurse at an unnecessary risk professionally. Nurses were advised that if a signature was not on the prescription they could refuse to administer, which would then have caused delay or omission of therapy to the patient.

A proportion of OPEs (9.5%; 123/1291) were a failure to complete a procedure or plan. This is similar to the failure to review except from initiation there is a clear ongoing pathway or guideline to follow and it has not happened. For example dose escalation of beta blockers or ACEIs following admission for heart failure.

The top three categories described above accounted for 78% (1022/1291) of the inpatient OPEs and related to not completing or reviewing the prescribing process. It was not clear if this was a lack of awareness, lack of time to review or poor attention to detail. These omissions represented a potentially important delay to the care being provided and might have been addressed by a supplementary prescriber.

The important OPEs on discharge (53.2%; 207/389) were regular medicines omitted. This relates to medicines consumed by the patient prior to, or during the hospital episode, that were not written on the ‘medicines for discharge’ or TTO form. It was unusual for these to be deliberate omissions. It was common for the pharmacist to be asked to add these medications to the discharge prescription and to supply them. A proportion of discharge OPEs (15.7%; 61/389) were dose mismatches between inpatient chart and TTO. These were where the dose had been omitted or a reducing dose schedule had not been updated. A small proportion of discharge OPEs (11.1%; 43/389) were classed as omitted duration. This was a failure to indicate when a course of antibiotics, steroids or antiplatelet therapy should be stopped.

These top three categories described above represented 80% (311/389) of the OPEs on discharge. If they had not been intercepted they would have produced poor communication to the GP and patient about what should be continued or stopped after the hospital episode. Anecdotally, they contributed to a perception in primary care, of
poor practice within hospitals. They were the source of complaints and queries and significantly impacted on time and reputation. A major contributory factor was the urgency of a new admission (trying to create a bed) or a lack of interest in completing the task. They were essentially poor attention to detail. There was a significant risk that if uncorrected, they could have caused confusion or readmission.

5.4.2.7 Non-prescribing errors (NPEs)
This category was essentially what remains when the prescribing errors were removed from the intervention dataset.

Almost a third of NPEs (31.3%; 578/1849) related to choice of drug or need for a drug. As these were not prescribing errors, they related to discussions between pharmacist and doctor on what could (or should) be prescribed. In the author’s opinion, this is a positive statement on collaborative inter-professional working. Inter-professional learning has been reported as useful but lacking in many medical schools. They were examples of doctors and pharmacists working together, each contributing their own expertise, to benefit patients. NPE interventions did not relate to a written prescription; they were a discussion about future prescribing, or sharing of knowledge. One of the most important roles of the pharmacists was to act as a source of accurate drug information; another was as an educator.

A NPE classified as ‘choice of drug’ was an intervention that referred to compliance with a hospital formulary; but also the choice of individual drugs within a therapeutic group, or the need for a prophylactic agent. Junior doctors frequently asked the clinical pharmacist for advice regarding pharmacology and therapeutic drug choices. There were also many NPE interventions made to standardise drug choices to match local guidelines or optimise choices to safer alternatives. Sometimes this was also to minimise the likelihood of technical prescribing errors. These were not prescribing errors as they occurred before prescribing; so they represented active advice, recommendations or optimisation by the pharmacist.

From Table 5.16, Section 5.3.2.4, it can be seen that NPEs contained an appreciable proportion (19.4%) of interventions related to dosage and dose modification in liver or renal dysfunction. Often this was where what was originally prescribed was
appropriate but as the patient’s condition changed, the doctor sought advice about the dose or frequency that should be used.

A small proportion of NPEs (8.6%;159/1849) reflected the pharmacist warning the doctor about potential side-effects, ADRs or interactions so they were either avoided or suitably monitored to avoid harm. Awareness of potential problems ensured any adverse signs were quickly detected and patient harm minimised. Anecdotally, junior doctors really appreciated this function of the pharmacist as it avoided them getting into trouble and protected their patients. There was clearly no blame to be attributed because nothing adverse had been initiated.

Table 5.19 combines the 2005-9 intervention data set, Table 3.1 (Section 3.3.3) and the NPE data from this chapter. This composite table shows the proportions of each type of intervention and illustrates which category is larger in the two data sets.

<table>
<thead>
<tr>
<th>Table 5.19 Comparison of intervention data with NPE data for 2005-9</th>
</tr>
</thead>
<tbody>
<tr>
<td>A*</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>PE predominate</td>
</tr>
<tr>
<td>Choice of dose/frequency</td>
</tr>
<tr>
<td>TTO/IP discrepancy or IP drug omission</td>
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<td>Drug duration</td>
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<td>Documentation</td>
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<td>Therapeutic substitution</td>
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*Columns A and D contain the category descriptors used in Chapter 3. Column B (NPE %) is the percentage of non-prescribing errors distributed across the categories in columns A and D. Column C is the percentage of interventions distributed across the categories in columns A and D.

The data categories on the left (column A) were where the proportion of interventions was greater than NPE. This suggests that these categories contained a
disproportionately larger number of prescribing errors. In other words, prescribing errors predominated in choice of dose or frequency. The doctor made an error more frequently than the pharmacist offered advice or recommendations.

So ‘Choice of dose/frequency’ was larger (22.4% vs. 19.4%) in the intervention data. If the PEs were removed from the data, the NPE proportion decreases to 19.4%, therefore PEs predominated in that category. In other words, pharmacists detected more PEs in choice of dose/frequency than answered questions or offered advice about dose or frequency.

The data categories in column D are where the proportion of interventions was greater than NPE. This suggests that these categories contained a disproportionately larger number of interventions. In other words, interventions predominated in choice of, or need for a drug. The pharmacist offered advice or made a recommendation more frequently than the doctor made an error.

So from this we can see where prescribing errors were most abundant. We can also see areas where the pharmacist tried to optimise treatment where no prescribing error had apparently occurred. No-one would doubt that pharmacists have greater knowledge and experience with drug interactions, or of improving documentation (how to prescribe more safely). It might be surprising that pharmacists offered frequent advice on TDM and nutrition. This might be a good area for pharmacist prescribers to practice in. Increasingly, pharmacist recommendations on TDM were written in the notes as a plan for the doctors and nurses to follow. During the study, pharmacists prescribed the majority of all parenteral nutrition (PN) at Southampton.

Summarising, the data in this chapter have shown the magnitude of the problem of PEs that were detected by the pharmacist. The pharmacist had a clear role in preventing these errors from reaching the patient. In those cases where this had happened already, the pharmacist quickly identified the cause to mitigate any harm done. There are signs that the skills and the contribution of pharmacists have been recognised and pharmacists are now commissioned to teach pharmacology and therapeutics at the local medical school. Pharmacists have also been commissioned to provide teaching to junior doctors on safer prescribing techniques in a formal course.
Pharmacists routinely advise informally on improvements to doctors’ prescribing decisions.

5.4.3 EQUIP study

Why do doctors omit or inaccurately replicate dosage? Is it lack of knowledge about doses and consequences? As discussed in the EQUIP study report, the answer is multi-factorial and lack of drug knowledge may not be the single causative factor in any incident. Although a particular action or omission may be the immediate cause of an incident (described as an active failure or error), closer analysis usually reveals a series of events and departures from safe practice, known as an error chain.

Is it because it is a detail that they consider less important to moving onto diagnostic questions? It has been reported in interviews with doctors that they perceive the task of prescribing as quite tedious and that writing discharge prescriptions and transcribing drug charts were particularly boring tasks. It has been reported that when a senior doctor gives an instruction it is assumed to be correct, should not be challenged and need not be checked against a guideline. In addition, is it something they consider they will complete later, or is it a form of ‘moral hazard’ where they consider that the pharmacist will check it out—a reliance on the ‘safety net’? This cannot be answered from this author’s research but could have been elucidated in a follow up interview as was conducted in the EQUIP study.

The EQUIP study was a research project commissioned by the GMC to determine the prevalence and causes of prescribing errors made by first year foundation trainee (FY1) doctors. Pharmacists detected prescribing errors on seven census days across 19 acute hospital trusts in North-West England. Almost all of the 11,000 errors were intercepted by pharmacists before they could affect patients. Doctors were then interviewed about the causes of errors they had made to identify the reasons behind why they occurred.

Routine violations of prescribing rules were reported as understandable adaptations to a busy and stressful environment. Other explanations offered were that junior doctors could not adapt the theoretical concepts they had been taught into the practical clinical setting. Alternatively, the doctors did not understand the factors in the clinical
situation that were relevant to prescribing. The study reported that there was a lack of evidence about the causes of prescribing errors.

The report recommended that further research should look at educating doctors so they did not make mistakes. This seems inconsistent with the error theories reviewed in Chapter 1 where organisational and process changes are recommended including barriers (such as pharmacists) to trap and deflect errors from reaching the patient. Indeed, to the author, the report appeared to play down the fact that pharmacists prevented patient harm from the errors that arose. There was an identified need to provide knowledge about medicines at the point of prescribing, but this was not apparently linked to the role of the pharmacist.

The active failure most frequently cited was a mistake due to inadequate knowledge of the drug or the patient. Skills-based slips and memory lapses were also common. Where error-provoking conditions were reported, there was at least one per error, including lack of training or experience. Latent conditions included reluctance to question senior colleagues and inadequate provision of training.

In reviewing the literature, the report found no evidence about the impact of basic medical education on prescribing errors but found that continuing professional development was more effective at changing physicians’ behaviour. Particularly important was ‘at elbow’ advice or advice provided when it was needed for prescribing. The report claimed that information technology was the answer. However in Section 1.7, the author has discussed how the implementation of CPOE and CDS can introduce new errors (such as juxtaposition selection errors). The EQUIP report appeared to overlook the fact that the research was only possible by using the routine identification of prescribing errors by pharmacists.

The EQUIP report recognised pharmacists as a hospital safety mechanism and their vigilance prevented rule-based mistakes from causing harm to patients. Doctors were unaware of their ignorance about rule-based mistakes. They were also unaware of the support provided by pharmacy – such as a medicines information service.
The EQUIP study did identify that some repeated errors occurred because the doctors never resolved their lack of knowledge, particularly when they believed their errors would be corrected further down the line of the prescription process. Maybe if the findings of the author’s research was presented to junior doctors, this might stimulate CPD such that repeated errors diminish.

The report identified doctors’ concerns that if they admitted their lack of prescribing knowledge, this would have a negative impact on their image. The strong hierarchical structure of doctors led to prescribing instructions from senior doctors being followed without question. Pharmacists were discussed a safety net by all interviewees. They were commonly approached for advice about prescribing and many doctors felt they were a valuable resource.

5.5 Limitations of this study
This research shows a prescribing error rate of 5.5 per 100 items which is less than the 8.9% found in the EQUIP study. This probably reflects an underreporting with this methodology. This dataset was achieved by encouraging pharmacists to report the interventions made. It was often seen as work that was additional to routine activities. Whilst some were motivated to report all the interventions made, and therefore prescribing errors detected, others were not. This explains some of the variability of the results. There was no team of motivated researchers supporting the study and reminding pharmacists of the importance of this work. There was no implied contract to achieve results in response to a research grant.

The EQUIP study was externally funded and motivated pharmacists were coordinating the reporting of errors as part of a big project. It is likely that this achieved better data capture than the author’s longitudinal study. The EQUIP study was conducted across many hospitals whereas the author’s study was only in one hospital trust. There may have been many local factors that introduced a bias, although that bias should have been consistent over the period of study. For example, there may have been a predominance of junior doctors from Southampton school of medicine. The EQUIP study included junior doctors who had been educated in many different schools of medicine, although there were none from Southampton University.
Clinical pharmacy practice may have geographical influences and pharmacists at Southampton may have failed to detect a whole cluster of errors, leading to under-detection of prescribing errors.

Whilst every effort was made to avoid double-counting it is possible that there was overlap between errors reported by PODtechs and pharmacists. This would over-inflate the denominator in the prescribing error rate per item. The error rate per patient was 0.468 in this research and this is consistent with the EQUIP study error rate of 50% of hospital admissions.

5.6 Recommendations

CPEs concerned incorrect route or formulation. These were not a desire to give a licensed drug via an unlicensed route. They were a very concerning group of active prescribing errors. More training on technical prescribing errors could resolve them and a series of ‘safer prescribing’ lectures with a workbook has been delivered at Southampton. This is to ensure that the doctors know how to prescribe correctly.

However it is more difficult to instil a culture of self-checking what has just been written on the prescription. If junior doctors know that pharmacists are checking their prescriptions for errors this might introduce a competitive incentive to not make errors. However the EQUIP study\textsuperscript{72} suggested that doctors were inappropriately confident that they did not make mistakes. Perhaps sharing the data in this research might raise awareness that errors are made frequently. It might be helpful to illustrate the consequences that flow from a lack of self-checking and the subsequent events in the process. An example from EQUIP\textsuperscript{72} was the consultant looking up a dose in the BNF and therefore demonstrating that it was acceptable for all doctors to do this.

As with intervention data, pharmacists are providing more and more recommendations and advice on need for a drug or choice of drug. Is this pharmacists being bolder to share expertise on drug choice or is this a lack of knowledge in junior doctors on pharmacology and therapeutics? We cannot tell from the present study but it suggests a growth area for pharmacists to exploit in the interests of patient care.
Clinical errors reflect poor knowledge about medicines and a lack of completion of clinical guidelines or following a process. These errors relate to things that should have happened but did not, rather than things that were actively done incorrectly. This also shows that pharmacists have an increased understanding of what should happen to patients and their medicines, and a real comprehension of therapeutics. Is this something that just pharmacists have seen or do medical consultants also observe this? Alternatively it may be that pharmacists’ knowledge of therapeutics enables them to make more pro-active interventions to correct these omissions before a medical consultant ward round occurs. This is something that merits further study.

5.7 Conclusions

- Pharmacists in the dispensary can detect technical prescribing errors where the prescription is written incorrectly. Pharmacists on the wards can also detect clinical prescribing errors where the drug is being prescribed inappropriately.

- These data were week-long point-prevalence studies conducted over 8 years. They have demonstrated that an average of 73.9 % (5151/6966) of pharmacist interventions were triggered by prescribing errors.

- Pharmacists’ intervention studies are a useful source of data for prescribing errors; this has not been described before.

- Combining with the activity data from Chapter 2 gives a prescribing error rate of 644 PE per week, or 6.2 PEs for each 100 items prescribed (644/10391).

- By comparison, the Trust submits an average of 910 medication errors each year to the NPSA.

- 67.1% (3457/5151) of prescribing errors detected by this methodology were errors of omission - things that had not been done which should have been. This was only possible because guidelines (national and local) now exist to describe what should be happen.
• Overall the largest proportion 45.3% (2334/5151) of prescribing errors occurred during the admission phase of the hospital episode. This is noteworthy because prior to 2005, this phase of the patient’s journey was largely ignored and had little or no pharmacy involvement.

• Prescribing errors of commission occurred mainly during the inpatient phase and errors of omission during the admission phase.

• 54.1% (916/1694) of prescribing errors of commission occurred during the inpatient phase of the hospital episode. This shows that active prescribing (doing something) produces more errors after admission and before discharge.

• 30.6% (280/916) of errors of commission related to selection of dosage. A further 29.9% (274/916) of inpatient CPEs concerned incorrect route of formulation; 17.8 % (163/916) of inpatient CPEs concerned choice of drug or combination. These were technical details of prescribing that were incorrect. This might be something that pharmacists should formally teach doctors.

• 17.8% (163/916) of inpatient CPEs concerned choice of drug or combination. These are planning errors and show the input of pharmacists into therapeutics.

• 51.4% (1777/3457) of prescribing errors of omission (OPE) occurred during the admission phase of the hospital episode.

• 81.1% (1442/1777) of prescribing errors of omission that occurred during the admission phase were the complete omission of a drug. This was a failure of the doctor to either elucidate the full drug history or to record this on the drug chart.

• 53.2 % (207/389) of prescribing errors of omission that occurred during the discharge phase were the complete omission of regular medicines. These were a failure to have transcribed an inpatient medication into a discharge prescription.
• 43.3%(559/1291) of prescribing errors of omission that occurred during the inpatient phase were a failure to review medication that had been prescribed. Pharmacists encouraged this review but perhaps prescribers should have had a culture of constant review.

• Transcription failures occurred on admission and discharge and were 21%(1084/5151) of all prescribing errors detected; 30.7%(1582/5151) of the prescribing errors were represented by poor attention to detail. A failure to have accurately undertaken a prescribing task.

• 25.6%(1317/5151) of prescribing errors were purely clinical and occurred 85.6%(1128/1317) during the inpatient phase. These were failures to follow guidelines, failures to review, manage interactions, and dosage adjustments in liver or renal failure or in response to TDM.

• The largest category of prescribing errors was a combination of technical and clinical errors where the pharmacist detected a drug discrepancy (on admission or discharge) or where the drug or combination chosen was inappropriate for a particular patient; 81%(946/1168) occurred during the admission phase. It is not clear if this was a lack of knowledge, poor attention to detail or a failure to review the patient’s condition.

• Looking at what remains from this dataset when prescribing errors have been removed, it can be seen that 31.3%(578/1849) of the interventions related to choice of drug or need for a drug. This described the discussions between pharmacist and doctor on what could (or should) have been prescribed. These were occasions where the pharmacist was informally educating the doctor about the need for medicines or how to distinguish between medicines. It demonstrated collaborative inter-professional working. These represent active advice, recommendations or contributions by the pharmacist to optimise the use of medicines for the benefit of patient care.
Key finding

73.9% (5151/6966) of pharmacist interventions were triggered by prescribing errors. This translates into a prescribing error rate of 644 PE per week or 6.2 PEs for each 100 items prescribed (644/10391). By comparison the Trust submits an average of 910 medication errors each year to the NPSA. The implications of this are that prescribing errors are a significant problem and that official data under-represents the size of this important problem. Pharmacists’ interventions represent a significant contribution to the reduction in patient risk from harm as a result of the prescribing errors that occur.
Chapter 6 Research Summary and suggestions for future work.

6.1 Introduction

Healthcare is more complex than the public imagines and errors are ubiquitous; however thankfully, few reach the patient and the majority of those that do cause minimal harm. This said, every incidence of harm is a tragedy for the patient and their relatives.

Within healthcare, complaints and litigation consume significant staff time and resources that have been deflected from patient care. Errors require management effort to resolve the problem and prevent future harm. The costs are therefore large. This can be seen in the American report to congress ‘To err is human’ and the UK response ‘Organisation with a memory’.23

These reports emphasised the need for a culture change where errors were openly reported and these data informed the redesign of processes that reduced the chance of reoccurrence. These reports called for more research and this prompted the investigations described in this thesis.

The DOH claimed that by 2005, the number of serious errors in the use of prescribed drugs would be reduced by 40%.21 At that time, there were no baseline data. This thesis provides the data for Southampton University Hospitals NHS Trust collected under the author’s direct supervision.

The voluntary reporting system set up by the NPSA had a bias at Southampton towards nurse reporting (61.1%) that might be assumed to be related to administration errors. Medication related adverse event forms submitted to the NPSA from 2004 to 2009 gave an average number of total reports per year of 918. This was about the same as the number of interventions reported in the annual pharmacy survey over one week.
Pharmacists made numerous interventions, yet were apparently reluctant to report using the NPSA system. Interventions were surveyed each year at Southampton and there was an opportunity to capture and analyse these data to inform the debate on errors - their generation, prevalence and possible solutions – to inform attempts to design them out.

Healthcare is a highly humane interaction and therefore errors should be expected. Error theory describes two types of errors and in this thesis the author has discussed errors that involve the details or technicalities of writing a prescription as an example of an execution error, where a planned action fails to be completed as intended. This thesis has also explored the growing trend of challenging the clinical aspects of prescribing; choosing what to write on the prescription as an example of a planning error, where the wrong plan is chosen to achieve an aim.

These errors were captured in the main study of Chapter Four where a new process was tested for its impact on medicines reconciliation and the generation of errors throughout the temporary secondary care loop.

Chapters Two and Three explored the trends in risk management activities of pharmacists and quantified the interventions that they made. Chapter Five focused on prescribing errors and their extraction from the intervention dataset.

The following sections summarise what the author has learnt from these studies.

6.2 Summary of Chapter 2

In the 1980s, pharmacists moved out of the dispensary and into the clinical areas. This early ward pharmacy service was focussed on improving the supply role and an earlier trapping of technical prescribing errors. Pharmacists were increasingly exposed to clinical practice throughout the late 1980s and early 1990s. This increased the pharmacist’s understanding about how medicines were actually being used and stimulated them to offer their professional advice on how to maximise the benefits and minimise the harm from medicines. Clinical pharmacists learnt from the adverse drug events that they observed. This experience improved their ability to identify and
trap the clinical prescribing errors. It also generated ideas to redesign the medicines usage process to make errors less likely to occur. Some of these initiatives are described in Chapter 2.

The data in Chapter 2 show the overall, dramatic increase in the number of patients whose care was reviewed each week from an initial 200 to 600 patients in the 1990s to over 1,000 since the year 2000. The number of items screened increased from 1,500 to approximately 8,000. This was a period of rapid expansion of the clinical pharmacy service at Southampton and a move to understand and focus on risk in drug usage rather than risk in supply. The amount of clinical use review increased and the frequency of intervention increased from an average of once every 5.8 patients (40 items) to every 1.3 patients (8.2 items).

New services emerged monitoring the effects of drugs and monitoring drug levels themselves. There was also an increasing emphasis on getting an accurate discharge prescription, and developing an advance dispensing of discharge medication service. A policy of therapeutic substitution emerged to facilitate compliance with the formulary before becoming a prelude to pharmacist prescribing. In the late 1990s, there was a drive to improving the accuracy of drug histories. There was an appreciable increase in both the range and quantity of risk management activities.

### 6.3 Summary of Chapter 3

#### 6.3.1 Numbers and severity scores

The annual survey on clinical pharmacy activities was accompanied by an intervention survey. These data describe what pharmacists did -their ‘outputs’ - which and are analysed in Chapter 3. This chapter focussed on the period 1999-2009.

There was a statistically significant increase in the average number of interventions each week from the surveys in 1999-2001 compared to those during 2005-9. In addition there was a trend to increase the proportion of the more serious interventions (4, 5, and 6). In the period 2005-2009 the average number was 973 per week including 30.9% with serious (4,5 and 6) severity scores.
Analysis of the most serious interventions shows the potential for preventing between nine and 47 patients a week from serious harm (score level 5) and preventing between one and five patients a week from death (score level 6). This was a significant patient benefit that was an almost invisible role of pharmacists. The human value is not measurable but the potential litigation cost avoided would be many times the annual cost of the clinical pharmacy service.

6.3.2 Types of intervention

Interventions made at the interface between primary and secondary care represented the largest category at nearly a quarter (24.2%) of interventions. The data were categorised so that transcription errors at the interface were grouped together. This did not allow differentiation between drugs omitted on entering secondary care and those on return to primary care. The majority of discrepancies on admission were largely slips and not positive decisions to omit these drugs. The role of PODtechs was relatively new and further investigation of their role may in future allow separation and depth of analysis into these errors during admission.

The second most frequent interventions (22.4%) for pharmacists concerned the dose or frequency of medicines. This was a fundamental role of pharmacists and remains a consistent contribution to avoiding patient harm as well as facilitating the efficient completion of the drug usage process.

The third most frequent intervention (18.6%) was concerned with the choice of drug and need for drug. Encouraging formulary compliance was part of this category but some of these interventions were concerned with the choice of drug within the formulary for a particular patient. National guidelines now play a part in identifying the need to start new drugs and this forms part of this category. From this dataset it was not possible to differentiate between these components, although that might prove an interesting subject for further study.

In 1999, interventions on documentation represented 13% out of a total of 613. In 2006 to 2009 this type averaged 4.7%. This shows that this type of intervention is decreasing. However many interventions were initiated from documentation
anomalies but then developed into further, more serious interventions. Computer prescribing should eliminate many of the documentation anomalies which were classed as technical prescribing errors. This might make it more difficult to detect the secondary but more serious errors, stemming from documentation failures.

6.3.3 Outcomes

Around 90% of pharmacist interventions were focussed on patient benefit and less than 10% were to save money. This has been a reasonably stable proportion over the years, despite a perception that the primary role of pharmacists was to reduce the costs of medicines. Safe use of medicines should decrease patient harm and consequential complaints and litigation costs. The effective use of medicines should decrease the total resource used by decreasing length of stay and reduced readmissions.

The contributions that pharmacists made were readily accepted by other healthcare staff increasing to an average of 86.8% in the 2005-9 cohort. Today the role of the pharmacist is more widely accepted and integrated into the work of clinical teams.

The pharmacists were known for their knowledge of the supply chain and choice of available products and different formulations. The analysis of interventions has shown their involvement in managing interactions and incompatibilities. The pharmacist’s knowledge of where and how errors arise in the use of medicines has been illustrated by this dataset.

6.3.4 High severity interventions

During 2006-9 more than half (52.5%) of the interventions, with score 5 and 6 involved two types of intervention. The first concerned the choice of, or need for, a drug and the second concerned interactions, side-effects and adverse reactions. The drug choice category could be further divided into: the need to start a drug, the need to stop a drug and the poor choice of a drug for the particular patient. These represented the most frequently occurring, serious, medication related interventions in
terms of potential consequences to patients. The intervention reports show that pharmacists prevented this harm from reaching patients.

6.3.5 Medicines education for other healthcare workers

The interventions showed that the pharmacists’ contribution to patient care made them a valued resource. As the medicines expert, the pharmacist’s knowledge was shared with other members of the team and ensured that nurses, and other healthcare staff, were kept informed and up-to-date about the medicines commonly used on the ward. However this sharing of knowledge was so embedded in clinical practice that pharmacists may not have perceived this educational role as an intervention at all and did not report interventions that were purely educational.

The reporting, analysis and discussion of pharmacist interventions had not really occurred outside of pharmacy before about the year 2000, because of a fear of damaging the relationship between pharmacist and doctor. The dataset had only been used to educate junior pharmacists on the meaning of clinical pharmacy. The free text on intervention reports described specific examples of the application of the pharmacist’s knowledge. The new culture should enable the data to be used to inform educational training sessions for junior doctors on how to prescribe with greater safety. In the last five years, the pharmacy induction of junior doctors at SUHT has included examples of prescribing errors. More recently, pharmacists have been involved in formally teaching junior doctors safer prescribing techniques.

The interventions were often a correction of errors and raised the principle of continuous quality improvement or ‘getting it right first time’. This forms the basis of the experimental intervention in Chapter 4.

6.4 Summary of Chapter 4

The third strand of the author’s research was to test an intervention where a pharmacist obtained an accurate medication history and drafted the first inpatient prescription. The A&E setting was chosen because this was the earliest opportunity in the hospital episode. The reduction in errors was to be assessed over the whole of the
temporary secondary care loop as it was hypothesised that errors on admission create further cumulative errors later in the hospital episode and possibly impact on the length of stay.

A nurse administered questionnaire was incorporated into the recruitment and consent process to assess the proportion of patients who brought in their own medicines, and their understanding of why they were prescribed. It was hoped the questionnaire would increase patient involvement, benefit all participants and produce some qualitative findings about patient perceptions around likely areas of error such as allergy, analgesics, and antibiotics.

The main study was designed to detect medication related admissions (MRAs). These might be related to side-effects or adverse reactions (AMRARs) or a more indirect medication related adverse event (AMRAEs); for example, a vasodilator produced postural hypotension as an adverse reaction and which then produced a fall as an adverse event. Incomplete drug histories made it difficult to detect AMRARs and AMRAEs, so the starting point was to ensure that the drug history was complete and accurate. It seemed a logical step to transcribe this onto the drug chart. The pharmacist’s knowledge of formulary products and available formulations improved the technical aspects of writing the first prescription.

The project concept and design were compromised by logistical and workload concerns. It was hoped that by investigating patients with three or more medicines, this would increase the chance of detected errors, interactions and medication related admissions. It was also important to ensure blinding of the A&E doctors to the parallel process in order to avoid a Hawthorne effect. Yet at the same time, participants should have been adequately informed to give valid consent to the research. A few senior doctors raised concerns about whether the research could be conducted safely without interfering with the normal admission process.

Whilst the randomisation worked well, the logistics produced a much larger drop-out rate than had originally been expected and so recruitment was less than required from the power calculations. One hundred and forty-nine patients were recruited to the main A&E study over five months in 2004, but only 115 were able to be analysed.
Implementation of the intervention by a Band 7 pharmacist was designed to improve the generalisability of the findings to other hospitals.

From the questionnaire it was found that many patients were ill informed and lacked knowledge about the medicines they took. There is potential here for community pharmacists to conducting MURs before elective admissions and provide more information to patients. This might also improve the accuracy of drug histories and facilitate transcription onto hospital prescriptions. There is also potential for developing information leaflets for patients who might be admitted to hospital to recommend that they bring their own medicines with them, to improve data on medication histories. Only 42% of patients brought in their medicines and a further 12.4% brought in a list or GP repeat printout.

The questionnaire produced useful information on the distribution of the number of medicines being consumed. The change to two, rather than three medicines or more had very little impact on recruitment to the study. Many patients entered hospital on multiple medications; almost two thirds (64%) reported taking five or more medicines from a range of two to 14. It was not clear how this might compare to a national average but it is probable that patients admitted to hospital consume more medicines than those in the community.

Over one quarter of patients (45/177; 25.4%) declared they had allergies to drugs. However some of the ‘allergic’ symptoms described drug side-effects or symptoms of their illness. There is clearly more work to be done in educating the public about the meaning of true drug allergy and differentiating this from intolerance due to side effects.

Over one fifth of patients (25/115; 21.71%) had events or symptoms that contributed to the admission that could be explained by the medicines they were consuming (AMRAEs and AMRARs). Over half of these were potentially avoidable by better monitoring or product selection.

There was a noticeable lack of records of the actions of pharmacists in the medical notes, so more events may have occurred but were not detectable by the time the notes
were reviewed. In future it may be helpful if pharmacists were to record in the notes more details of what they have done.

In addition to any medication-related events, during the admission phase alone, 14 of 59 patients (23.7%) in the control group had 22 prescribing anomalies. This contrasts to the pharmacist (intervention) cohort where only four out of 56 patients (7.1%) had 7 prescribing anomalies in the admission phase. Drug histories conducted by pharmacists contained fewer omissions and errors than those conducted by junior doctors but this did not reach statistical significance. If more patients had been recruited in the study then this might have achieved statistical significance with adequate power.

A similar pattern was seen during the inpatient phase where there were nine events in the doctor cohort and none in the intervention cohort. During the discharge phase there were 14 events in the control cohort and 11 in the intervention cohort.

Overall, during all three phases of the hospital episode (admission, inpatient and discharge) 34 patients in the control (doctor) cohort of 59 patients experienced a total of 45 medication anomalies. Twenty-five patients in the intervention (pharmacist) cohort of 56 experienced a total of 18 medication anomalies during their hospital stay. Across the whole episode the reduction seen in the intervention cohort did reach statistical significance.

The pharmacists’ interventions included not just taking a drug history but also getting the pharmacist to transcribe this data onto the first hospital prescription, ready for the doctor to sign. In this study, it was shown it was logistically feasible for a pharmacist working in the A&E department to do this. However, several of the pharmacist’s first prescriptions were re-written by the doctor on the ward. It was not clear whether this was a lack of information about the project or a rejection of the concept. Anecdotal feedback was that the doctors welcomed the pharmacist contribution as it helped their workload.
It would require more than one pharmacist to provide sufficient input to review the majority of patients admitted. A pharmacist prescriber attached to the clinical team may have been able to take this further.

This study was conducted before 2007 when NICE and the NPSA recommended that medicines reconciliation should be conducted in the first 24 hours of an admission and that pharmacists should be involved. It would be interesting to survey current junior doctors’ opinions about whether the first chart should be reconciled with primary care before amendments are made relating to this admission. At the time of this study it was clear that doctors were combining these two stages and apparently not recording in the notes the reason for their changes on admission.

SUHT protocols have changed over time. Today there is greater familiarity with the role of PODtechs and two pharmacists are now employed in the medical admissions unit (MAU) and participate in a consultant-led, post-take ward round. The MAU was created to facilitate reducing A&E waiting times to less than four hours and it was sited adjacent to A&E. Today there is greater visibility and acceptance of the pharmacist’s role in this area so it is likely that a pharmacist writing first inpatient prescriptions would be accepted.

### 6.5 Summary of Chapter 5

#### 6.5.1 Overview

Prescribing errors can either be acts of commission or acts of omission. A hospital prescription is a primary communication device that translates the prescriber’s thoughts into what they want the pharmacist to supply and what they want the nurse to administer.

Pharmacists’ interventions have detected many technical prescribing errors where what was intended to be prescribed was not exactly what was written. Historically clinical or planning prescribing errors were more difficult to detect. Experienced pharmacists knew the expected pathway that patients should follow and were able to detect when standard therapeutic additions had not been made. This has been further
clarified in some specialities by the construction of national guidelines. Since about 2005 there have been more interventions that relate to the need for a drug – a clinical or planning error. Prior to 2005, the only planning errors detected by pharmacists would occur if the doctor’s choice of treatment was inappropriate, or did not take account of all relevant patient factors.

In Chapter 5, the intervention dataset captured over the period 2001-2009 was re-evaluated and coded to see if the cause could be attributed to a prescribing error. Note that the 2002-2004 data were unavailable. Chapter 5 reports a specific investigation for 2007 and a review of the 2001-2009 dataset that had been recoded for prescribing errors.

Non-prescribing errors focused on optimisation or improving the planning part of prescribing; so Chapter 5 looked at prescribing errors of commission, PEs of omission and non-prescribing error (NPE) minimisation. It also looked at events that occurred during the admission, inpatient and discharge phases of the hospital episode.

### 6.5.2 Phase of secondary care loop

Overall the discharge phase represented 8.8% of all events (PEs plus NPEs); inpatient events were 55.8% of all events and admissions represented 35.4% events. However this conceals a change from the early years (2001-2005) where admission events were 27.5 % of the total compared to latter years where admission events increased to 43.2%. This relative increase of 15.7 percentage points in admissions events reflects the deployment of extra pharmacy staff in the acute admissions / assessment units. Pharmacy staff intensified their focus on obtaining an accurate drug history and ensuring the first prescriptions were complete and a true reflection of medicines consumed prior to admission to hospital. This was partly from the expanding role of technicians taking drug histories from patients, assessing PODS and informing pharmacists about any anomalies. It is only after 2007 that this became linked to the NPSA medicines reconciliation guidance. So by adding in the detection of PEs during admission, the pharmacists had nearly doubled (2817 to 5151) the number of detected PEs.
6.5.3 Changing the culture

The call from the GMC for research proposals on prescribing errors in 2007 started a year of collaboration between doctors and pharmacists. It revealed that senior medics were interested in finding out from pharmacists where prescribing errors occurred. This was in itself a cultural shift and demonstrated an important change in medical attitudes to the role of the pharmacist.

6.5.4 All prescribing errors

The data presented in Chapter 5 demonstrated that an average of 73.9% (5151/6966) of pharmacists’ interventions was triggered by prescribing errors. It also showed that pharmacists’ intervention studies could be a useful source of data for prescribing errors; this has not been extensively described before. The errors were collected over an extended period of time, (2001-2009) which was unusual.

Over two thirds of prescribing errors (67.1%; 3457/5151) detected by this methodology were errors of omission—things that had not been done. This was only possible because guidelines (national and local) emerged to describe what should have happened. Such errors were planning errors and would have occurred in addition to the often reported technical or execution errors such as missing strengths, doses and signatures.

Overall the largest portion of prescribing errors (45.3%; 2334/5151) occurred during the admission phase of the hospital episode. This is noteworthy because prior to 2005, this phase of the patient’s journey was largely ignored and had little or no pharmacy involvement.

Prescribing errors of commission occurred mainly during the inpatient phase and errors of omission during the admission phase.

6.5.5 Prescribing errors of commission (CPEs)

Over half of CPEs (54.1%; 916/1694) occurred during the inpatient phase of the hospital episode. This showed that active prescribing (doing something) produced more errors after admission and before discharge.
Just under one third of CPEs (30.6%; 280/916) occurring during the inpatient phase were related to the selection of a correct dose. A further 29.9% (274/916) of inpatient CPEs concerned incorrect route or formulation; 17.8 % (163/916) of inpatient CPEs concerned choice of drug or combination. These were execution errors - technical details of prescribing that were incorrect. This might be something that pharmacists should formally teach doctors.

6.5.6 Prescribing errors of omission (OPEs)

About a half of OPEs (51.4%; 1777/ 3457) occurred during the admission phase of the hospital episode; 81.1% (1442/1777) of OPEs that occurred during the admission phase were the complete omission of at least one drug. These were the failure of the doctor to either elucidate the full drug history or to have recorded this on the drug chart.

Two fifths of OPEs (43.3 %; 559/1291) that occurred during the inpatient phase were the failure to review medication that had been prescribed. Pharmacists encouraged this review but perhaps prescribers should have had instilled in them, a culture of constant review.

About a half of OPEs (53.2 %; 207/389) that occurred during the discharge phase were the complete omissions of regular medicines. These were the failure to have transcribed an inpatient medication onto a discharge prescription.

6.5.7 Transcription errors

Transcription failures occurred on admission and discharge and were about one fifth (21%; 1084/5151) of all prescribing errors detected; 30.7% (1582/5151) of the prescribing errors were reflected by poor attention to detail. This was a failure to have accurately undertaken a prescribing task - an execution error.
6.5.8 **Technical and clinical PEs**

One quarter of PEs (25.6%; 1317/5151) and 85.6% (1128/1317) of these occurred during the inpatient phase. These were failures to follow guidelines, failures to review, manage interactions, and adjust dosage in liver or renal failure or in response to TDM - all planning errors.

The largest category of prescribing errors was a combination of technical and clinical errors where the pharmacist detected a drug discrepancy (on admission or discharge) or where the drug or combination chosen was inappropriate for a particular patient. 81% (946/1168) occurred during the admission phase. It was not clear if this was a lack of knowledge, poor attention to detail or a failure to review the patient’s condition.

6.5.9 **Non-prescribing errors**

Looking at what remains from this dataset when prescribing errors have been removed, it can be seen that 31.3% (578/1849) of the interventions related to choice of drug or need for a drug. This described the discussions between the pharmacist and doctor on what could (or should) have been prescribed. These were occasions where the pharmacist was informally educating the doctor about the need for medicines or how to distinguish between medicines. It demonstrated collaborative inter-professional working. These represent active advice, treatment recommendations or contributions by the pharmacist to optimise the use of medicines for the benefit of patient care.

6.5.10 **Summary comparison with the EQUIP study**

In EQUIP, the majority of errors were deemed potentially significant (53%) or potentially minor (40%). Potentially serious errors were less common (5%) and potentially lethal errors were found in fewer than 2% of erroneous medication orders. As with the author’s study, it is important to stress that those figures were a measure of potential severity and not actual severity because pharmacists detected most errors before they affected patients.72
Some doctors, in hindsight, reported a lack of expertise in dosing, drug-drug interactions, formulations, contra-indications, controlled drug regulations and drug indications.\textsuperscript{72} This was also reflected in the interventions reported in this thesis.

The EQUIP study showed that medication orders issued at the time of hospital admission were 70\% more likely to be associated with a prescribing error (adjusted OR 1.70 95\% CI 1.61 – 1.80) in comparison to medication orders issued during the hospital stay.\textsuperscript{72} Regression analyses showed that junior doctors were twice as likely as consultants to make a prescribing error. EQUIP also revealed that new prescribers (i.e. nurses and pharmacists) had similar error rates to consultants. This was not studied in the author’s research, but would make an interesting investigation at SUHT.

The author of this thesis is not aware of any interventions made on prescriptions written by non-medical prescribers; but again, a study comparing non-medical and medical prescribing errors might prove informative.
Chapter 7 Overall Conclusions

This thesis has examined the role of pharmacists in the capture of medication errors and the prevention of harm reaching patients from errors. Pharmacist intervention surveys have been shown to be a useful tool in identifying medication errors and specifically, prescribing errors.

The studies have shown sampling of interventions made by pharmacists and indicate the true extent of the number of serious errors in the use of prescribed drugs. Detection and interpretation of errors related to prescribing broadened and intensified over the study period. This dataset was however different from that reported to the NPSA both in number and the type of medication errors reported.

In the period 2005-2009, the average number of interventions was 973 per week including 30.9% with serious (4, 5 and 6) severity scores. On average 73.9 % (5151/6966) of pharmacist’s interventions were triggered by prescribing errors. In the period 2004-2009 the average number of reports to the NPSA was 918 per year; 61.1% were reported by nurses and might be assumed to be related to administration errors.

The number of interventions made per week increased from 200, in the early 1990s, through 600 in the late 1990s, to over 1000 since the year 2000. The rate of interventions also increased from between one per every five and seven patients (31 to 45 items) to one per every one to two patients (8 to 20 items). The severity of interventions also increased, with between one a five deaths avoided each week. These data translate into a prescribing error rate of 644 PEs per week, or 6.2 per 100 items.

A quarter of interventions were transcription errors at the interface between primary and secondary care. A fifth of interventions involved the dose or dose frequency of medicines. The third most frequent interventions (18.6%) were concerned with the choice or need of drug.
A third (31.3%) of the interventions related to discussions between pharmacists and doctors on optimising the choice of drug or identifying the need for a drug. Nearly nine tenths of interventions were positively accepted by other healthcare staff; the majority were not initiated simply to save money.

New risk management activities have been developed. ADDM facilitates an accurate and early discharge prescription. Therapeutic substitution facilitates formulary compliance and corrects simple errors. Pharmacist prescribing is developing as a tool to correct errors and develop specialist prescribing services such as TPN, pre-admission clinics and clinics for complex drugs.

Despite challenges with recruitment, the project in A&E showed that 25/115 (21.71%) of the patients had events or symptoms that contributed to the admission that could be explained by the medicines they were consuming. Over half of these were potentially avoidable by better monitoring or product selection.

A pharmacist working in A&E to obtain complete and accurate drug histories, then transferring the data by writing the first prescription, was proven to be successful. There was a statistically significant reduction in the generation of errors throughout the whole hospital episode.

Over half of all interventions (related to prescribing and non-prescribing errors) were made during the inpatient phase, a third during admission and the remainder during discharge. Nearly three quarters (73.9%) of pharmacists’ interventions were triggered by prescribing errors.

This thesis has shown that pharmacists’ intervention studies provide useful data on prescribing errors. Trends in prescribing errors have been analysed over an extended period of time, (2001-2009) from a single organisation and medicines usage process.

Nearly half (45.3%) of all prescribing errors detected by recoding pharmacist interventions, occurred during the admission phase of the hospital episode. Two thirds (67.1%) of prescribing errors detected by this methodology were errors of omission -
things that had not been done. Prescribing errors of commission occurred mainly during the inpatient phase and errors of omission during the admission phase.

Four fifths (81.1%) of the prescribing errors of omission that occurred during the admission phase were the complete omission of at least one drug. A quarter of prescribing errors were planning errors. These were failures to follow guidelines, failures to review, manage interactions, and adjust dosage in liver or renal failure or in response to TDM, all planning errors.

In previous chapters, the author has suggested ways in which the clinical pharmacist can and does, contribute to minimising these errors for the ultimate benefit of patients.
Recommendations for future research and future practice developments

1. To continue the annual activity and intervention surveys

These surveys should be continued with some modifications. Future surveys could include the further division of some categories. For example, the transcription of the drug history into the first prescription could be separated from the transcription of the inpatient chart into the discharge prescription. Also the need to start a drug could be separated from the need to stop a drug and from a poor initial choice. There could also be clearer recording of whether the intervention occurs during admission, discharge or during the inpatient phase. There could be clearer data capture or OPE, CPE and NPE. The paper system could be converted into an electronic database to facilitate analysis.

2. Research into the impact of electronic prescribing

Research questions will be generated as this transition is made such as:
Will is decrease mismatches between drug, dose and frequency?
How much pharmacist time does it release?
Can E-prescribing facilitate transcription of inpatient to discharge medicines?

3. Explore impact of pharmacist prescribers

Prepare a business case for a pharmacist prescriber to write the first hospital prescriptions for elective cardiac surgery. Draft a research protocol to analyse the impact of this and the conversion into a prescriber role. Prepare and draft a guideline for post-operative cardiac surgery in terms of compliance with MINAP data. Conduct research pharmacist prescribers’ role in delivering this guideline.

4. Writing in medical records

Investigate what pharmacists write in medical notes and why? This could facilitate the preparation of a detailed policy that could then be audited. It could also be determined if pharmacist prescribers write more frequently in the notes than other pharmacists.
5. Attitudes to first hospital prescriptions
Organise a project to look at 5th year medical student attitudes to the drafting of the first hospital prescription. In particular this is to question whether the first prescription chart should it be a duplication of the drug history? Follow up with a repeat survey of junior doctors in the first year of prescribing. A parallel project could be conducted to assess pre-registration hospital pharmacists and Band 6 and 7 hospital pharmacists’ attitudes to first prescriptions and a separate drug history.

6. Wider collaboration
Collaborate with community pharmacists in a research project to establish the impact of pre- and post-hospital MURs.

7. Reporting of medication errors
Analyse the proportion of different staff groups employed and compare these to the staff who complete forms for the NPSA.
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Appendix 1

Data collection form used in point prevalence activity studies.
Clinical Activity data collection form

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Number of beds on this ward

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<th>Patient Name</th>
<th>Number of charts seen</th>
<th>Number of newly prescribed items</th>
<th>Annotations</th>
<th>Interventions</th>
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Appendix 2

Data collection form used in the intervention studies (2006 version)
INTERVENTION DETAILS

Pharmacist’s name…………………

Please tick
Dispensary ☐ Ward Pharmacist ☐ POD Technician ☐

Date……………………………..
Ward……………………………
Patients Name/Hospital Number……………………………………………..
Age……………………………..

INTERVENTION FOR SCORING

1 ☐ Negative i.e. detrimental to patient
2 ☐ Information provision only
3 ☐ Minor intervention
4 ☐ Major intervention
5 ☐ Save a major organ/serious
6 ☐ Save a life

Please give brief details of intervention:

Drug with narrow therapeutic index 31 ☐
INTERVENTION MADE ON WARD ROUND 29 ☐
More than 24 hours before action 30 ☐

PTO FOR INTERVENTION CODING
**CLINICAL PHARMACY INTERVENTION REPORT FORM**

Only tick one box in each section

### INTERVENTION RECORDING

**DOCUMENTATION** – Prescription
- Illegible, ambiguous
  - Illegal, incomplete
  - TTO/IP discrepancy or IP drug omission
- Choice of / need for drug
- Choice of dose/frequency/timing
- Choice of form/strength/route
- Drug duration
- Pharmacokinetics/TDM
- Drug admin/incompatibility/calc
- Drug interaction/ADR/SE/monitoring
- Drug supply/storage
- Other drug information
- Nutrition

### CLINICAL

- Nutrition

### THERAPEUTIC SUBSTITUTION

- Cost information/analysis
- Formulary compliance
- Attempt to decrease costs
- Non financial

### FINANCIAL

- Positive
  - Treatment altered/actioned
  - Chart altered
  - Information accepted
- Information
  - Known/problem not pursued
- Negative
  - Treatment unaltered

See thesis, Table 3.3 for intervention severity scoring
Appendix 3

Patient information and consent forms for controlled study.
‘You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

**What is the purpose of this study?**
The purpose of this study is to find out how many patients admitted into hospital through the Emergency department (A&E) have had problems with their medicines. It is also to find out if a pharmacist based in the Emergency department can improve the way we look after you in hospital by asking you about all medicines you have taken in the last 6 months. This is to build up a detailed picture of the medicines you have taken in order to more fully understand the health reasons that have brought you into hospital.

**Why have I been chosen?**
You have been given this information sheet because you have recently taken 3 or more medicines. You will only enter the research project if you also need to be admitted into the hospital. This research will not alter whether or not you are admitted.

**Do I have to take part?**
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What will happen to me if I take part?**
Sometimes because we do not know the best pathway for patients, we try to explore new ways of working and then make comparisons with the historical approach. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance. Patients in each group then have a different way of being treated and these are compared. In this case the new way of working (a chat with a pharmacist) is being compared with the current system. You will have an equal chance of being in either group.

In a blind trial you will not know which group you are in. This is a double blind trial in the emergency department as the A&E doctor will be unaware that the recording of you medication is different, as it will occur after he has spoken to you. However the doctors and nurses on the ward will be able to see the additional records made by the pharmacist.

If you agree to take part in this project the research nurse will ask all patients some general questions about taking medicines. This should take no more than 5 minutes to complete.

The research nurse will then randomly put you into one of two groups. If you are in the control group the doctor will ask you about the medicines you take and prescribe them in the normal way. The doctors and
nurses will not know you are part of this research project. A pharmacist will review your medicines during your hospital stay, although you may not be aware of this.

If you are in the active group the research nurse will introduce you to a pharmacist who will talk to you about the medicines you have recently taken. They will ask you about any problems, side effects or changes in your medicines. These will be recorded in your notes and seen by the doctor on the admission ward. Unless you are experiencing any difficulties with your medicines the junior doctors in the Emergency department will not know you are part of a research project.

The interview with the pharmacist should take about 15 minutes and will take place whilst the other preparations are made for you to be admitted to hospital. Therefore the interview should not alter or delay the way you are admitted into a hospital bed. After this interview you will probably be unaware that you are part of this project, which will end when you leave hospital. The success of this new way of working will probably not be known until months after you have left the hospital and most doctors and nurses looking after you will not know you are part of this research project.

What do I have to do?
The only thing you have to do is talk to the pharmacist honestly and openly about the medicines you have been prescribed or bought from a pharmacy or supermarket, including nutritional supplements (such as vitamins and minerals), herbal medicines, homeopathic preparations or recreational substances that you have consumed recently. The purpose of knowing about non-prescribed medication is only because they may be relevant to treatments we may give you.

What is the drug or procedure that is being tested?
There is no new drug or treatment being tested. It is only the way in which the hospital obtains information and records the medicines you have taken. It is a new way of working with you, but should not otherwise affect the way we care for you.

What are the alternatives for diagnosis or treatment?
Doctors and nurses will continue to diagnose or treat your medical condition in the usual way. This research only tests if the information obtained and recorded by the pharmacist assists the speed with which we find out what is wrong with you and provide your treatment.

What are the possible benefits of taking part?
We hope to be able to record more detailed data about the medicines you take and any problems you have had. If this information allows a more rapid or fuller understanding of your problems, then we plan to treat yourself and future patients more rapidly by introducing this new way of working. We do not know if the interview with a pharmacist will help and it may be no better than current practice.

What if new information becomes available?
This study is only about obtaining information and a new way of doing this – no treatment is involved. Once entered into this study it will not be possible to withdraw the information that was available.

Will my taking part in this study be kept confidential?
‘All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.’

The senior hospital doctors looking after you will be aware of this research project and the entries in the notes.

Sometimes we phone general practitioners about the medicines you take. This is normal practice, when we need to clarify details of what has been prescribed. If we do this we will send a letter to them confirming what we have recorded about the medicines you take. You are fully at liberty to discuss this with them after your hospital admission is completed.

What will happen to the results of the research study?
It is anticipated that the results of this will be published in professional healthcare journals. No patient will be identified in any report or publication. This work will also be reported in a PhD thesis on medication problems by the chief investigator.
Who is organising and funding the research?
Southampton University Hospitals NHS Trust funds this research. There is no payment for patients taking part.

Who has reviewed the study?
The Southampton and South West Hampshire Research Ethics Committee have reviewed this study.

Contact for further information.
If you wish to contact someone about this study please talk to Mark Tomlin, Chief Investigator on 023 80 795117

version 2
You will be given a copy of this Patient Information Sheet and a signed consent form to keep.
Study Number:
Patient Identification Number for this trial:

**CONSENT FORM**

**Title of Project:**
A&E Medication Project

Name of Researcher:
Jennifer Irving
Mark Tomlin
Mike Clancy
Rob Crouch

1. I confirm that I have read and understand the information sheet dated 27/9/2003................. (version 1............) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from [company name] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

4. I agree to take part in the short nurse survey about medicines generally.

5. I agree to take part in the pharmacist interview about my medicines.

__________________________________________  ____________________________  ____________________________
Name of Patient  Date  Signature

__________________________________________  ____________________________  ____________________________
Name of Person taking consent Date  Signature
(if different from researcher)

__________________________________________  ____________________________  ____________________________
Researcher Date  Signature

Please initial box

1 for patient; 1 for researcher; 1 to be kept with hospital notes
Appendix 4

Process map for the controlled study.
A&E Medication Research Protocol

Patient attends A&E

Patient enters triage

Patient waits to see doctor

Doctor sees patient and notes medicines as part of routine clerking

Research nurse identifies those taking 3 or more medicines

Research nurse obtains patient consent

Patient given research information sheet

Doctor decides to admit Patient

Admission process begins

Research nurse obtains patient consent

Research nurse allocates patients into groups

Research nurse introduces pharmacist to relevant patients

Brief nurse survey

Research pharmacist records medication in medical notes and writes out inpatient prescription chart

Research pharmacist conducts medication history review

Admission process continues

Urgent problems identified to A&E doctor

Admitting Doctor sees patient and prescribes medication

Patient waits to see doctor

Admitting Doctor sees patient and signs prescription, or amends it

Patient arrives on admission ward and seen by nursing team

Patient transfers to admission ward

Medication related problems written in notes and communicated to clinical team on admission ward

Common pathway from here
Appendix 5

A&E side-study questionnaire.
Resolution of medication related problems by a pharmacist in the emergency department

Questionnaire sub-study by research nurse:

An exploration of patient experience and understanding of medication related matters for patients attending the emergency department.

Structured Medication Questionnaire – interview schedule

1. How many different prescribed/non-prescribed medicines do you take? and how many tablets per day?
2. At what times do you find it easier to take your medicines?
3. Which medicines, if any, do you most frequently forget to take?
4. Does taking medicines disrupt your daily routine?
5. Can you remember the names of any prescribed medication that you take?
6. Do you know what they are for?
7. Have you taken any medication such as painkillers before coming here today (particularly if injury related)? If not why?
8. Do you have any allergies to drugs (if yes, what happened)?
9. If you have taken antibiotics before, have you ever had any form of reaction to them? If so what happened?
10. Do you often take antibiotics? If so why?
11. If you take medication regularly have you brought them with you?
12. Have you ever used somebody else’s prescribed medication because you have a similar problem?
Appendix 6

Definitions of prescribing errors.
Definitions of prescribing errors

1. **Pharmacist interventions that are Not a prescribing error (NPE)**

When the prescription was safe, but not in accordance with hospital policy or the hospital formulary (for example Gaviscon instead of Gaviscon advance); or the venous thrombo-embolic risk assessment form had not been completed, or the doctor sought advice about how to do something before initiating the process; or the prescription was intrinsically safe but the pharmacist made it safer (IV to oral conversion or addition of a maximum dose); or more effective (changing from oral tablets to liquids); or cheaper; or the detection of a nurse administration error.

2. **Prescribing errors of Omission (OPE)**

A prescribing error arose when the doctor omitted to undertake a clinically important action or omitted to include essential technical prescribing details.  
A Technical prescribing detail was the signature, date, dose, frequency, route, allergy status, or controlled drug requirements. This included illegible or ambiguous details, such as writing a dose as 1mg/kg with no weight on the chart so that nothing was given. It includes the unintentional omission of medicines from the patient’s drug history.  
A clinical prescribing error includes not initiating anticoagulants for an appropriate indication at a suitable time after diagnosis or operation; or prophylactic agents for deep vein thrombosis or stress ulceration. This included failing to review medication when the patient’s condition changes (such as altered renal function). It also included failure to initiate beta-blockers or anti-platelet agents in line with a national guideline such as secondary prevention of myocardial infarction.

3. **Prescribing errors of Commission (CPE)**

A prescribing error arose when the doctor wrote something that was incorrect such as prescribing a penicillin antibiotic for a patient who was allergic to this.  
Technical errors would be to have prescribed a drug detail, such as the dose, that was inconsistent with the drug or other details (for example flucloxacillin 200mg three times a day)  
Clinical errors would be to have prescribed an interacting pair of drugs, or failed to follow a guideline accurately such as choosing the wrong dose of enoxaparin (1.5mg/kg daily for unstable angina).
Appendix 7

Data collection form (post 2007) – not used.
INTERVENTION DETAILS

Please tick
Dispensary  Ward Pharmacist  POD Technician  Name Dr/bleep/G MC

Date……………………………..

Ward…………………………….. Grade doctor - F1 F2 Reg Cons

Patients Name/Hospital Number………………………………………….
Age………………………………. Intervention/prescribing error

Please give brief details of intervention: (please list drug names)

Drug with narrow therapeutic index 33 □

INTERVENTION MADE ON WARD ROUND 31 □

More than 24 hours before action 32 □

PTO FOR INTERVENTION CODING
**CLINICAL PHARMACY INTERVENTION REPORT FORM**

Only tick one box in each section

### INTERVENTION RECORDING

**DOCUMENTATION** – Prescription

- Illegible, ambiguous
- Illegal, incomplete

- First prescription error
- Choice of / need for drug
- Choice of dose/frequency/timing
- Choice of form/strength/route
- Drug duration
- Pharmacokinetics/T.D.M.
- Drug admin/incompatibility/calc
- Drug interaction/ADR/SE/monitoring
- Drug supply/storage
- Other drug information
- Nutrition
- IP/TTO discrepancy
- TTO error

### CLINICAL

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### THERAPEUTIC SUBSTITUTION

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### FINANCIAL

- Cost information/analysis
- Formulary compliance
- Attempt to decrease costs
- Non financial

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### OUTCOME

- **Positive**
  - Treatment altered/actioned
  - Chart altered
  - Information accepted
  - Known/problem not pursued
  - Treatment unaltered

- **Information**
- **Negative**

PTO FOR INTERVENTION DETAILS AND SCORING