School of Pharmacy

The Study of Medication Errors at a Teaching Hospital Using Failure Mode and Effects Analysis.

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Dedication

To my parents, for their support in all areas of my life and especially in my academic career and to Andrew and James, who make everything worthwhile.

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GLOSSARY OF TERMS

FMEA (Failure mode and effects analysis) - method of systems analysis where the system is broken down into small steps. Each step is then analysed to detect problem areas with a high probability of causing errors. The system can then be modified to prevent errors from occurring

SCGH (Sir Charles Gairdner Hospital) - study hospital in Perth, Western Australia

USIPD (Unit supply individual patient dispensing system) - medication distribution system trialed where 5 day supply of medications is dispensed for each patient by pharmacy

UDDD (Unit dose drug distribution) - medication distribution system used in 90% of hospitals in the USA where a 24 hour supply of medications is dispensed for each patient by pharmacy

WS (Ward stock system) - medication distribution system used at the study hospital where bulk supplies of medication are stored in a ward cupboard and transferred to drug trolleys by nursing staff prior to administration to the patient. Also known as imprest or traditional system

ABSTRACT

The prevalence of medication errors in a major teaching hospital was investigated using several methodologies. The existing ward stock drug distribution system was assessed and a new system designed based on a novel use of failure mode and effects analysis. The existing system was compared to the new unit supply individual patient dispensing system on two wards in terms of medication errors, nursing time, pharmacy time, drug costs, drug security and nurses' opinion. A review of a one year sample of reports submitted under the existing incident reporting scheme was also undertaken. Errors were categorised according to drug group, error type, reason cited for the error, and probability ranking (probability of occurrence, detection and harm). In addition, a "no-blame" medication error reporting scheme was implemented and assessed.

Results of the study showed that in the newly designed individual patient dispensing system there was a reduction in nursing time associated with medication activities of approximately 29%, an increase in pharmacy staff time of 64%, a reduction in drug costs and an increase in drug security. Using the disguised observer methodology a reduction in medication errors by 23.5% (including timing errors) and 7.3% (excluding timing errors) was seen on Ward A. Similarly a reduction of 21.1% (including timing errors) and 9.8% (excluding timing errors) was observed on Ward B. Significant support for the individual patient dispensing system was given by nursing staff. Of the errors self-reported under the existing incident/accident reporting scheme the most common type of error was omissions (32.2%), the most common drug group was cardiovascular drugs (19.8%), and the most common cause of the error cited was a faulty check (42.3%). The probability ranking showed that 75% of errors reported scored between 12 and 17 points (from a possible 30 points). In the no-blame error reporting system, an error rate of 2.1% was detected in the existing system and 1.7% in the failure mode analysis designed phase.

1. INTRODUCTION

1.1 Purpose of the study and study aims.

The occurrence of medication administration errors has been documented in the literature for over thirty years. Barker and McConnell discussed the problems of detecting medication errors in hospitals in 1962 and described a disguised-observer method that had not been used previously.[1] Based on this landmark study and others that followed, a method of drug distribution and administration, unit dose drug distribution (UDDD), was developed in the United States of America.[2,3,] With UDDD, a 24 hour supply of drugs was dispensed for each patient on a daily basis. UDDD was shown to reduce the prevalence of medication administration errors and is the system now used in over 90% of hospitals in the USA.[4,5]

In contrast to the USA, hospitals in Australia have not embraced UDDD on a large scale due to the differences in charging methods and remuneration.[4] Most Australian hospitals use an imprest or ward stock (WS) system where bulk supplies are kept on each ward for administration to all patients. Few studies reporting the medication error rate in Australian hospitals have been published. While the medication error rate is known to be reduced in a UDDD compared to a WS system, there is an increase in pharmacy time taken to perform medication distribution related activities. In addition drug security has been shown to be increased along with a decrease in nursing time taken to undertake medication administration related activities and a decrease in overall drug costs.

Medication administration errors have historically been blamed on the individual staff member. This human error focus has been shifted in a variety of other fields to a systems approach, where any error is seen as a systems failure. Failure mode and effects analysis (FMEA) is a method used to assess a system and predict where an error may occur. The use of FMEA has been recently trialed in medical practice. Medication errors can be examined to highlight flaws in the drug distribution and administration system with an aim to improving the system.

The majority of hospitals in Australia use a self-reporting method for staff to report any medication error related incidents. While this method is cheap and easy to administer, the actual error rate is probably seriously underestimated since the majority of errors made are unknown and staff must feel compelled to report an error they know they have committed. Fear of retribution has been reported as a leading reason for staff not reporting errors they know have been made.[6] A non-punitive method of reporting of all known errors has been used in other industries, in conjunction with FMEA, to improve systems.[7]

In 1961 a total of 656 drugs were available for therapeutic use in the United States.[8] In 1995 there were more than 9000 registered drug products, 800,000 registered prescribers, 1.5 million hospital beds and a further 1.5 million long-term-care and nursing home beds. Billions of doses are administered in the United States on an annual basis. [9] In Australia, there were 10690 registered drug products at the end of September 1997, with 4620 of these being prescription only Schedule 4 or Schedule 8 items.[10] The increasing number and complexity of drugs available in the 1990's has

the potential to make medication administration errors an increasingly hazardous phenomenon.

This study was undertaken with the aim of researching the existing Australian traditional drug distribution and administration system at a teaching hospital and comparing it to a patient specific dispensing system. Systems analysis, using FMEA, was applied to the existing system to identify potential errors. A further aim was to study medication administration errors by three methods; direct observation, self-reporting and no-blame self-reporting.

The study is divided into three parts. The specific aims of this study are;

Part One

To compare the existing ward stock (WS) system of medication distribution and administration at Sir Charles Gairdner Hospital (SCGH) with a decentralised unit supply individual patient dispensing (USIPD) system. Comparisons of drug costs, medication error rates and personnel resources (i.e. nursing and pharmacy) in the two systems are made.

Part Two

To analyse the medication errors submitted over a one year period by SCGH hospital staff via a "self-reporting" scheme. Errors are classified according to error type, drug group and cause of the error and given a probability ranking based on the probability of the error occurring, being detected and causing harm.

Part Three

To use FMEA to develop a model to assess potential areas of failure in the WS system with respect to medication errors. The model is then evaluated by assessing the influence of a group of interventions, devised to overcome the areas of failure identified, on the medication error rate.

1.2 Background

1.2.1 Drug Distribution in Hospitals

Drug distribution in hospitals has been defined as a system by which medications are transferred from outside the hospital to the patient.[4] The goal of this process is to ensure that the correct drug is administered in the correct dose to the correct patient at the correct time. This procedure involves many steps and includes a variety of staff to undertake the steps. The safe and appropriate use of drugs is, therefore, an outcome of the quality of the drug distribution and administration system in the hospital. There are a number of methods of drug distribution that exist in various health care facilities around the world.

Research has been done to compare the quality of several methods of drug distribution. The criteria generally used to compare and contrast the systems are;[4]

a). drug costs - including drug acquisition costs, wastage and recycling of drugs, packaging, pilferage, patient consumption and inventory

b). medication error incidence - including omission, extra dose, unauthorised drug, wrong dose, wrong formulation, wrong route, documentation, timing and transcription errors

c). nursing time - involved in administration related activities, enabling the calculation of staffing level and staffing costs

d). pharmacy time - involved in distribution related activities, enabling the calculation of staffing levels and staffing costs, and range of pharmacy services offered.

Drug distribution in hospitals can be achieved by one of six main systems.[4] These are ward stock (or imprest), individual prescription, unit dose, modified unit dose, unit of use and controlled dosage.

1.2.1.1 Ward stock drug distribution

Ward stock, floor stock, traditional or imprest systems are all terms used to describe a method whereby routinely used drugs are issued by the pharmacy department and stored in bulk packs in an imprest cupboard on the ward. The locked imprest cupboard is usually situated at the nurses' station. In two common variations of the ward stock system, a single compartment drug trolley or the patient's bedside drawer are used for the storage of medications in current use. Nurses are required to transfer the stock from the cupboard to either the trolley or the drawer for later administration to the patient. The quantity of stock in the imprest cupboard is kept at a predetermined level and is generally restocked on a regular basis by a pharmacy technician. Standard imprest packs are supplied to replace the drugs that have been removed from the cupboard.

Benrimoj et al [4] discussed the advantages and disadvantages of the ward stock system. Advantages of the ward stock system centre on the ready availability of medications at ward level. Disadvantages have been reported to be the high incidence of medication errors (up to 20.7%),[1,2,11] costs due to wastage and pilferage (25-50%), [12] a large amount of nursing time devoted to medication related activities, [13,14] and less opportunities for the implementation of clinical pharmacy services.[15]

The frequency of drug errors in ward stock distribution systems has been reported to be as high as 20.7% of opportunities for error. [1,2,11] Research into the error rate in ward stock systems in United States hospitals was carried out in the 1960's and 1970's when the majority of institutions used this method. Barker and McConnell [1] first studied the medication error rate in 1962, with results showing that the average nurse in the hospital made approximately 18% of opportunities for error observed, or one error for every six medications given. They concluded then that the incidence of medication errors was much higher than previously suggested.

Australian based research into the medication error rate has not been extensive. Miller [16], in 1977, reported research into the medication errors and found a rate between 28% and 34%. This research, however, included errors from both pharmacy and the physicians' prescriptions, making comparisons difficult. Goodman and Woodbridge [17] reported, in 1979, an error rate of 13% in the ward stock system compared to 3.2% in a unit of use distribution system. Rippe and Hurley [18] have reported in 1988 a study where 312 opportunities for error were observed. This small study detected an error rate of 17%, or 8.9% if timing errors were excluded. The study hospital, however, used a mobile drug trolley which contained an individual drawer for each patient. Stewart et al [19] studied 2017 opportunities for error over a six day period. In this study the error rate in the traditional ward stock system was found to be 18.3%, 14.6% excluding timing errors. This study consisted of a significant number of observations of opportunity for error but did not go on to compare a second method of drug distribution. In 1996 Camac et al [20] studied 370 opportunities for error over five shifts. An error rate of 12.7% was discovered using

the disguised-observer technique. Only a relatively small number of observations were made. In addition all observations were made by nurses which could be considered a further study limitation.

A study by Dean et al [21] reported in 1995 discussed the error rate in a United Kingdom hospital using a ward stock system and compared it to a United States hospital using a unit dose system. The error rate was found to be 3.0% in the ward stock system (2756 opportunities for error observed) compared to 6.9% in the unit dose system (919 opportunities for error observed). Differences in error rate were thought by the authors to be due to errors associated with the US system of transcription of physicians' orders. Errors in the US system may have also been due to the automated dispensing device (Medstation, Pyxis, San Diego, CA) that dispensed a number of floor stock items. The low error rate found in the UK hospital may be due to a number of factors. Data collection in the UK hospital did not include drugs administered outside the usual medication rounds. A modification of Barker and McConnell's technique was used in the UK but not the US hospital. Data was collected retrospectively in the US system and concurrently in the UK system. In the UK hospital the observer intervened before erroneous doses were actually administered. These factors may have affected the error rate.

Drug costs have been reported to be higher in ward stock systems compared to unit dose drug distribution. There are a number of reasons proposed for this including wastage, pilferage and floor stock costs.[3,12,22,23] A high level of drug wastage has been noted with the ward stock system.[22] Studies indicate that medication wastage may be 13-15% of the total patient medication cost, or up to 25-50% if pilferage is

also counted.[12,22] A further cost in the ward stock system is the provision of large quantities of floor stock to each ward area. These drugs require periodic checking to ensure they have not exceeded the expiry date, enable unauthorised use of the drugs and represent a significant cost hospital-wide. [24,25]

Nurses spend approximately 27 to 42% of their time on medication related activities in a ward stock system of drug distribution. This has been shown to decrease by 25 to 50% in a unit dose drug distribution system.[23] It is generally accepted that the time taken by nursing staff can also be reduced with other methods of drug distribution.[4] Australian research by Stewart [19] et al reported that nursing staff on a ward spent a mean time of 10 hours and 34 minutes each day for 30 beds on activities concerned with medications. Of this, 8 hours and 42 minutes was associated directly with drug administration, the remainder consisting of other medication related activities. Again, this study did not go on to assess any change possible by the introduction of an alternative distribution system.

1.2.1.2 Individual prescription

The individual prescription system is often used in private hospitals in Australia since drugs are dispensed within the National Health Pharmaceutical Benefits Scheme (PBS). The PBS has a set list of drugs in a defined maximum quantity that may be prescribed and dispensed and that are partly funded or subsidised by the Australian Commonwealth Government. As such the patient has the quantity of tablets/capsules dispensed and labelled by the pharmacy and is charged accordingly. Any of this supply left when the patient is discharged from hospital is given to the patient. Drugs

are stored in a general cupboard, trolley or in a patient specific area (for example the bedside drawer) and are used only for the specific patient.

Advantages of this system are control of pharmacy revenue, control over drug inventory and closer liaison with the healthcare team.[4] Disadvantages are the high incidence of medication error (8-20%),[26] time and labour intensive nature of dispensing and delays in obtaining medications.[4] In the study by Hynniman et al,[26] medication omissions were found to be the most common error.

1.2.1.3 Unit dose drug distribution

Unit dose drug distribution is a pharmacy coordinated method of dispensing and controlling medications in organised health-care settings[27]. It is the system used in approximately 90% of hospitals in the United States.[4,5] Drugs are dispensed in single unit packages, in a form as ready-to-administer as possible. Pharmacy staff dispense a 24-hour supply of medication for each patient. This is then delivered to the ward and is ready to be administered to the patient by the nursing staff when required. Drugs are stored in a patient specific area, usually in individual drawers in a drug trolley. This system provides a "double check" between pharmacy staff dispensing the medication and nursing staff administering it to the patient.

In 1977, unit-dose was the system of drug distribution recommended by the American Joint Commission of Accreditation of Hospitals.[28] Numerous studies have been published over the past several decades which indicate that unit dose drug distribution systems are safer for the patient and more efficient and economical for

the institution. In view of these documented benefits, the American Society of Health System Pharmacists considers the unit dose system to be an essential part of drug distribution and control in organised health-care settings in which drug therapy is an integral component of health-care delivery.[27]

The nature of the system necessitates a significant input from pharmacists at the dispensing level. Individual doses for each patient must be dispensed and checked by a pharmacist prior to delivery to the patient care area. While this is pharmacy labour intensive it also increases the potential for pharmacist involvement at the clinical level and reduces the amount of time spent by nursing staff in medication administration related activities.

Advantages of unit dose distribution over the ward stock system include a reduction in the frequency of medication errors (0.5-4%),[1-3,6,11] a reduction in drug costs since inventories at the ward level are smaller and drug waste is minimised (savings of 15-20% in cost per patient day),[29-31] increased drug control (because drug security is increased),[3,30] and more efficient use of nursing and pharmacy personnel.[3,31]

Disadvantages of unit dose include increased packaging time, need for additional pharmacy support staff and costs associated with packaging.[4]

It has been stated that the greatest benefit for the patient with a unit dose system is the reduction in error rate. Error incidence has been shown to be significantly reduced compared to the ward stock method of drug distribution.[1-3, 6,11]

Reasons for the reduction in error rate have been suggested to include increased pharmacist involvement in the drug use process and also because single unit packages maintain the identity of each drug until it is ready to be administered.[28]

1.2.1.4 Modified unit dose drug distribution

Modified unit dose or unit-supply individual patient dispensing is an adaptation of the unit dose method. Adaptations may include provision of only oral solid doses in unit dose form, supply of a small amount of floor stock, supply of more than 24 hours of doses to the ward area (often 3-7 days supply) or less than 90% of the hospital beds receive a unit dose service.[32-34] Cost savings associated with modified unit dose are primarily due to minimised drug wastage and reduced drug inventory.[22,32] This system is less labour intensive for pharmacy staff than unit dose but does not encompass the full benefits of unit dose.[4] Modified unit dose provides a number of the advantages of unit dose including a reduction in medication error rate, reduced drug inventory and wastage and increased ability to distribute "prn" drugs.[4]

Lepinski et al [24] investigated the medication error rate in a study where patient medication drawers were checked after each major drug administration round and discrepancies in drug quantity or documentation were noted. These discrepancies were considered drug errors and a rate of 1% (18 out of 1847 observations) was found, primarily as omissions or documentation errors. Limitations of this study include the retrospective nature of the data collection compared with the disguised-observer technique. In 1994, Thornton and Koller [35] reported an error rate of 8.3%

or 7.4% when excluding timing errors in a 7-day issue individualised patient dispensing system, using the disguised observer technique. Only 242 opportunities for error were observed, however this limited study was the first to document error rates in a modified unit dose distribution system in Australia.

No systematic study of errors has been previously reported on this system of drug distribution.

1.2.1.5 Unit of use drug distribution

Unit of use distribution systems package drugs in a sufficient quantity to provide a course of treatment. Since the system tailors the dispensing of drugs to the prescribed course, wastage of medications is reduced. Advantages of unit of use systems have been suggested to include a lower medication error rate (3-4%),[17] minimisation of drug wastage and greater control of drugs. Disadvantages, however, include wastage if the courses are not completed and medications cannot be recycled and benefits are restricted to medications that are commonly prescribed as a course for example antibiotics.

Various authors have investigated the potential financial advantages of unit-of-use systems in Australian hospitals.[15,17,36,37] Savings were attributed to reduction in wastage, decreased floor stock holdings, reduction in drug deterioration and also pilferage.

In addition Greenhill and Plumridge reported that clinical pharmacy services were enhanced, nursing workload was reduced, medication errors were reduced and patients could self-medicate under supervision, thereby enhancing education programs.[15] This study was undertaken over a 25 day period on one ward to compare an existing ward stock system to a unit of use system where drugs were stored in the patient's bedside drawer. The relatively short time frame and limited number of patients and staff involved in this study, however, make extrapolation to the remainder of the hospital or other hospitals difficult. Naismith [36] has reported similar results and discussed the enhanced role of the pharmacist in a unit of use system.

1.2.1.6 Controlled dosage drug distribution

Controlled dosage systems are used in many aged care facilities and consist of the provision of individual blister packs containing medications for a set period of time. The sheet containing the blister pack is annotated with details of the patients' name, drug name and strength and directions for use. This system is particularly useful in institutions where the carer, who may not be a registered nurse, assists in the administration of medications.

Reported advantages of the controlled dosage system include reduced medication error rates, convenience in long-stay facilities and reduction in floor stock levels. Disadvantages include increased packaging time and that the system is only suitable for solid dose medications. [4] The stability of drugs in this packaging system is also usually unknown.

Rivers and Poston[38] and Prior[39] have reported large reductions in floor stock and more efficient stock control. Costs involved in the equipment and blister packaging required, along with the increased pharmacy time needed should also be considered. This point was investigated by Prior[39] who found repackaging into blister packs took three times longer than into standard bottles. Time to administer drugs was, however, found to be reduced using the blister pack system. An additional finding was an incidence in medication error of 2-3% however error rates in the initial system were not reported.

The optimum drug distribution system for a specific hospital will depend on a number of factors, including the number of nursing and pharmacy staff available, the types of patients present in the hospital, funding, patient payments, perceived or real error rate and the philosophy of the hospital management[4,21,40]

Australian public hospitals primarily use one of the variations of the ward stock system of drug distribution.[4] This system has been used over time since there has not been the economic impetus to document each dose given to a patient for charging purposes as seen in the United States of America. While the economic considerations of the WS system have led to ongoing use in Australia, the literature has reported that an overall benefit can be gained by using patient specific individually dispensed medications in terms of a reduction in medication errors, ongoing drug costs and staff time. This can be viewed as potentially saving money in the long term.

1.2.2 Errors in Medical Practice

Evidence from a number of sources over several decades indicates that a substantial number of patients suffer iatrogenic injuries while in hospital.[41-45] In 1964 Schimmel[41] reported that 20% of patients admitted to the study hospital suffered an iatrogenic injury and that 20% of those injuries were serious or fatal. In 1981 Steel et al[42] reported comparable results finding 36% of patients admitted suffered an iatrogenic event with 25% of those serious or life threatening. Bedell [43] reported, in 1991, that 64% of cardiac arrests at a teaching hospital were preventable, with drugs the leading cause. In New York State in 1984, almost 4% of patients hospitalised suffered an injury due to medical treatment, with the leading cause being drug therapy (19.4% of the injuries). [40] The Harvard Medical Practice Study (HMPS) in 1984, which involved the review of 30 000 randomly selected medical records, found that adverse events occurred in 3.7% of hospitalisations.[44] An adverse event in that study was defined as an injury caused by medical management and which prolonged the period of hospitalisation or produced a disability at the time of discharge, or both. Medical negligence was cited as the cause of 27.6% of these adverse events and 69% by human error. Approximately 19% of these adverse events were drug related. When the causes of the iatrogenic injuries are studied, it is found that most are due to errors and therefore are potentially preventable.[43,46]

Leape[7] notes that given the complex nature of medical practice and the multitude of interventions that each patient receives, a high error rate is perhaps not surprising. A study undertaken in an intensive care unit revealed that patients received, on average,

178 "activities" per day. The error rate was found to be 1.7 errors per patient per day (29% had the potential to cause serious or fatal injury), indicating that staff were functioning at a 99% level of proficiency.

Aside from studies of medication errors, the literature on medical errors is sparse.[7] This is possibly due to the perception by hospital staff that errors rarely occur and that any error that does occur is an isolated and unusual event. Accident prevention has not been a primary focus of the practice of hospital medicine.[7]

Unintended injuries associated with medical therapy have been estimated to affect 1.3 million people each year in the United States. Using a "cost of illness" probability pathway model, Johnson and Bootman[47] estimated that drug-related morbidity and mortality in the ambulatory care setting cost the United States $76.6 billion annually. Of this cost, the largest component is due to hospital admissions. An Australian study found that 16.6% of hospital admissions studied were associated with an adverse event that was caused by faulty health care management.[51] Of those events, 49% occurred before and were responsible for all or part of the hospitalisation, and the remainder occurred during the hospitalisation. Approximately 9.9% of the adverse events were classified as drug related. Leape et al[48] found that 77% of medication errors occurred at the ordering and administration stages of the drug-use process. It is likely that many medication errors go undetected. Symptoms or signs in a patient, or the failure of a patient to respond, may in fact be due to an omission, an extra dose, a wrong drug, or a wrong dose.[3,49]

Medication administration errors in hospitals can be a significant source of morbidity and mortality in the hospitalised patient.[48] Medication errors occur when there is a deficiency in either knowledge or performance.[50] Inadequate knowledge can relate to a lack of technical knowledge or ignorance that a specific procedure or protocol exists. A variety of factors can cause poor performance such as stress, interruptions, carelessness, hurried work, inefficiency, inadequate work conditions or intentional avoidance of proper procedures.[50] The outcomes of medication administration errors range in severity from no effect on the patient to death. The 1994 Quality in Australian Health Care Study (QAHCS) reviewed over 14 000 admissions to 28 Australian hospitals and reported that 16.6% of these admissions were associated with an adverse event, with 10.8% drug related.[51]

1.2.2.1 Costs of errors

The financial cost of errors to a hospital are difficult to quantify. Two recent studies have sought to calculate the cost of medication-related problems or adverse drug events in hospitalised patients.[52,53] In the 1997 study by Bates et al,[53] 190 adverse drug events of which 60 were preventable were reported. Adverse drug event (ADE) was defined as an injury resulting from medical intervention related to a drug including medication errors. Results showed the additional length of stay associated with an ADE was 2.2 days and the increase in cost associated with an ADE was $3244. Based on these costs and data about the incidence of ADEs, the authors estimated annual costs attributable to all ADEs for a 700 bed teaching hospital are $5.6 million.

Classen et al[54] have also presented data on the excess length of stay, extra costs and attributable mortality associated with adverse drug events (ADE) in hospitalised patients. In this study ADEs complicated 2.43 per 100 admissions. The occurrence of an ADE was associated with an increased length of stay of 1.91 days and an increased cost of $2262. There was also found to be an almost 2 fold increased risk of death.

Similarly, a study published in 1995 by Schneider et al [52] reports the cost to an institution of medication related problems (MRP). This included costs involved in the consequences of adverse drug reactions and medication errors, with 1911 MRPs reported. The total cost for these, ranging from additional laboratory tests to intensive care treatment, was estimated to be $1.5 million for the year at The Ohio State University Medical Centre. While each of these studies include adverse drug events and not just medication errors, the scope of the cost implications is evident.

An additional cost of medication errors can include malpractice suits. According to Barker et al [11] most claims related to medication errors are settled out of court since they are so hard for the hospital to defend. Schneider reports the cost impact of medication-related errors in the United States could be more than $1 million a year within a single institution and many billions of dollars nationwide.[55]

1.2.3 Methods used to detect and report medication errors

Medication errors should be identified and documented in order to recognise recurring causes and therefore develop systems to minimise them. The difficulty, however, in detecting medication errors has been recognised for many years.[1]

A medication error is generally defined as a deviation from the physician's medication order as written on the patient's chart.[6] It is accepted that most medication errors are probably undetected,[56] and that of those that are detected only 5% are reported.[57,58] The remainder are not reported for a variety of reasons including lack of awareness that an error has been made, lack of familiarity with reporting mechanisms, difficulty/time constraints in completing report forms, fear of possible legal ramifications for both the individual and the organisation, and lack of feedback to staff causing a reduction in motivation to continue submitting reports.[6,59]

Barker et al [60] reported the error rate in ward stock drug distribution systems to be about one per patient per day, based on data from a number of studies and excluding wrong-time errors. However, error rates as low as two to three per patient per week have been achieved by installing unit dose distribution systems. The reasons why most errors go undetected have been studied by Barker and McConnell.[1] Nurses were found to be unaware of the majority of errors they were associated with. They were also found to be unwilling to report omissions or wrong time errors they were aware of unless a drug they deemed to be therapeutically potent was involved.

Direct comparison of error rates between studies becomes difficult when a variety of error definitions and data collection methods have been used. Allan and Barker [6] have discussed the fundamentals of medication error research and categorised errors into 14 groups. These are omission error, commission error, wrong-dose error, unordered drug error, wrong dosage form error, wrong time error, wrong route error, deteriorated drug error, wrong rate of administration error, wrong administration

technique error, wrong dose preparation error, extra dose error, discrepancy and other error.

The term "opportunity for error" was coined for use as the basic unit of data in medication error studies.[1] An opportunity for error includes any dose given plus doses ordered to be given but omitted. Doses given can only be correct or incorrect to prevent the error rate from exceeding 100%.[6] The medication error rate is then calculated as the number of medication errors divided by the total opportunities for error, and converted to a percentage.

Ongoing monitoring programs for the detection and management of medication errors within a hospital are needed. [56] According to the American Society of Health System Pharmacists guidelines on preventing medication errors in hospitals, medication errors should be identified and documented and their causes studied in order to develop systems that minimise recurrence. Monitoring programs, they state, should consider the following risk factors:[45,61-63]

a) shift work, with higher error rates typically occurring during the day shift

b) inexperienced and inadequately trained staff

c) medical speciality (eg; paediatric, geriatric, critical care)

d) increased quantity of medications per patient

e) environmental factors (interruptions, noise, light, heat)

f) staff workload and fatigue

g) poor communication among health care professionals

h) dosage form (injectable drugs associated with more serious errors)

i) type of drug distribution system

j) improper drug storage

k) number of dosage or dilution calculations required

l) confusing drug product nomenclature, packaging or labelling

m) drug category

n) poor handwriting

o) verbal orders

p) lack of effective policies, procedures and protocols

q) poorly functioning management committees

A first step toward improving the quality of a drug distribution system and reducing drug-related errors is to employ an effective mechanism for systematic collection and feedback on errors. A number of different methods for detecting medication administration errors have been used. Four most commonly used techniques are anonymous self-reports (questionnaires), incident reports, critical-incident reports and direct observation.

a) Anonymous self-reports have the advantage of being cheap and easy to administer. In this system the person committing the error can report the error without being linked to it.[1] Fear of disciplinary action does not exist since reports are anonymous. Limitations of this system are that a report cannot be made if the nurse is unaware that an error has occurred. Even if the nurse is aware, a report may not result if the physician advises against reporting the error, the nurse believes the error was harmless or if the errors were omissions or wrong-time errors.[1] In the study by

Barker and McConnell,[1] only six anonymous self-reported errors were submitted over a seven month period in the hospital studied.

b) The term "incident report" refers to an official report of a medication error as documented by hospital staff. Reported advantages of the incident report include the provision an ongoing reporting mechanism for the hospital and low cost compared to direct observation techniques.[6] Cost savings, however, have been disputed.[6] Time taken by staff to review the error and complete associated paper work can be significant. Disadvantages of the incident system, as with the anonymous self-reporting method, include the fact that the error cannot be reported if the nurse is unaware that an error has occurred. As a result there is a risk of significant underreporting of errors which may lead to complacency. Barker and McConnell [1] studied the use of incident reports over a one year period and found that thirty six errors were reported. Extrapolating the figures they obtained using direct observation in the same hospital, they calculated that 51,200 errors may have occurred during this one year period.

Fear of disciplinary action deters nurses from reporting errors they have made.[59,64,65] Action that may be taken by the institution has included education and counselling, suspension or termination of employment or legal proceedings[7,48,56,62,65,66] . Cohen [64] and others have proposed that no disciplinary action be taken against staff who report errors.[59,65,67,68] A no-blame or non-punitive method of allowing staff to record and report their medication administration errors has been suggested as one approach to focus on hospital systems and aid continuous quality improvement rather than

concentrate on individuals.[59] Pepper[69] states that punitive responses to drug errors foster fear and deception and have no place in current practice.

Most nurses interviewed in a United Kingdom hospital tended to blame themselves for medication errors and stated that they were reluctant to report such errors.[67] Almost all of the 17 nurses interviewed for the study considered that not all errors were reported by nurses for fear of disciplinary action. An anonymous error reporting system for nurses was suggested as a means of reporting errors without this fear.

In an 18 month study undertaken by Classen et al, [57] adverse drug events for all 36 653 hospitalised patients were monitored. During the study period, 731 adverse drug events were detected by computer using an integrated hospital information system to allow for multiple source detection. Of these, 701 were classified as moderate or severe and 664 were classified as dose-dependant or predictable. During the study period physicians, pharmacists and nurses voluntarily reported 92 of the 731 adverse drug events detected using this automated system. The authors stated that nurses detected and reported the majority of these adverse drug events.

c) Critical incident reports have been used in an attempt to uncover the cause of errors that have occurred.[6] In this system indepth analysis of a number of individual errors is undertaken to identify common causal factors. Both direct observation and interviewing of staff who have committed an error can be used. Subjective information gained from the subjects involved in the incident can give a useful insight into the processes associated with the error occurring. This has been reported as an

advantage of the critical-incident system. Disadvantages include problems with data-interpretation, solution development and multiple sources of bias.[6]

d) Direct observation or the disguised observer technique is known to be the most accurate and all encompassing of the methods used to detect medication errors.[6] Allan and Barker [6] have stated that administration-based error rates, as detected by observation, are an outcome measure of the quality of a drug distribution system. They have also noted that the medication distribution and administration system in hospitals is probably the most important area to concentrate on in an effort to reduce the prevalence of medication errors.[6] The disguised-observer technique was first described by Barker and McConnell[1] in 1962 and involved the use of a trained observer following and recording all doses administered to a patient by the subject nurse. The observer records these doses given without viewing the medication chart, thus eliminating the ethical conflict of knowing that an error has been committed, without intervening for the patient's sake. Observations are then checked against the medication chart at a later date, and discrepancies noted. The subject is not made aware that the observer is aiming to detect medication administration errors and is often informed that the study is being undertaken to time nurses administering medications or study the drug distribution system.[1] Advantages stated by Barker [70] are effectiveness and objectivity. Observation is free from dependence on the subject's knowledge of the information that is wanted and is also free from the dependence on the subject's willingness to report. By comparison, the use of questionnaires and interviews is limited by the fact that the investigator must deal

with emotional subjects, potentially damaging reponses and the subject's fear of meeting standards.[70] Potential disadvantages of disguised observation include observer fatigue, influence of the observer, observer inference and cost. Direct observation is recognised as being a physically and mentally demanding activity.[70] The influence of the observer must be considered and the study designed to reduce that effect. When subjects are observed doing activities that are familiar to them and when the observer is unobtrusive and non-judgmental, the subjects return to their usual pattern of activity after one to three hours of observation.[70] Observer inference may be a potential problem when the observer incorrectly processes what is seen. Careful training and proper category definitions can minimise this problem.[70] Cost is also an issue with the use of a trained professional necessary to detect subtleties in medication nomenclature, formulation and strength. As such direct observation using the disguised-observer technique is the method of choice for the study of a medication distribution system to determine the medication administration error rate and for the periodic assessment of the error rate within a hospital. It would be prohibitively expensive, time consuming and disruptive to use this method for the routine review of all errors that occur on an ongoing basis within an institution.

An alternative would be to use another method on an ongoing basis with regular checks, for example each year, using the disguised-observer technique to assess whether the baseline error rate has altered. Continued review as to whether there is a correlation between the error rate observed and that being reported by the ongoing method would be required. An obvious limitation to this proposal is that regular use of the disguised-observer technique followed by release of the error rate would lead

to staff being aware of what was actually being evaluated. The use of a direct-observer rather than a disguised-observer technique, where staff are aware of the nature of the study, would then be required. The use of technology, such as video, may be another approach.

1.2.4 Clinical significance of medication errors

The consequences of most medication errors are probably minor, but in a proportion of cases the error may be clinically significant and could lead to permanent disability or death of the patient.[71] There are numerous reports in the literature of the tragic results of medication administration errors. Administration of vincristine by the intrathecal rather than intravenous route, administration of pancuronium to a non-intubated patient, administration of potassium chloride as a bolus dose and administration of 1g of lignocaine instead of 100mg during cardiac arrest are all examples of errors that have occurred, with lethal consequences.[6,69,72]

The clinical significance of medication errors is often reported as a separate issue to the rate of medication errors. While most studies analysing a drug distribution system report the rate and the type of error within the system, the effect on the patient is not included.[19,21,35,73,74] Reports of the clinical sequelae of medication errors generally appear in the literature as either a single case report or a series of patients. Journals such as Hospital Pharmacy and the Australian Journal of Hospital Pharmacy include a regular column detailing medication errors that have occurred and their outcome. Publication of this information serves to alert practitioners to errors that have occurred in other institutions, with the aim of preventing similar problems.

In 1991 Hartwig et al [63] reported a severity-indexed, incident report based medication error reporting program. In this system, medication errors were reported through traditional incident reports, with additional information collected including the type of error and class of drug. A severity ranking that reflected the patient outcome was

assigned to each error, with level zero indicating no error occurred and level 6 indicating death of the patient.

Level 0 - no medication error occurred (potential errors may be classified here)

Level 1 - an error occurred that did not result in patient harm

Level 2 - an error occurred that resulted in the need for increased patient monitoring but no change in vital signs and no patient harm

Level 3 - an error occurred that resulted in the need for increased patient monitoring with a change in vital signs but no ultimate harm to the patient, or any error that resulted in the need for increased laboratory monitoring

Level 4 - an error occurred that resulted in the need for treatment with another drug or an increased length of stay or that affected the patient participation in an investigational drug study

Level 5 - an error occurred that resulted in permanent patient harm

Level 6 - an error occurred that resulted in patient death

Results showed that over a one year period 1281 errors were reported with the majority (76.4%) being level one, described as an error which resulted in no harm to the patient. No error in the study was given a ranking over level 4. Of the errors reported, 36.9% were omissions and 28.3% involved the administration of unauthorised drugs. The majority (44.7%) occurred at the administration stage, and the most common drug group involved was intravenous anti-infective agents (13.5%). This study used voluntary rather than observation based reporting

techniques. The authors state the quality rather than the quantity of the reports submitted voluntarily led them to question the need for an observation based system. The American Society of Health System Pharmacists have included the severity levels in their guidelines on preventing medication errors in hospitals.[56]

In 1988, Rippe and Hurley [18] reported the observation of twelve medication administration rounds in a community hospital. During 312 opportunities for error, 52 errors were detected (17%). Ranking of the errors determined that 15.4% were of low significance, 65.4% were potentially significant and 19.2% were significant. While this study is relatively small, it is one of the few that reports clinical significance in an Australian hospital.

Bates et al [53] detected 247 adverse drug events of which 70 (28%) were deemed to have been preventable. Adverse drug event was defined as an injury resulting from medical intervention and included side effects and prescribing errors as well as administration errors. Of all 247 events, 57% were judged significant, 30% serious, 12% life-threatening and 1% fatal. Analgesics (30%) and antibiotics (30%) accounted for the majority of non-preventable events followed by antineoplastic agents (8%) and sedatives (7%). The largest percentage of preventable events were caused by analgesics (29%), sedatives (10%) and antibiotics (9%).

1.2.5 Failure mode and effects analysis

Failure mode and effects analysis (FMEA) is a process of quality improvement that concentrates on the overall system in an environment rather than assigning all mistakes to human error.[48,72,75-77] It refers to a qualitative evaluation of the

interrelationship of various components of an organisation.[48] FMEA breaks a given process, such as a drug distribution and administration system, into small steps and then studies each of these steps to predict problem areas that might cause errors. FMEA identifies errors that will happen, if the system is used often enough, before they happen and determines if the consequences of those mistakes would be tolerable or intolerable.[72] Then, if the consequences are intolerable, actions are taken to eliminate the possibility of the error, trap the error before it can reach people, or minimise the consequences of the error if it cannot be eliminated. FMEA assumes that no matter how careful humans are, there are always some situations in which errors are possible or even probable.[78] Methods of quality assurance used in other industries, such as sacrificing a percentage of a product batch for testing, cannot be done in a drug administration process involving humans. The objective of FMEA is to use the expertise of people in the field to evaluate a system and anticipate possible ways it can fail. Once the basic failure modes and mechanisms have been established, the relative importance of each to the overall system is rated. Modifications of a system can then be based on these ratings. This method is used in a variety of industries, including the aviation industry, the aerospace industry, the chemical industry, the nuclear industry, and the automobile-manufacturing industry, in which the financial and human costs would be too great to allow the usual prospective quality assurance testing.[50,72,79,80] In the automobile industry, FMEA has also been used as a strategic business tool, shortening product development cycles, addressing environmental and regulatory factors, predicting product performance demands and responding to the need for innovation in the marketplace.[79]

The concept of system failures as the underlying cause of medication errors has not been widely accepted in medicine.[48] Systems have been a focus of pharmacy attention for some time, however.[49] Kelly [81] has reported the classes of system-failure errors that have resulted in serious injury or death. These include the use of oral orders, poor allergy information, inferior medication distribution systems, lack of double checks, confusing product labelling and underreporting of medication errors that do occur.

Organisational, technical and equipment-interface problems interact with the human error aspect in a manner which is not only unpredictable but often causal. Equipment or system failures and human error are rarely the sole cause of errors with up to 90% having a mixture of both.[48,71,82] These can be termed latent errors since they are faults in design, maintenance, training and management that induce people to make mistakes. While an operator error may be the proximal cause of the accident, the primary causes have often been present in the system for some time.[83] In this case the operator is "set-up" to fail. System factors may be related to poor or non-existent warning mechanisms, the type of drug and route of administration, the physical appearance and availability of the drug product, look-alike labelling, poorly conceived drug nomenclature, inappropriate pharmaceutical packaging, faulty design of devices, lack of protocols, and substandard documentation.[48,50,72,78] Examples of components of a good systems design are redundant checkpoints in a unit-dose system, fail-safe equipment, enhanced efforts to overcome confirmation bias, and the use of well placed warnings.[78] Human factors may involve a health professional's

knowledge, experience, education, interruptions, distractions and fatigue.[56,76] Cohen states[78] that human error, since it is inevitable, must be anticipated.

Human error may lead to a medication error, therefore developing a safe system of medication distribution and administration can help filter errors, preventing them from actually reaching the patient.[50] Human error plays a role in 70-80% of incidents and accidents arising in complex systems, including systems involved in the provision of health care.

Human factors engineering (ergonomics) is an applied science that evaluates human performance in interaction with technology and the environment.[84] Human error is seen as the result of mismatches between what users are expected to do and what they are able to do. The result of human factors analysis of a system is a detailed description of what people within a system are required to do in relation to the system, their purpose, goals and functions. The analysis of the tasks performed by people specifically identifies many of the things necessary to support the required level of task performance such as needed information, control capabilities, sufficient time, step-by-step procedures, skills, knowledge, abilities, and environmental conditions. Systematic human factors evaluation also includes evaluations of the system's workspaces, human-system interfaces, training and organisational policies. The human-error approach, in which the individual is wholly blamed, has been rejected by human-factor specialists in favour of a more wide-ranging or holistic view.[85]

Senders[76] stated that error and the failure to detect one's error are induced by familiarity with procedures and materials, coupled with a tendency on the part of human beings to perceive confirming evidence more readily than disconfirming evidence. This equates to seeing what we want to see rather than the reality and is also known as confirmation bias. Confirmation bias is known to contribute to errors involving look-alike packaging, labelling and nomenclature.[1,78]

The cause of errors can be attributed to internal processes, location or mode.[76] Internal processes are divided into input error (or misperception), intention error (or mistake), or execution error (or slip). An input error occurs when the input data are incorrectly perceived, an incorrect intention is formed, and the wrong action is therefore performed. An intention error occurs when the input data are correctly perceived, an incorrect intention is formed, and the wrong action is performed. An execution error occurs when the input data are correctly perceived, the correct intention is formed and the wrong action is performed.

Location based causes are divided into endogenous and exogenous errors. Endogenous errors are those that arise from processes inside the human. The elimination or reduction of these errors must involve psychology, physiology or neurology. An exogenous error arises from processes outside the human. The elimination or reduction of these errors must involve engineering and design of objects and work environments.

If an error results in an action then a phenomenon can be observed. The appearance of the error is called its mode. These can be categorised as errors of omission, insertion, repetition or substitution. Error of omission refers to an error characterised

by the leaving out of an appropriate step in a process. Error of insertion involves the adding of an inappropriate step to a process. Error of repetition is characterised by the inappropriate adding of a step normally appropriate to a process, and error of substitution involves an inappropriate object, action, place or time instead of the appropriate object, action, place or time.

Williams and Talley [75] describe FMEA as a method of systems analysis where there is an abundance of expertise but not much information. They state that FMEA has healthcare applications because of its use of professional healthcare expertise to identify and prioritise potential failures in a patient setting. In 1994 Williams and Talley described the use of failure mode effect and criticality analysis in a medication error subcommittee. The subcommittee adopted and modified FMEA to identify and prioritise significant failure modes in its medication administration process. Errors were ranked based on the probability of the error occurring (remote to very high), the probability of the error being detected (very high to remote) and the severity of the error (slight annoyance to terminal injury or death). The five highest ranking criticality indices were having lethal drugs available as floor stock, errors in maths when calculating doses and flow rates, not checking patient identification bands before administration, and excessive drugs in the nursing floor stock. Based on this analysis, the subcommittee implemented solutions to these highest ranked failure modes. Because FMEA is a priority analysis, the top criticality indices are addressed initially, based on the theory that the solutions to the highest rated failure modes will also be solutions to the less significant failure modes. The remainder of the failures are then addressed in descending order.

The American Society of Health-System Pharmacists considers common causes of medication errors to be ambiguous strength designation on labels, drug product nomenclature (look-alike or sound-alike names), equipment failure or malfunction, illegible handwriting, improper transcription, inaccurate dosage calculation, inadequately trained personnel, inappropriate abbreviations used in prescribing, labelling errors, excessive workload, lapses in individual performance and unavailability of medications.[56] Of these causes of medication error, most if not all can be considered a systems error.

Based on actual reports received by the United States Pharmacopeia Institute for Safe Medication Practices Medication Error Reporting Program (USP-ISMP MERP), Cohen et al [72] devised a list identifying problematic drugs and procedures that are likely candidates for FMEA. Target drugs identified were aminophylline-theophylline, cancer chemotherapy, glucose 50%, heparin, insulin, lignocaine, neuromuscular blockers, parenteral narcotics, vasoactive drugs, parenteral calcium salts, parenteral magnesium salts, parenteral potassium salts and sodium chloride over 0.9% in strength. These drugs have all been repeatedly involved in medication related deaths. Target procedures identified were dose calculations, telephone and oral orders, choosing proper items from storage locations, administering oral medications via tube to patients who also have central intravenous lines in place and electronic infusion devices using sets that allow "free flow".

The objectives of system design for safety are twofold: to make it difficult for individuals to make an error and to "absorb" errors that do occur and permit their detection and correction before harm occurs.[48] Leape et al [48] state that one of the

most effective methods of reducing systems failures is to simplify the systems. Complex systems provide multiple opportunities for errors and to be "opaque". Because of the non-linear and interlocking relationship of components, the causes of failure are not apparent to operators who may, therefore, be unable to take corrective action in time.[48]

Methods used to enhance safety systems have been reported by Cohen et al.[72] These include:

a) fail-safes or redundancies built into the system

b) minimising the possibility of error or make it impossible to occur

c) eliminate certain items or procedures entirely

d) limit use of certain items or access to pharmacy for non-pharmacy personnel

e) limit confirmation bias by storing similar looking or named drugs in geographically distinct locations

f) limit confirmation bias by changing an aspect of the appearance of similar looking drugs

g) implement lock and key design for syringes used for intravenous and oral drugs to prevent drugs being administered by the incorrect route

h) tactile clues and special packaging

i) strategically placed warnings, signs and labels

j) technology such as computers, bar codes, voice and handwriting recognition and bedside terminals

k) audible alarms on infusion pumps, to restrict access to certain areas and for cold storage areas

l) protocols and procedures to limit drugs and doses that can be employed, provide necessary monitoring parameters, and ensure only trained individuals are involved

m) documentation of doses given, allergies and laboratory results

n) providing education about drugs given and about the patient

o) minimise the consequences of an error by reducing the number of tablets/ ampoules etc available

FMEA can be used not only by hospitals and practitioners but also by the pharmaceutical industry and regulatory agencies. Similar generic names, trade names, packaging and labelling should be avoided at an industry level.[72,76] Disadvantages of FMEA may include the theoretical nature of the analysis and the time taken to assess each step of the process being studied.

Leape[83] states that redesign of systems should be directed to two objectives, preventing errors and detecting errors. Changes in the work environment to reduce stress, equalise workload and ensure appropriate training of personnel are as important as technical innovations.

The present study assesses two methods of drug distribution in an Australian tertiary hospital. The existing ward stock system is compared to a unit supply individual patient dispensing system (or modified unit dose system). Comparison of nursing time, pharmacy time, drug costs, medication error rates and nurses' opinions of the two systems is made.

The ward stock system is the system currently in operation at the study hospital, however the USIPD system has been designed using failure mode and effects analysis. FMEA enables modifications to be made to a system to reduce the incidence of incidents and accidents.

The direct observation or disguised observer technique is used to compare error rates between the two drug distribution systems. Errors reported by an incident reporting scheme in place at the hospital are also analysed according to error type, drug group, cause of the error and error probability. In addition a "no-blame" method of error reporting is introduced and assessed.

2. RESEARCH METHODOLOGY

All three parts of the study were carried out at Sir Charles Gairdner Hospital (SCGH), a 680 bed teaching hospital in Perth, Western Australia.

Part One was a prospective study of two wards, A and B, and involved a sequential analysis of the two methods of drug distribution (WS and USIPD).[86] Disguised observers collected the data as described below.

Part Two of the study involved the retrospective review of all medication error incidents reported through the usual incident/accident reporting channels over a twelve month period. Reports submitted by all hospital staff and including all twenty two wards in the hospital were included.

Part Three was a prospective sequential study involving two wards, Ward C and Ward D. For Ward C, all errors submitted by ward staff in the existing system and in a modified system were included. Error incident forms were submitted on a "no-blame" basis. Ward D was used as a control ward. Reports submitted under the existing incident/accident reporting scheme during the study period were included.

2.1 Part One - Ward Stock versus Unit Supply Individual Patient Dispensing

The study protocol, including its disguised-observer method of data collection,[1] was reviewed and approved by the University of Western Australia Committee for Human Rights and the Curtin University Human Research Ethics Committee. In addition approval and co-operation was gained from the Pharmacy Department, Nursing

Executive, Drug and Therapeutics Committee, Clinical Drug Trials Committee and the Nursing Research and Ethical Review Committee. Two wards were chosen to be involved in the study, one general medical (Ward A) and one general surgical and renal medicine (Ward B), with 30 beds on each ward. The two wards were chosen because of their proximity to the satellite pharmacy and the general rather than specialty nature of the patients treated in these wards (with the exception of six renal beds on Ward B).

2.1.1 Drug Distribution Systems Studied

The two methods of drug distribution studied were the existing ward stock (WS) system and a unit supply individual patient dispensing (USIPD) system implemented specifically for the study.

2.1.1.1. The Ward Stock system.

The WS system (Figure 2.1) was one where medications were stored in a locked cupboard on the ward and stock requirements were replenished on an imprest system by a pharmacy technician on a twice weekly basis. Approximately 7-10 days supply of drugs, specific to the usual historical requirements of the medical specialty on the ward, were held as imprest stock. All drugs were supplied as an "imprest pack" containing approximately thirty tablets or capsules and labelled with the generic and trade name of the drug, the strength of the drug, the batch number and expiry date. The imprest packs were a combination of manufacturers' original packs and those

repackaged into appropriate sizes by pharmacy staff. None of the medications was supplied in unit dose packaging. Overall review of the imprest list, drugs supplied and "non-imprest" drugs required was undertaken by the ward clinical pharmacist.

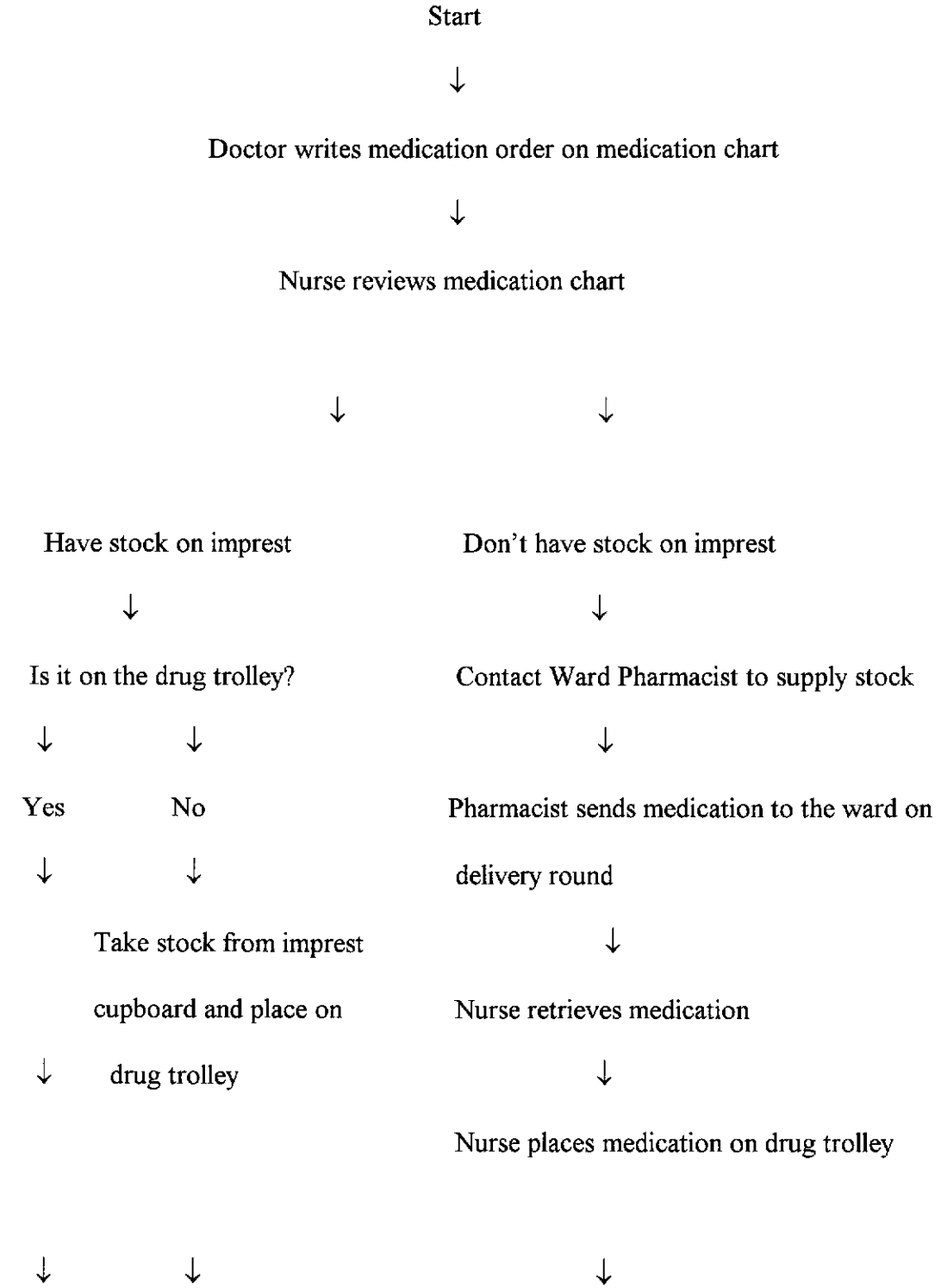
Medications were removed from the imprest cupboard and stored in drug trolleys by nursing staff for later administration to the patient. The drug trolley was a small, mobile single compartment trolley which was wheeled from bedside to bedside during the drug administration rounds. There were three such trolleys per ward, necessitating several nurses to wait for the drug trolley while another was administering medication at a designated round time. Drug trolleys were restocked by nursing staff. Any stock from the drug trolley or imprest cupboard no longer required on the ward was returned to pharmacy by either pharmacy or nursing staff for review by a pharmacist and then salvage or destruction based on set criteria (hygiene, expiry date, brand, ability to identify item, condition of the item and packaging, number of tablets/capsules remaining in the container and cost of the item).

Hours of pharmacy services in this system were Monday to Friday 0830 to 1700 and Saturday and Sunday 0900 to 1600 (for I.V. admixture services and urgently needed drug supplies only). Outside these hours an on-call pharmacist could be contacted for urgent drug requirements. Any other drugs required after hours were obtained by nursing staff by borrowing stock from other wards.

The number of individual medications (bottles or boxes) found on each drug trolley was counted daily to determine the average number of items the nurses had to select from when administering a dose.

Figure 2.1

Flow-chart of Ward Stock (WS) drug distribution system



→ Medication administration round at "usual" or "unusual" time

↓

Nurse selects medication/s from stock on drug trolley

↓

Nurse administers medication to patient

↓

Medication chart is signed by nurse to indicate medication given

↓

Stop

2.1.1.2. The Unit Supply Individual Patient Dispensing system.

The USIPD system (Figure 2.2) trialed at SCGH was designed and implemented specifically for the study. In this system, a five day quantity of drugs was individually dispensed and supplied for each patient. A five day supply was chosen to reflect the medication requirements for an average length of stay of patients in the hospital. Dispensing was carried out by pharmacy staff from a satellite pharmacy situated in close proximity to the ward and geographically separate from the central pharmacy. Medication charts were collected from the ward on an hourly basis, taken to the satellite, reviewed by a pharmacist, photocopied to facilitate dispensing and the originals returned to the ward. Medications were then dispensed and labelled with the generic and trade name of the drug, the strength of the drug, quantity dispensed,

expiry date, batch number and patient's name. None of the medications was dispensed in unit dose packaging.

Medications were next placed in a locked drawer by the patient's bedside by pharmacy staff. A master key that could access each bedside drawer on the ward was given to each registered nurse at the start of each shift and collected at the end of the shift. The nurses administered medication to each patient from the bedside drawer as required allowing a double check between the pharmacist dispensing the medication and the nurse administering it. Medication rounds were conducted at the usual designated times.

Drugs discontinued during the patient's hospitalisation were removed from the drawer by the pharmacist. Unused medications were removed from the bedside drawer when the patient was discharged and returned to the satellite for review by a pharmacist and then salvaged or destroyed under the same criteria used for the WS system. Changes in therapy were noted by either the nurse or clinical pharmacist and the drugs and charts placed in the tray for collection and alteration at the next pharmacy round. Patients' bedside drawers were moved with them if they were transferred within the ward. The existing ward stock system was resumed for patients transferred off the study ward to another SCGH ward.

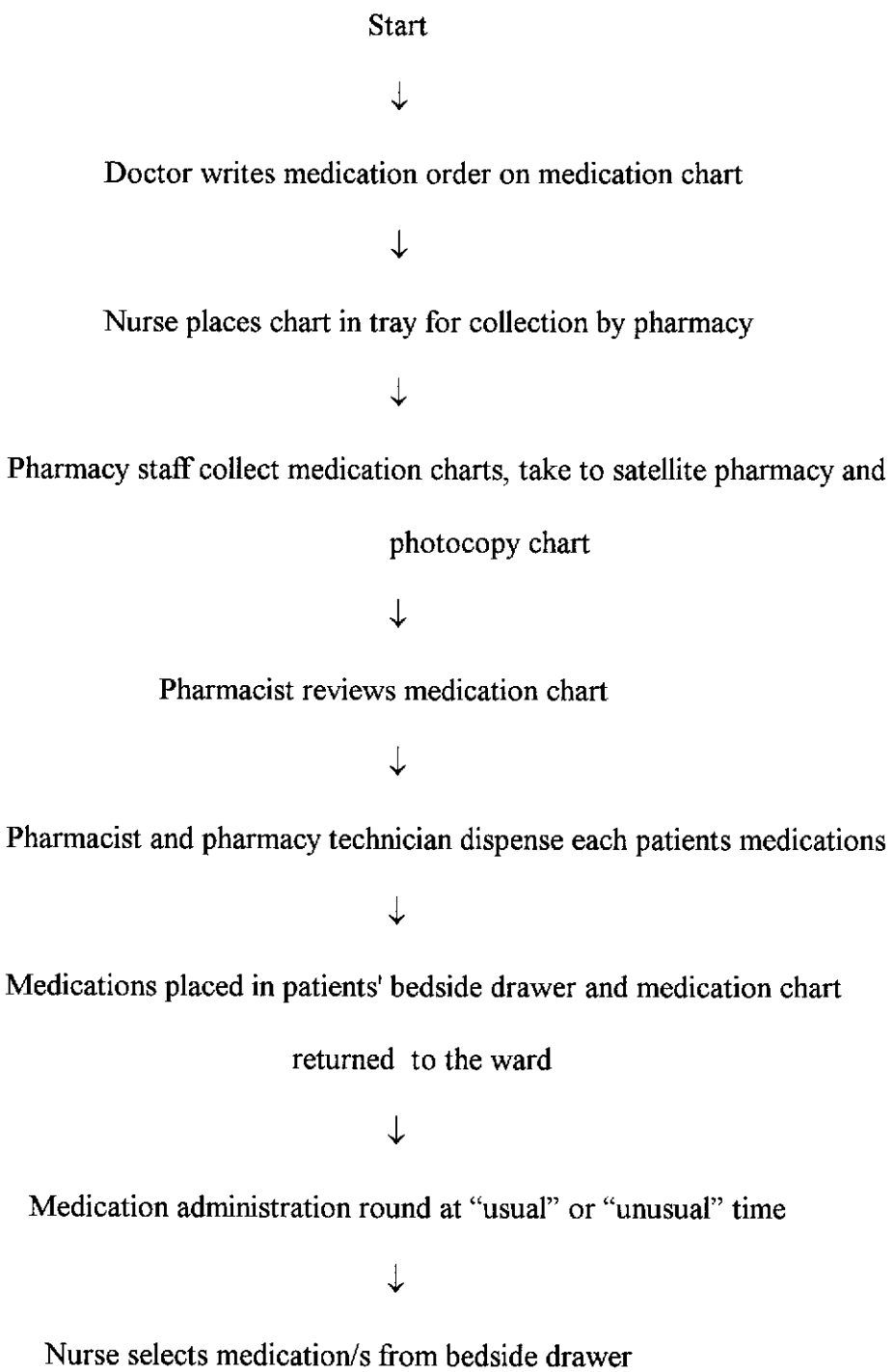
Hours of pharmacy services in this system were 0800 to 2000 seven days a week. An after-hours cupboard was available with a limited selection of drugs for urgent use. These included a small packet (20 tablets/capsules) of paracetamol, paracetamol/codeine, temazepam, nifedipine, metoclopramide, antacid, and potassium chloride elixir. The increase in pharmacy hours compared to the WS system was

necessary to allow the quantity and range of these urgent use drugs to be kept to an absolute minimum and to allow individual patients' medications to be reviewed and dispensed by pharmacists as much as possible (since most patients were admitted to the ward between the hours 0800 and 2000). The on-call pharmacist was also available for urgent after hours requirements.

The number of items dispensed for each patient and stored in the bedside drawer was recorded to determine the average number of items the nurses had to select from in each drawer.

Figure 2.2

Flow-chart of Unit Supply Individual Patient Dispensing (USIPD) drug distribution system



↓

Nurse administers medication to patient

↓

Medication chart signed by nurse to indicate medication has been given

↓

Stop

2.1.2 Observers and Timing

Two observers were used throughout the study, one a pharmacist and one a registered nurse. The pharmacist observer was responsible for the timing of nursing staff, the timing of pharmacy staff, detection of medication errors, determination of medication costs and monitoring of the security survey. The nurse observer was responsible for timing of nursing staff. The two observers were compared for interrater reliability in timing of nursing staff with a co-relation factor (κ) calculated on observations made simultaneously. Reliability can range from zero to 1.00, an acceptable level of reliability is 0.80 or higher.[87]

All timing was undertaken using a stop-watch.

2.1.3 Parameters Measured

To compare the two systems, the following parameters were studied;

2.1.3.1. Nursing time

The time spent by nursing staff in all medication related activities was measured and recorded in both systems. Preparation and administration of injections and narcotics were not studied since these medications were routinely given in a separate round subsequent to the oral medication round and the standard hospital practice for these drugs was for two nurses to check the item prior to administration to the patient. Intravenous additives at SCGH are manufactured and dispensed by a centralised IV additive service and other injectable drugs are prepared by nursing staff immediately prior to administration to the patient. These practices were maintained for both systems.

All nursing staff working on the study wards were informed as to the aims and procedures of the study, excluding information regarding collection of medication error data. Registered nurses were asked to volunteer and gave written consent to be observed.

At least five individual nurses per ward were observed on at least two separate occasions for a 7.5 hour shift. According to the protocol, the volunteer nurses were informed that the pharmacist observer would be timing all medication related activities undertaken during the course of observed shift.

Medication related activities for nursing staff included administration of medications at regular intervals dictated by the doctors' prescription in the form of a medication chart. Drugs could either be given during regular round times (eg: 0800, 1200, 1400,

1600, 2000, 2200), at other times as specified by the doctor (eg: 1500) or on an "as required" basis at variable times throughout the day. The administration rounds were classified as either "usual" rounds or "outside usual" rounds. Other activities included ordering drugs from the pharmacist, replenishing and stocking the drug trolley, finding patients' own medications and contacting other wards after hours to locate stock required. Timing was undertaken during both the morning (0700 to 1530hrs) and afternoon shifts (1300 to 2130hrs). The night shift (2100 to 0730hrs) was not observed since the majority of oral medications are given between 0700 and 2130hrs.

Observation was made of the following in both systems;

Table 2.1

Timed Medication Related Activities Undertaken by Nursing Staff in Ward Stock (WS) and Unit Supply Individual Patient Dispensing (USIPD) systems

a) Patient Requirements: time taken to attend to any patient requests (eg: assist the patient to sit up, wind up the bed, adjust pillows, talk to patient) during medication round

b) Interruptions: time taken to attend to interruptions by medical staff, nurses, patients' relatives, catering staff and other patient's during medication rounds

c) Cupboard: time taken to walk to the imprest cupboard at the nurses station to obtain stock during medication rounds

d) Lock: time taken to lock or unlock either the drug trolley (WS system) or bedside drawer (USIPD system) during medication rounds

e) Locate Chart: time taken to locate the drug chart when not at patients bedside during medication rounds

f) Keys: time taken to obtain the keys required to unlock the drug trolley or main imprest cupboard prior to or during medication rounds

g) Non-oral medications: time taken to prepare and administer non-oral medications (ie: nebulised solutions, oxygen, eye drops, ear drops, creams, ointments) during medication rounds

h) Chart: time taken to read, interpret and sign the drug chart during medication rounds

i) Drug: time taken to remove drug from packaging (bottle or box) and place into pill cup during medication rounds

j) Administration: time taken to administer drug/s to the patient during medication rounds

k) Trolley: time taken to wheel the drug trolley to and from the nurses station and from patient to patient (WS system) prior to or during medication rounds

l) Walk: time taken to walk from the nurses station to and from patients, and from patient to patient prior to and during medication rounds

m) Preparation: time taken to make any preparation required before drug/s could be given (eg: crush tablets, dissolve tablets, take patients pulse, flush nasogastric tube, pour water) during medication rounds

n) Restocking: time taken to restock the drug trolley from the imprest cupboard

o) Ordering: time taken to page the pharmacist, write requests for medication in the pharmacy order book, page orderly to collect stock, place orders in the pharmacy tray (USIPD system), contact other wards after pharmacy hours to obtain stock

p) Other: time taken to complete other miscellaneous tasks (eg: cleaning out drug trolley, returning unwanted stock to pharmacy)

This information was categorised as time taken to administer each medication during "usual" and "outside usual" round times, time taken to administer medication to each patient during "usual" and "outside usual" round times and time taken to perform all other medication related activities. From these data a total time for all medication related activities during the shift could be calculated.

2.1.3.2. Pharmacy time

The time spent by pharmacists and pharmacy technicians in medication distribution related activities was measured and recorded in both systems. The various duties were carried out by four categories of pharmacy staff; junior and senior technicians and junior and senior pharmacists.

The junior technician was responsible for drug delivery to the ward, drug repackaging and for dispensing support at central pharmacy level. These functions were not required in the USIPD system due to the nature of the satellite pharmacy.

The senior technician was responsible for the supply of imprest stock in both the WS and USIPD systems since injectable drugs were still supplied under the imprest

system during the USIPD trial. The senior technician was also involved in dispensing support in the satellite pharmacy.

The junior pharmacist was involved in dispensing both in central pharmacy for the WS system and in the satellite for the USIPD system.

The senior clinical pharmacist undertook usual clinical duties, including medication chart review, and was responsible for provision of non-imprest drugs in the WS system and identification of new or discontinued drugs in the USIPD system.

All pharmacy staff were informed as to the aims and procedures of the study and volunteers were called for. Those staff being directly involved in the study gave written consent to be observed.

Pharmacy staff were timed on at least three separate occasions for each parameter in each system. The pharmacist carrying out time measurements was separate from these functions.

Specific areas assessed can be seen in Table 2.2.

Table 2.2

Medication Distribution Related Activities Undertaken by Pharmacy Staff in Ward Stock (WS) and Unit Supply Patient Dispensing (USIPD) systems.

A: Pharmacy Technician

a) Deliver non-imprest ward stocks, discharge prescriptions and IV additives to all wards (WS)

b) Repackage imprest stock (WS)

c) Assist pharmacists with dispensing in central pharmacy (WS)

d) Replenish imprest stock at ward level (WS and USIPD)

e) Collect and photocopy medication charts and print labels (USIPD)

f) Satellite drug ordering (USIPD)

B: Pharmacist

a) Perform medication chart review (WS and USIPD)

b) Check stock requirements (WS and USIPD)

c) Dispense individual patients' drugs (USIPD)

d) Dispense non-imprest ward stock (WS)

e) Deliver medications to bedside drawer (USIPD)

f) Check imprest stock prepared by technician (WS)

g) Drug salvage (WS and USIPD)

2.1.3.3. Drug costs and security

A record was made of all drugs sent to and returned from each ward in each system including imprest and non-imprest drugs, patients own medications not taken with the patient on discharge and drugs returned to the pharmacy (Table 2.3). Those items sent to pharmacy as "returns" were reviewed by a pharmacist and either salvaged to be reused or destroyed. All drug values were calculated using prices paid by SCGH in Australian dollars. The value of drugs consumed by each patient was calculated during the USIPD system. This was not able to be done in the WS system owing to a lack of accountability in that system.

A survey of paracetamol/codeine containing analgesics was undertaken in both systems to assess the security of each system. These agents were chosen as the Pharmacy Department had previously noted a discrepancy in the amount of stock of

paracetamol 500mg, paracetamol 500mg/codeine 8mg and paracetamol 500mg/codeine 30mg supplied to the wards at SCGH and that known to be administered to patients. All stock of these three products sent to the ward during the study period was documented. All stock administered to patients was also recorded by the clinical pharmacist. Differences between the two figures were then calculated.

Table 2.3

Drug Costs Determined in the Ward Stock (WS) and Unit Supply Individual Patient Dispensing (USIPD) systems.

a) Cost of imprest stock held on each ward (WS and USIPD)

b) Cost of imprest stock supplied during the study period (WS and USIPD)

c) Cost of non-imprest drugs sent during the study period (WS and USIPD)

d) Cost of stock held in the satellite (USIPD)

e) Cost of stock held in drug trolleys (WS)

f) Cost of drugs returned to pharmacy (WS and USIPD)

g) Cost of individual patients' medications (USIPD)

2.1.3.4. Medication errors

The prevalence of medication errors in each system was determined using the disguised observer technique.[1] According to the study protocol, the volunteer nurses were informed that the pharmacist observer would be timing their medication related activities (rather than observing for medication errors) thus blinding them to the dual purpose of the study. Any error deemed to be due to a prescribing error or dispensing

error was not recorded as an administration error made by the nurse. The pharmacist observer, in addition to collecting data for timing purposes, recorded each medication and dose given to the patient without viewing the drug chart. Any potentially dangerous error that the pharmacist determined might endanger the patient was identified and highlighted to the nurse prior to the drug being administered. At the end of the observation period (nurse's shift), the pharmacist observer compared observations to the medication chart to ascertain any discrepancies. In this manner it was possible to determine an error rate. The number of observations was calculated to be the number of doses actually observed to be given plus the number of doses charted to be given but omitted. This number is known as the "opportunities for error".[1] The total number of observations required was calculated to be 1000 in total, with 250 in each ward in each system, based on an estimated error rate in the WS system between 10-15% for errors not related to the timing of doses. A medication error was defined as a deviation between the medication orders prescribed and that administered. Errors were categorised as shown in Table 2.4.[1,3,56]

Errors were further categorised as either a timing error (ie: medication given more than 30 minutes before or after the time prescribed to be given) and "all others". A timing error was not recorded if the patient was not on the ward (eg: in the operating theatre, having an x-ray, undergoing dialysis etc) at the time the medication was due to be given.

Table 2.4

Types of Medication Administration Errors

a) Omission: any ordered dose not given at all or not given by the time the subsequent dose was due

b) Wrong Dosage: any dose administered either above or below the ordered dosage

c) Extra Dose Given: any dose given more often than ordered

d) Unordered Drug Given: administration of an unordered medication

e) Wrong Formulation: administration of an incorrect formulation of the correct drug

f) Wrong Route: administration of a correct drug by a different route than that prescribed

g) Documentation: failure to adequately document doses given (ie: dose given but not documented on chart, dose documented on chart but not given, number of tablets given not specified if a dose can be "one or two")

h) Wrong Time: Minor - any drug given more than 30 minutes but less than 2 hours before or after the ordered time

Major - any drug given 2 hours or more before or after the ordered time

2.1.3.5. Nursing opinion survey

A survey was undertaken to ascertain the opinion of nurses relating to their satisfaction with specific aspects of the distribution and administration of oral medications. A questionnaire was distributed twice; once at the commencement of

the evaluation of the WS system (Time 1) and again at the completion of the evaluation of the USIPD system (Time 2) on each ward.

Seven factors related to medication associated activities were assessed on a seven point scale, ranging from "1" (very dissatisfied) to "7" (very satisfied).

The responses were added for each individual subject giving a total score of "satisfaction" with each system. Total scores could range from 7 to 49. It was not feasible to pair the results of the questionnaire for a specific nurse between the two systems because of the availability of staff on the wards throughout the study period.

The seven areas assessed were;

a) Time taken to administer oral medications

b) Time taken for new orders of oral medication to arrive from pharmacy

c) Availability of keys to access drug trolleys and cupboards to enable oral medications to be administered

d) Administration of oral medications close to the time they were charted to be given

e) Administration of "when required" oral medications close to the time requested by the patient

f) Amount of time that medication charts were away from the ward area (in pharmacy)

g) Having enough time available to administer oral medications

An overall preference between the WS system, the USIPD system, or either was called for on the second questionnaire, with space available for additional comments provided to encourage further information on the advantages and disadvantages of each system.

No reliability or validity testing was conducted on the questionnaire. The seven statements tested were developed from a working knowledge of the areas which may cause problems for nurses working on hospital wards.

2.1.4 Study Time-Line

The study was undertaken over a ten week period. Two weeks were spent on data collection for each system on each ward. Before each phase of the study began on each ward, approximately three days was spent on education and training, acclimatisation of staff, and a dry run of data collection. During this period, pharmacy and nursing staff members were able to work in the USIPD system before data collection began. Data were then collected over a two-week period.

Week 1	Education of staff, Study set-up - Ward A
Week 2&3	WS system Ward A. Data collection
Week 3	Education of staff, Study set-up - Ward B
Week 4&5	WS system Ward B. Data collection
Week 6	Education of staff, Study set-up - Ward A
Week 7&8	USIPD system Ward A. Data collection
Week 8	Education of staff, Study set-up - Ward B
Week 9&10	USIPD system Ward B. Data collection

2.1.5 Subjects and Protection of Human Rights

All staff involved with or affected by the study were informed about the aim of the study, methods of data collection and the time-line prior to commencement of the study. Information regarding the detection of medication errors while timing nursing staff was withheld as per the study protocol. Education on specific procedures required in the USIPD system was undertaken just prior to initiation of the new system.

Written, informed consent was gained from participating nurses and pharmacy staff. Anonymity, confidentiality and the voluntary nature of the study were assured. Name identified data were required to facilitate the drug audit for calculation of the prevalence of medication errors. All data were kept in a secured area and was only available to the researcher. All name identification was removed and destroyed following completion of the study.

2.1.6 Statistical Analysis

Interrater reliability, the index of intraobserver reliability, was used to assess agreement between the two observers. κ is defined as the agreement beyond chance divided by the amount of agreement possible beyond chance. [87]

Statistical analysis of nursing time and drug related activities was undertaken using the chi-square test, t-test, one and two way analysis of variance, contrast coefficient matrix, Scheffe procedure and the Mann-Whitney test.

Pharmacy time differences between the two systems were tested using the chi square test.

Differences between the two systems with respect to drug costs were not statistically analysed but rather expressed in dollar terms. Similarly, security differences were not analysed statistically.

Statistical analysis of the differences in medication error rate was undertaken with the chi-square test (apriori level of significance, $\alpha = 0.05$).The study was calculated to have sufficient power such that an 80% probability of detecting a reduction in error rate of 50% or more between the WS and the USIPD system ($\alpha = 0.05$ and $\beta = 0.8$) was possible.

Differences arising in data from the nursing opinion survey were analysed using the t-test. Any score that had one or more missing data was not included in the calculation of the mean or in the analysis.

2.2 Part Two - Error probability

Medication errors reported by nursing staff via a "self-reporting" incident method currently operating at SCGH were analysed. In this system, reports are submitted on an incident/accident report form (Appendix 7). All reports submitted over a one year period, during 1995, were evaluated including those involving injectable drugs.

2.2.1. Classification of Medication Errors

All errors reported were classified using four categories; error type, drug group, cause of error and error probability ranking.

2.2.1.1 Error Type

Classification of each error was made according to the type of error made (Table 2.5)

Table 2.5

Types of Medication Administration Errors

a) Omission: any ordered dose not given at all or not given by the time the subsequent dose was due

b) Wrong Dosage: any dose administered either above or below the ordered dosage

c) Extra Dose Given: any dose given more often than ordered

d) Unordered Drug Given: administration of an unordered medication

e) Wrong Formulation: administration of an incorrect formulation of the correct drug

f) Wrong Route: administration of a correct drug by a different route than that prescribed

g) Documentation: failure to adequately document doses given (ie: dose given but not documented on chart, dose documented on chart but not given, number of tablets given not specified if a dose can be "one or two")

h) Wrong Time: Minor - any drug given more than 30 minutes but less than 2 hours before or after the ordered time

Major - any drug given 2 hours or more before or after the ordered time

2.2.1.2 Drug Group

Errors were also categorised according to the group of drugs from which the error was made (Table 2.6)

Table 2.6

Classification of Drugs According to Drug Group

a) Anticoagulant

b) Immunosuppressant and Cancer Chemotherapy agents

c) Antidiabetic

d) Cardiovascular

e) Antibiotic

f) Electrolyte

g) Antiepileptic

h) Antipsychotic

i) Gastrointestinal

j) Sedative

k) Analgesic

l) Topical agent

m) Pre-medication (prior to procedure)

n) Others

2.2.1.3. Cause of Error

The reason or possible reason given by the reporting staff member as to why the error occurred (Table 2.7)

Table 2.7 Reported Causes of Medication Errors

a) Communication

Lack of communication or inadequate communication described between nurse doctor, nurse and another nurse, nurse and patient, nurse and pharmacist

b) Documentation

Documentation of orders by medical staff not clear or easy to interpret by nurse, dose not signed for as being given by nursing staff (requiring follow up as to whether dose was given or not)

c) Lack of Knowledge

Lack of knowledge of drug therapy being administered, equipment being used or general hospital policy regarding drugs

d) Faulty Check

Inadequate check of drug chart for orders (dose, date and time to be administered, rate of administration), inadequate check of drugs prior to administration (for injectable drugs where two nurses must check drug according to hospital policy), inadequate supervision of patient actually taking their medication (ie: leaving drugs at bedside), drugs given to incorrect patient (identifying name band on patient not checked according to hospital policy), medications belonging to the patient left with the patient (rather than locked away to prevent duplication)

e) Workload

Workload documented to be excessive at the time the error was made

f) Lapse

Inexplicable lapse in concentration and usual work practices

2.2.1.4. Probability Ranking

An equal denominator weighting score out of ten points was given by a panel of four (two pharmacists and two nurses) by averaging results for each of the following;

a) probability of error occurring

b) probability of error being detected

c) probability of error causing harm

Assessors ranked each error on a scale from one to ten with the multiple rankings available within some categories (eg: for occurrence - 2, 3 and 4 related to low occurrence) giving a degree of flexibility.

Table 2.8

Ranking of error probability

Occurrence	Detection	Harm
1 - remote	1 - very high	1 - no problem to patient
2 - low	2 - high	2 - slight annoyance
3 - low	3 - high	3 - affects patient progress
4 - low	4 - moderate	4 - affects patient progress
5 - moderate	5 - moderate	5 - minor injury to patient
6 - moderate	6 - moderate	6 - minor injury to patient
7 - high	7 - low	7 - minor injury to patient
8 - high	8 - low	8 - major injury/danger to patient
9 - very high	9 - remote	9 - major injury/danger to patient
10 - very high	10 - remote	10 -death

Analysis of these documented errors involved a retrospective review of each error and classification according to the four categories listed above. The probability ranking gives an overall "score" of the probability of an error occurring and the potential of the error to cause harm to the patient. This ranking is based on a technique described by Williams and Talley.[75] Each error is given a ranking for each of the three probability categories which are then summed to give a total score out of 30. Each of three categories is given equal weighting in determining the overall score. The total score is an arbitrary number used to rank the errors reported. Those given the highest score were seen as the most serious of the errors. Williams and Talley [75] stated that when using this process the top rating errors are addressed initially, based on the theory that the solutions to the highest rating failure modes will also be solutions to less significant failure modes.

Errors were then placed in order according to their probability ranking. System failures were identified based on the most frequent and serious errors that repeatedly occurred.

2.2.2 Study time line

All reports submitted over a twelve month period, during 1995, were studied. They were analysed retrospectively and included all reports of medication errors made throughout the hospital campus. Reports detailing errors involving injectable drugs were included.

2.2.3 Subjects and Protection of Human Rights

Medication error analysis was undertaken without recording the patient or nurses name. The age and sex of the patient were required to help assess the potential significance of the medication error. This was necessary in order to rank the probability of the error causing harm appropriately.

2.3 Part Three -Failure Mode and Effects Analysis and "no-blame" error reporting

Part Three of the study involved two model systems as described below. These are the USIPD system, described in Part One of the study and "no-blame" error reporting system (Phases One and Two).

2.3.1. Failure Mode and Effects Analysis

The process of FMEA was applied to the existing system of medication distribution and administration at SCGH in the following manner. Each component of the WS medication administration and distribution system was broken down in a stepwise fashion as seen in Figure 2.1. This was done using expertise from pharmacy staff and nursing staff and by way of the nursing opinion survey. A panel of four (two pharmacists and two nurses) was involved in the process. Discussion of each of the steps in the process was undertaken with problems known to the pharmacists or nurses highlighted. The objective of FMEA is to gather the opinions of experts in the respective technical disciplines involved to evaluate the system and pick out possible failure mechanisms.

Each of the individual steps was studied in detail with potential areas of failure in each step highlighted. The failures in the system as a whole were therefore exposed. Once the basic failure modes and mechanisms have been identified, their relative importance to the function of the overall system is rated. These can be ranked from most to least important. The result is a weighting scheme in which the most critical

failures receive greater weights than less serious problems, therefore enabling resources to be focussed on the most serious problem.

Strategies to overcome these potential failures were formulated. Two model systems were devised. The first model system consisted of individual patient dispensing, review of medication charts by a pharmacist before the first dose was administered to the patient, restricted availability of drugs and a reduced number of medications to choose from. The second model system consisted of current textbooks available on the drug trolley, excess stock on drug trolleys removed daily, standardisation of medication administration times, standardisation of medication protocols for commonly used drugs, and education of nursing staff. The two model systems were then tested to assess the influence these interventions made on the medication error rate.

2.3.2 Model Systems Tested

2.3.2.1 Unit supply individual patient dispensing system

The first FMEA designed system has previously been described, implemented and tested in part one of the study as the USIPD system.

2.3.2.2 Ward Stock "no-blame" reporting system

The study protocol for this section was reviewed by the Curtin University Human Research Ethics Committee and the University of Western Australia Committee of Human Rights. In addition approval and co-operation was gained from the Pharmacy

Department, Nursing Executive, Drug and Therapeutics Committee, Clinical Drug Trials Committee and the Nursing Research and Ethical Review Committee. A specialty surgical ward (neurosurgery), with 30 beds, was chosen to be involved in the study (Ward C). A second specialty surgical ward (plastic surgery), with 30 beds, was chosen to act as a control (Ward D).

This second FMEA designed system to be studied encompassed a number of aspects of the existing system previously identified by the nurses' survey and Part Two of the study as contributing factors to the medication error rate. The new system involved multiple components that were viewed as a single intervention to attempt to overcome potential failures in the system. The intervention consisted of the following measures; current reference texts available on each drug trolley, regular ordering and appropriate restocking of the drug trolley, clarification and standardisation of all medication charts by a clinical pharmacist, standardisation of all commonly used regimens on the ward, standardisation of medication administration round times, education of ward staff as to correct hospital policy and common errors that occur in the system, and increased availability and input from a clinical pharmacist on the ward.

A "no-blame" error reporting system was used to assess any impact of these interventions. This differs from the system of error reporting currently in place at SCGH. The current "self-reporting" incident system consists of staff submitting written reports to the hospital administration detailing any incident or accident that has occurred within the hospital. These report forms are used for a variety of incidents including patient falls, development of pressure sores on patients, needle-

stick injuries and lost property reports as well as medication incidents. The reports are usually submitted voluntarily and often implicate other staff rather than the person submitting the report. Many incidents are probably never reported since the problem is solved, the staff member feels the incident does not warrant the work involved in completing an incident form or the staff member fears retribution if the incident was reported. There is, at present, no system of reporting an error in a "no-blame" method at SCGH.

The new "no-blame" method of error reporting implemented for the purposes of the study consisted of a scheme whereby nurses could report any medication error or any situation they thought had a high potential to cause an error without fear of disciplinary action. Reports were made on a simple form (Appendix 6) that required the nurse to circle one of the relevant categories with additional space available to add any further comments. The date and time of day as well as the nurses name was also recorded on the report sheet by the reporting nurse. Approximately 170 - 180 error reports were collected in each phase of the study.

Ward D was used as a control ward for the purposes of the study. The number of incident forms submitted under the existing incident/accident reporting scheme was documented. The staff on this ward were not given any education or information regarding the study and were therefore unaware that the study was in progress.

2.3.3 Study Time-Line

The "no-blame" error reporting system was studied over a seven week period; three weeks before the intervention and four weeks afterwards on Ward C at SCGH. The

difference in study time during each phase was due to the rate of error reporting being faster in phase one. Education of ward staff was conducted prior to the commencement of the study and included oral presentations at ward meetings, informal education with specific staff if required and the availability of written material on the ward. Reports were collected over the same timeframe as for Ward C.

2.3.4 Subject Protection and Human Rights

Medication incidents were reported by staff on a voluntary basis. The possibility of patients being adversely affected by staff not reporting a serious event during this study was eliminated by a dual reporting system. Staff were instructed to document any incident they would usually reported through the usual procedures in addition to those reported to the investigator. Analysis of the medication incidents reported was undertaken without knowledge of the patients' name.

2.3.5 Statistical Analysis

The study was calculated to provide a sample size for the detection of a change in error rate from 3% to 2%, statistically significant at $p \leq 0.05$, between the two phases ($\alpha = 0.05$, $\beta = 0.20$). The significance of the differences was determined with the chi-square test with Yates correction (apriori level of significance, 0.05). The null hypothesis was that there would be no difference in the medication error reporting rates between the two phases on Ward C. Linear regression was performed on data using a linreg computer library program.

3. RESULTS

3.1 Part One - Ward Stock versus Unit Supply Individual Patient Dispensing

3.1.1 Comparison of wards and observers

Comparison of the two wards shows a similar throughput of patients (mean number of patients, admissions, discharges and bed changes per 24 hours) during the study period. Table 3.1 shows movement of patient's into and out of wards A and B during the study period.

Table 3.1

Mean number of patients, admissions, discharges and bed changes for Ward A and Ward B in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems.

Ward	Mean No Patients at 0800hrs	Mean No Admissions Prev 24 hrs	Mean No Discharges Prev 24 hrs	Mean No Bed Changes Prev 24 hrs
A WS	28.8 ± 1.9	4.0 ± 2.4	4.4 ± 2.4	2.7 ± 2.4
USIPD	29.1 ± 1.7	4.3 ± 2.4	4.2 ± 2.8	3.0 ± 3.0
B WS	27.3 ± 2.2	5.1 ± 2.7	4.6 ± 2.2	3.5 ± 2.4
USIPD	28.7 ± 1.3	4.4 ± 2.1	3.8 ± 2.2	1.9 ± 1.7

The number of observations undertaken by each observer, number of morning and afternoon shifts and number of shifts observed on various days of the week is shown in Table 3.2.

Table 3.2

Number of rounds, number of patients, number of morning (am)/afternoon (pm) shifts, number of shifts observed by observers 1 and 2 and number of shifts observed on each day of the week for Ward A and Ward B in ward stock (WS) and unit-supply individual patient dispensing (USIPD) systems.

	WS Ward A	WS Ward B	USIPD Ward A	USIPD Ward B
Number of rounds	39	49	31	42
Number of patients	188	176	149	171
Number of am shifts	6	8	7	10
Number of pm shifts	4	7	4	5
Observer 1 shifts	5	11	7	10
Observer 2 shifts	5	4	4	5
Monday shifts	1	3	1	2
Tuesday shifts	1	3	2	3
Wednesday shifts	0	1	3	2
Thursday shifts	2	2	2	2
Friday shifts	2	2	2	4
Saturday shifts	3	2	1	1
Sunday shifts	1	2	0	1

Interrater reliability between the observations made by Observer 1 and Observer 2 in the measurement of nursing time was found to be $\kappa = 0.892$ at the commencement of data collection for the WS system and $\kappa = 0.912$ at the commencement of data collection for the USIPD system, with κ defined as the agreement beyond chance divided by the amount of agreement possible beyond chance.[87]

3.1.2 Nursing Time

Of 25 nurses working on Ward A, 6 (24%) volunteered to be observed during the study with four of these taking part in both the WS and the USIPD parts of the study (Nurse subject 1-6, Table 3.3). During the WS phase the five nurses were all observed for two shifts each, while during the USIPD phase four nurses were observed for two shifts each and one was observed for three shifts.

Of 24 nurses working on Ward B, 8 (33%) volunteered to participate with five taking part in both the WS and USIPD parts (Nurse subject 7-14, Table 3.3). During the WS phase four nurses were observed for two shifts, one for three shifts and one for four shifts. During the USIPD phase, six nurses were observed for two shifts and one for three shifts.

Variability in the number of shifts observed and whether particular nurses were observed under one or both systems was due to the nursing staff roster. All nurses were observed at least twice under one system. A total of 51 nursing shifts were observed during the study, 25 in the WS system and 26 in the USIPD system. The total time taken for drug administration related activities for each observed nurse during the shifts is also shown in Table 3.3.

Table 3.3

Nursing shifts observed for individual nurses (1-14) and total time (mins) observed undertaking medication related activities for Wards A and B in ward stock (WS) and unit-supply individual patient dispensing (USIPD) systems

Nurse	WS (mins)				USIPD (mins)		
Obs No	1	2	3	4	1	2	3
1	67	62			27	37	
2	130	97			86	95	
3	101	108					
4	115	88			118	44	
5	67	77			65	57	
6					60	60	55
7	34	35	59		41	19	
8	20	87			31	45	
9	39	53					
10	97	26	119	72	66	72	40
11	32	35			16	20	
12	55	60			50	37	
13					25	54	
14					26	49	

During the 51 shifts that were observed during the study, 161 medication rounds were undertaken and 684 patients were administered medications. The time of day

that rounds were observed, round number, patient number, nurse observed, observer, observation number and time taken for the medication round can be seen in Appendices 1-4 for the WS and USIPD systems.

The mean time taken by all nursing staff on all medication-related activities per shift is shown in Table 3.4. The mean time taken by nursing staff to perform all medication related activities during the observed shifts was reduced in the USIPD system. Mean total time spent by the observed nurse during the shift was reduced by 27.2 minutes ($p = 0.02$) on Ward A and by 15.9 minutes ($p = 0.07$, not statistically significant) on Ward B, using the t-test.

Table 3.4

Mean time (± 1 standard deviation) spent by nursing staff on all medication-related activities per shift in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

Ward	WS (min)	n	USIPD (min)	n	% time reduction in USIPD system
A	91.2 ± 22.9 CV = 25.1%	10	64.0 ± 26.5 CV = 41.4%	11	29.8 ($p = 0.02$)*
B	55.3 ± 28.5 CV = 51.5%	15	39.4 ± 16.9 CV = 42.9%	15	28.8 ($p = 0.07$)

* Significant at $p < 0.05$

n = number of observations (nursing shift of 7.5 hours)

CV = coefficient of variation

Results for time taken by nursing staff to complete specific medication related activities in the two drug distribution systems are shown in Tables 3.5 to 3.9. These are divided into medications given during the " usual" and "outside usual" administration rounds. Results are further divided into the time taken to give each individual medication and total time taken to administer all medications to each patient.

Table 3.5

Mean time (± 1 standard variation) taken by nurses to administer individual medications during "usual" medication rounds in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

Ward	Administration time (sec)	
	WS system	USIPD system
A	107.3 ± 38.9 (n = 319)	85.6 ± 30.0 (n = 299)
B	89.8 ± 23.4 (n = 279)	75.8 ± 27.9 (n = 309)

Table 3.6

Mean time (± 1 standard variation) taken by nurses to administer all medications to each patient during "usual" medication rounds in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

Ward	Administration time (sec)	
	WS system	USIPD system
A	193.2 ± 49.1 (n = 167)	185.5 ± 51.9 (n = 135)
B	175.1 ± 59.2 (n = 150)	149.3 ± 51.9 (n = 160)

Table 3.7

Mean time (± 1 standard variation) taken by nurses to administer individual medications "outside usual" medication rounds in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

Ward	Administration time (sec)	
	WS system	USIPD system
A	150.7 ± 97.5 (n = 30)	70.7 ± 71.2 (n = 16)
B	86.9 ± 84.6 (n = 39)	32.9 ± 55.8 (n = 14)

Table 3.8

Mean time (± 1 standard variation) taken by nurses to administer all medications to each patient "outside usual" medication rounds in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

Ward	Administration time (sec)	
	WS system	USIPD system
A	259.8 ± 379.3 (n = 21)	76.1 ± 77.2 (n = 14)
B	119.2 ± 113.6 (n = 26)	47.1 ± 82.7 (n = 11)

Table 3.9

Mean time (± 1 standard variation) taken by nurses to perform all other medication related activities per shift in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

Ward	WS (sec)		USIPD (sec)	
	During rounds	Outside rounds	During rounds	Outside rounds
A	613.9 ± 501.9 (n = 10)	483.6 ± 574.2 (n = 10)	382.0 ± 278.4 (n = 11)	8.3 ± 15.8 (n = 11)
B	627.1 ± 522.4 (n = 15)	375.7 ± 460.0 (n = 15)	149.2 ± 233.8 (n = 15)	5.7 ± 17.6 (n = 15)

Analysis of the data for Ward A, by t-test, is shown in Tables 3.10. Differences between the WS and USIPD systems for the total time to administer drugs and the time taken to perform all tasks was found to be not significant.

Table 3.10

Total time to administer drugs (Drug) and total time to perform all tasks (All) for Ward A in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems.

		No cases	Mean	Std Dev	Std Error	Pooled Variance t value	° freedom	2 tail prob
Drug	WS	157	60.57	49.89	3.98			
						0.22	280	0.82
	USIPD	125	59.28	45.84	4.10			
All	WS	222	215.43	214.39	14.39			
						1.40	395	0.16
	USIPD	175	188.75	148.37	11.21			

Analysis of the data for Ward B, by t-test, is shown in Tables 3.11. Again differences between the WS and USIPD systems for the total time to administer drugs was found to be not significant. However the difference between the WS and USIPD systems for the total time taken to perform all tasks was significant.

Table 3.11

Total time to administer drugs (Drug) and total time to perform all tasks (All) for Ward B in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems.

		No cases	Mean	Std Dev	Std Error	Pooled Variance t value	°freedom	2 tail prob
Drug	WS	148	49.03	42.09	3.46			
						0.81	270	0.42
	USIPD	124	45.24	33.11	2.97			
All	WS	213	202.36	227.77	15.61			
						3.27	394	0.001
	USIPD	183	141.34	117.28	8.67			

The t-test was also used to determine any difference between the two distribution systems (WS and USIPD) and results can be seen in Table 3.12. Differences between the two systems for the time taken to administer drugs was not significant, however the time taken to perform all tasks was found to be significantly different.

Table 3.12

Total time to administer drugs (Drug) and total time to perform all tasks (All) in ward stock (WS) system for Wards A and B and unit supply individual patient dispensing (USIPD) system for Wards A and B.

		No cases	Mean	Std Dev	Std Error	Pooled Variance t value	°freedom	2 tail prob
Drug	WS	305	54.97	46.56	2.67			
						0.71	552	0.47
	USIPD	249	52.29	40.54	2.57			
All	WS	435	209.02	220.89	10.59			
						3.33	791	0.001
	USIPD	358	164.51	135.29	7.15			

The two-tailed Mann-Whitney test was also used to identify differences between the ward and the system on the total time taken to administer drugs and the total time taken to perform all medication related tasks for Wards A and B.

Table 3.13 shows an association with the system used for the total time taken to perform all tasks but not for the total time taken to administer drugs using the Mann-Whitney test. As seen in this table, an association with the system (WS or USIPD) was found for the total time taken to perform alll tasks (p= 0.000) but not for the total taken to administer drugs (p=0.637). Using the Mann-Whitney test, Table 3.14 shows an association with the ward tested (Ward A and Ward B) for both the total

time taken to perform all tasks (p = 0.001) and also for the total time taken to administer drugs (p = 0.000).

Table 3.13

Total time to administer drugs (Drug) and total time to perform all tasks (All) in ward stock (WS) and unit supply individual patient dispensing (USIPD) system

	System	No cases	Mean Rank	Sum Ranks	p
Drug	WS	305	280.40	85523.00	
					0.637
	USIPD	249	273.94	68212.00	
All	WS	435	423.45	184201.00	
					0.000
	USIPD	358	364.86	130619.99	

Table 3.14

Total time to administer drugs (Drug) and total time to perform all tasks (All) for Ward A and Ward B

	Ward	No cases	Mean Rank	Sum Ranks	p
Drug	A	282	301.58	85046.50	
					0.000
	B	272	252.53	68688.50	
All	A	397	423.77	168237.50	
					0.001
	B	396	370.16	146583.50	

One way analysis of variance was used to detect any difference in total time taken to administer drugs and total time to perform all medication related tasks between Wards A and B. It was found that there was a significant difference in the time taken to administer drugs as seen in Table 3.15. The time taken to perform all medication related tasks was also significantly different as seen in Table 3.16.

Table 3.15

Difference between Wards A and B in total time taken to administer drugs in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems using one way analysis of variance

Source	D.F.	Sum of Squares	Mean Squares	F ratio	F prob
Between groups	3	23386.1738	7795.3913	4.1054	0.0068
Within groups	550	1044351.321	1898.8206		
Total	553	1067737.495			

Table 3.16

Difference between Wards A and B in time taken to perform all medication related tasks in wards stock (WS) and unit supply individual patient dispensing (USIPD) system using one way analysis of variance

Source	D.F.	Sum of Squares	Mean Squares	F ratio	F prob
Between groups	3	608665.9797	202888.6599	5.8231	0.0006
Within groups	789	27490299.48	34841.9512		
Total	792	28098965.46			

Analysis of variance was also used to detect any difference in the total time taken to administer drugs and the total time taken to perform all medication related tasks between the WS and USIPD systems. The total time taken to administer drugs was

not significantly different in the two systems as seen in Table 3.17. The time taken to perform all medication related tasks in the WS and USIPD systems was found to be significantly different as seen in Table 3.18.

Table 3.17

Difference between ward stock (WS) and unit supply individual patient dispensing (USIPD) systems for total time to administer drugs for Wards A and B using one way analysis of variance

Source	D.F.	Sum of Squares	Mean Squares	F ratio	F prob
Between groups	1	985.5794	985.5794	0.5100	0.4754
Within groups	552	1066751.915	1932.5216		
Total	553	1067737.495			

Table 3.18

Difference between ward stock (WS) and unit supply individual patient dispensing (USIPD) systems for time taken to perform all medication related tasks for Wards A and B using one way analysis of variance

Source	D.F.	Sum of Squares	Mean Squares	F ratio	F prob
Between groups	1	389072.3893	389072.3893	11.1064	0.0009
Within groups	791	27709893.07	35031.4704		
Total	792	28098965.46			

Two way analysis of variance, using natural log transform, was also undertaken to assess differences between the wards and the drug distribution systems simultaneously. Natural log transform was used since the data were not normally distributed. Table 3.19 shows a significant difference between the wards but not the systems with respect to the total time taken to administer drugs. Table 3.20 shows a significant difference between the systems and the wards with respect to the time taken to perform all medication related tasks. The model is seen to have predictive power.

Table 3.19

Difference between system (ward stock versus unit supply individual patient dispensing) and ward (Ward A versus Ward B) for total time taken to administer drugs using two way analysis of variance with natural log transform

Source	Sum of Squares	D.F.	Mean Squares	F ratio	p
Main Effects	7.899	2	3.949	6.958	0.001
System	0.185	1	0.185	0.327	0.568
Ward	7.686	1	7.686	13.541	0.000
2 way interaction					
System Ward	0.094	1	0.094	0.166	0.684
Explained	7.899	3	2.633	4.639	0.003

Table 3.20

Difference between system (ward stock versus unit supply individual patient dispensing) and ward (Ward A versus Ward B) for total time taken to perform all medication related tasks using two way analysis of variance with natural log transform

Source	Sum of Squares	D.F.	Mean Squares	F ratio	p
Main Effects	19.019	2	9.510	12.830	0.000
System	12.824	1	12.824	17.302	0.000
Ward	5.813	1	5.813	7.842	0.005
2 way interaction					
System Ward	2.111	1	2.111	2.848	0.092
Explained	20.526	3	6.842	9.231	0.000

Differences between the groups were also considered. Groups were based on the ward and distribution system (ie: Group 1 Ward A-WS system, Group 2 Ward A-USIPD system, Group 3 Ward B-WS system, Group 4 Ward B-USIPD system).

Using the contrast coefficient matrix, it was found that there was no significant difference in the time taken to administer all drugs between Ward A and Ward B in the WS system or between Ward A and Ward B in the USIPD system. There was, however, a significant difference between the WS system (Wards A and B combined) and the USIPD system (Wards A and B combined) for the total time taken to administer drugs (probability = 0.001). Using the Scheffe procedure it was found

that the only groups significantly different at the 0.050 level were Ward A in the WS system and Ward B in the USIPD system.

The time taken to perform all tasks was also analysed using the same tests. Using the contrast coefficient matrix, it was found that there was no significant difference between Ward A and Ward B in the WS system. There was a significant difference found between Wards A and B in the USIPD system (T probability = 0.001). There was also a significant difference between the WS system (Wards A and B combined) and the USIPD systems (Wards A and B combined) for the time taken to perform all tasks (T probability = 0.018). Using the Scheffe procedure it was found that, at the 0.050 level), there was a significant difference between Ward A in the USIPD system and Ward B in the USIPD system and between Ward A in the WS system and Ward B in the USIPD system.

Patients received a varying number of drugs during any given administration round based on what was prescribed for them by their doctor. The minimum number of drugs given to a patient during a round was zero and the maximum number was nine. The mean time taken by the nurse to give each medication, along with the minimum and maximum times taken, plus the number of patients given that drug number can be seen in Table 3.21.

Table 3.21

Mean time taken to give drug, standard deviation (std dev), minimum time taken to give drug (min), maximum time taken to give drug (max), and number of cases of that number of drugs being given for 1 drug to 9 drugs in ward stock and unit supply individual patient dispensing systems during study period.

No. of Drugs	Mean (sec)	Std Dev	Min (sec)	Max (sec)	No. of Cases
1	24.29	18.88	4	269	554
2	21.34	11.11	6	78	298
3	22.77	17.77	3	151	195
4	23.05	16.39	6	136	116
5	25.27	20.10	7	101	71
6	18.91	16.09	3	102	34
7	13.86	7.44	2	28	14
8	27.00	14.28	4	47	7
9	32.00	-	32	32	1

The time taken by nursing staff to perform all other medication related duties during the observed shifts was determined under the following classifications;

a) Patient Requirements: time taken to attend to any patient requests (eg: assist the patient to sit up, wind up the bed, adjust pillows, talk to patient) during medication round

b) Interruptions: time taken to attend to interruptions by medical staff, nurses, patients relatives, catering staff and other patients during medication rounds

c) Cupboard: time taken to walk to the imprest cupboard at the nurses station to obtain stock during medication rounds

d) Lock: time taken to lock or unlock either the drug trolley (WS system) or bedside drawer (USIPD system) during medication rounds

e) Locate Chart: time taken to locate the drug chart when not at patients bedside during medication rounds

f) Keys: time taken to obtain the keys required to unlock the drug trolley or main imprest cupboard prior to or during medication rounds

g) Non-oral medications: time taken to prepare and administer non-oral medications (ie: nebulised solutions, oxygen, eye drops, ear drops, creams, ointments) during medication rounds

h) Chart: time taken to read, interpret and sign the drug chart during medication rounds

i) Administration: time taken to remove drug from packaging (bottle or box) and place into pill cup during medication rounds then administer drug/s to the patient during medication rounds

j) Trolley: time taken to wheel the drug trolley to and from the nurses station and from patient to patient (WS system) prior to or during medication rounds

k) Walk: time taken to walk from the nurses station to and from patients, and from patient to patient prior to and during medication rounds

l) Preparation: time taken to make any preparation required before drug/s could be given (eg: crush tablets, dissolve tablets, take patients pulse, flush nasogastric tube, pour water) during medication rounds

m) Restocking: time taken to restock the drug trolley from the imprest cupboard

n) Ordering: time taken to page the pharmacist, write requests for medication in the pharmacy order book, page orderly to collect stock, place orders in the pharmacy tray (USIPD system), contact other wards after pharmacy hours to obtain stock

o) Other: time taken to complete other miscellaneous tasks (eg: cleaning out drug trolley, returning unwanted stock to pharmacy)

The time taken to perform each of these categories can be seen in Table 3.22.

Table 3.22

Mean time taken (sec), standard deviation (std dev) and number of cases of each item; patient requirements, interruptions, cupboard, lock, locate chart, keys, non-oral medications, chart, administration, trolley, walk, preparation, restocking, ordering and other per shift in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems during study period

	WS system			USIPD system		
	Mean (sec)	Std Dev	No. cases	Mean (sec)	Std Dev	No. cases
Patient	37.31	43.68	231	40. 41	44.36	220
Interruptions	35.76	67.87	137	48.81	68.61	107
Cupboard	67.91	51.21	40	35.70	32.86	8
Lock	15.71	10.81	146	12.01	8.52	244
Locate Chart	59.35	49.23	21	55.66	79.99	10
Keys	40.35	55.91	29	28.88	19.03	11
Non-oral	71.62	129.88	9	31.70	20.77	29
Chart	35.84	31.07	335	33.80	27.87	330
Administration	32.72	33.52	302	22.26	23.42	221
Trolley	36.14	36.25	247	24.00	10.53	3
Walk	36.54	18.07	37	17.61	16.28	230
Preparation	35.39	47.47	232	26.20	31.39	182
Restocking	161.17	180.54	16	0	0	0
Ordering	195.12	152.81	16	38.20	27.26	10
Other	702.76	718.31	8	377.66	403.67	3

3.1.3 Pharmacy Time

The time spent on medication distribution-related activities was variable for different sections of pharmacy staff in the WS and USIPD systems. Time taken to perform each aspect of the activities undertaken by the section is shown below.

Junior Technician

Time taken by the junior technician in the WS system consisted of the following; delivery of drugs to the ward areas (13.8 ± 0.6 minutes per ward per day, n = 45 deliveries), packing/repacking of drugs into imprest packs (4.7 ± 2.7 minutes per ward per day, n = 30 batches), and assisting the pharmacist with dispensing in Central Pharmacy (2.9 ± 0.1 minutes per ward per day, n = 10 days). The junior technician performed no duties in the USIPD system.

Senior Technician

Duties undertaken by the senior technician in the WS system involved replenishing imprest stock on ward (20.5 ± 3.3 minutes per ward per day, n = 8 imprest supplies). The role of the senior technician was more time consuming in the USIPD system. Time taken consisted of the following; replenishing imprest stock of emergency supplied on ward (9.6 ± 1.4 minutes per ward per day, n = 8 imprest supplies), collecting charts (new and amended), photocopying and printing labels in the satellite pharmacy (87.4 ± 5.8 minutes per ward per day, n = 24 days), and ordering

of drugs for the satellite from Central Pharmacy (8.7 ± 2.3 minutes per ward per day, n = 8 days).

Pharmacist

The time taken for the pharmacist for the WS and USIPD systems was divided into the time taken for Ward A and Ward B, where appropriate. Time taken in the WS system consisted of the following; time taken to perform medication chart review (Ward A 92.7 ± 21.7 minutes per day, Ward B 68.8 ± 13.4 minutes per day, n = 3 days), checking stock requirements for both the cupboard and drug trolley (Ward A 7.9 ± 5.1 minutes per day, Ward B 6.4 ± 0.8 minutes per day, n = 3 days), dispensing non-imprest ward stock requirements (Ward A 15.6 ± 9.2 minutes per day, Ward B 10.5 ± 5.8 minutes per day, n = 3 days), checking imprest stock in Central Pharmacy - 0.6 ± 0.5 minutes per ward per day, n = 12 days), and drug salvage of returned drugs (1.4 ± 0.4 minutes per ward per day, n = 11 days). The total time taken was 118.2 ± 24.1 minutes per day for Ward A and 87.7 ± 14.6 minutes per day for Ward B.

In the USIPD system time taken to perform each activity consisted of the following; time taken to perform medication chart review (Ward A 82.4 ± 13.6 minutes per day, Ward B 58.5 ± 4.7 minutes per day, n = 3 days), checking stock requirements for both the cupboard and bedside drawers (Ward A 14.9 ± 1.1 minutes per day, Ward B 13.4 ± 1.8 minutes per day, n = 3 days), dispensing individual patient's drugs in satellite (26.6 ± 4.7 minutes per ward per day, n = 46 patient's drugs),

delivery of medications to patient's bedside drawer (17.4 ± 6.2 minutes per ward per day, n = 10 days), and drug salvage of drugs returned to satellite (22.4 ± 7.4 minutes per ward per day, n = 19 days). The total time taken was 163.7 ± 17.4 minutes per day for Ward A and 138.3 ± 11.8 minutes per day for Ward B.

The on-call pharmacist was available for any urgent drug needs after hours but was not required by either of the wards during the study.

The total time spent by the various pharmacy sections, as outlined above, is summarised in Table 3.23.

Table 3.23

Time taken (± 1 standard deviation) by all pharmacy staff to undertake medication distribution-related activities in the ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

	WS (min/ward/day)	USIPD (min/ward/day)	% time change in USIPD system
Junior technician	21.4 ± 2.8	0	-100
Senior technician	20.5 ± 3.3	105.7 ± 6.4	+415.6($p < 0.001$)
Pharmacist Ward A	118.2 ±24.1	163.7 ± 17.4	+38.5 ($p = 0.015$)
Pharmacist Ward B	87.7 ± 14.6	138.3 ± 11.8	+57.7 ($p < 0.001$)
Total	247.8 ± 48.9	407.7 ± 29.1	+64.5

3.1.4 Drug Costs and Security

The value of imprest items held on Ward A was $3104.50 which represented 3.39% of the total hospital ward imprest holdings. Non-injectable imprest stock accounted for $1101.71 of this total. Ward B held a total of $5518.42 which represented 5.85% of the total hospital imprest holdings with non-injectable imprest stock accounting for $2554.97.

No injectable drugs were kept on the drug trolleys during the study period. The value of drugs held in drug trolleys prior to commencement of the WS system was found to be $519.55 for Ward A and $642.38 for Ward B. Prior to the commencement of the USIPD system (end of WS system) the value of drugs held in the trolleys was $624.33 for Ward A and $718.49 for Ward B. The mean value of drugs held in drug trolleys was $671.41.

The average value of stock held in the satellite pharmacy during the study period was $1981.93.

The value of imprest and non-imprest stock sent to and returned from the two wards during the study can be seen in Table 3.24. Savings in the USIPD system for Ward A amounted to $327.57 over a two week period while savings for Ward B were $542.48 over a two week period.

Table 3.24

Cost (A$) of non-injectable imprest, non-imprest and individually dispensed drugs supplied and returned over a two week period in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems.

		Drug Cost ($)	
Ward		WS system	USIPD system
A	Stock issued	1450.58	1842.48
	Returns salvaged	(215.32)	(941.55)
	Returns discarded	130.50	32.48
	Trolley stock	(104.78)	
	Total	1260.98	933.41
B	Stock issued	2205.22	2321.89
	Returns salvaged	(299.95)	(1003.36)
	Returns discarded	54.53	22.68
	Trolley stock	(76.11)	
	Total	1883.69	1341.21

The proportion of patients bringing their own medications with them to SCGH, those leaving them behind and the value of these medications (value represents amount paid by SCGH rather than retail price paid by patient) during the study period is seen in Table 3.25.

Table 3.25

Number of patients leaving their own medications (brought with them to hospital) behind once discharged in ward stock (WS) and unit supply individual patient dispensing (USIPD)

Ward	% patients bringing drugs to SCGH	% patients leaving drugs at SCGH	Mean Value ($)*
A			
WS system	31.4	13.9	6.68
USIPD system	27.0	0	0
B			
WS system	28.4	6.3	9.43
USIPD system	24.6	0	0

In the WS system 44.2% of the patients on Ward A who brought their medications into SCGH left them behind at discharge and 22.2% on Ward B. This can represent both an inconvenience and cost to patients on discharge. In the USIPD system no patient left behind drugs they had brought to hospital.

Drug costs of individual patients was not done in the WS system. The average number of oral medications taken by each patient and the mean total cost of oral medications per patient in the USIPD system are shown in Table 3.26.

Table 3.26

Average value of oral medications consumed by patients over a two week study period in unit supply individual patient dispensing (USIPD) system

Ward	Mean Number oral drugs/patient	Mean total cost oral drugs/patient ($)
A	6.00 (n = 85)	9.44
B	5.56 (n = 62)	18.15

The cost of medications for patients on Ward B is greater than that for Ward A (by $8.71 per patient) due to the case-mix of patients on Ward B. This ward contained twenty four general surgical patients and six renal patients. The drugs prescribed to the renal patients (immunosuppressants, antihypertensives, antibiotics) contributed substantially to the overall cost of medications used by Ward B.

Drug security is a key issue in the WS system because of the potential for pilferage and the unordered administration of drugs. Results of the codeine containing analgesic's survey (Panadeine and Panadeine Forte) are shown in Table 3.27.

Table 3.27

Panadeine and Panadeine Forte doses recorded versus doses issued to Wards A and B in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

Ward	Panadeine	Panadeine Forte
	% doses recorded versus issued	% doses recorded versus issued
A		
WS system	75.0	42.0
USIPD system	95.0	100.0
B		
WS system	51.0	64.0
USIPD system	93.3	97.9

Discrepancies between the doses issued and those recorded as administered to the patient may occur because of failure to endorse the medication chart, errors in data collection, failure of once only doses to be charted, consumption of doses by ward staff, use of medication as discharge drugs and pilferage. Results show that the security of the USIPD is greater than in the WS system with almost all doses accounted for.

3.1.5 Medication Errors

There were no dispensing errors made by pharmacy during the USIPD study.

Medication errors detected in the WS and USIPD systems are shown in Table 3.28.[88]

Table 3.28

Type and frequency of medication errors in the ward stock (WS) and the unit supply individual patient dispensing (USIPD) systems

	Ward A		Ward B	
	Number of errors (%)		Number of errors (%)	
Error Type	WS	USIPD	WS	USIPD
Omission	1 (0.4)	2 (0.8)	12 (4.9)	5 (2.0)
Wrong dose	13 (5.3)	1 (0.4)	7 (2.8)	1 (0.4)
Extra dose	0	0	1 (0.4)	0
Unrecorded	1 (0.4)	0	0	0
Wrong form	1 (0.4)	0	1 (0.4)	0
Wrong drug	0	0	2 (0.8)	0
Wrong route	0	0	0	0
Documentation	5 (2.0)	0	10 (4.1)	3 (1.2)
Timing (minor)	126 (51.0)	87 (34.8)	67 (27.1)	50(19.8)
Timing (major)	8 (3.2)	8 (3.2)	14 (5.7)	4 (1.6)
Total	155 (62.8)	98 (39.2)	114 (46.2)	63(25.0)
Opportunities for error	247	250	247	252

The greatest contributors to medication errors were variations in administration time. These can be classified as minor (medication given between 30 minutes and two hours before or after the time prescribed to be given) or major (medication given more than two hours before or after the time prescribed to be given). With the exception of the rate of omissions observed on Ward A, all error categories showed a trend towards a reduction in the USIPD system. Statistical analysis was undertaken by collapsing all other than timing errors into an "others" category (Table 3.29).

Table 3.29

A comparison of timing and other errors in the ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

	Error	WS	USIPD		
Ward	type	No of errors (%)	No of errors (%)	χ^2	p value*
A					
	Timing (minor)	126 (51.0)	87 (34.8)	12.7	0.0004
	Timing (major)	8 (3.2)	8 (3.2)		NS
	Others	21 (8.5)	3 (1.2)	12.9	0.001
	Total errors	155 (62.8)	98 (39.2)	26.6	0.00005
Opportunities for error		247	250		
B					
	Timing (minor)	67 (27.1)	50 (19.8)		NS
	Timing (major)	14 (5.7)	4 (1.6)	4.9	0.045
	Others	33 (13.4)	9 (3.6)	14.3	0.0008
	Total errors	114 (46.2)	63 (25.0)	23.5	0.00005
Opportunities for error		247	252		

* Significant at $p \leq 0.05$, NS = not significant

In the WS system non-timing errors occurred in 21 of 247 (8.5%) opportunities for error on Ward A and 33 of 247 (13.4%) opportunities for error on Ward B. This is in comparison to the USIPD system where non-timing errors were made in 3 of 250 (1.2%) opportunities for error on Ward A and in 9 of 252 (3.6%) opportunities for error on Ward B.

The occurrence of medication administration errors during the various shifts is seen in Tables 3.30 to 3.33. Only those shifts observed by the pharmacist observer were included for analysis of medication error rates as it was felt the nurse observer had insufficient expertise to recognise the subtleties of drug dosage and form. As such the shift numbers and round numbers are not sequential.

Table 3.30

Ward A - Ward Stock System

Shift No	Round No	Opp for Error	Timing Errors	Other Errors
1	1-4	50	29	3
2	5-8	65	41	3
4	13-16	54	28	4
6	21-25	29	15	6
7	26-29	49	21	5
Total		247	134	21

Description of non-timing "other" errors

Shift 1 Wrong dose - phenindione 40mg charted, 10mg given

Wrong dose - Mylanta® 20ml charted, 30ml given

Documentation - paracetamol 500mg-1g charted, dose given not specified on chart

Shift 2 Wrong dose - potassium chloride SR 1200mg charted, 1800mg given

Unrecorded drug - artificial tears eye drops given, not charted

Wrong formulation - aspirin enteric coated 100mg charted, plain tablet given

Shift 4 Wrong dose - chlorothiazide 250mg charted, 500mg given

Wrong dose - frusemide 80mg charted, 40mg given

Wrong dose - paracetamol 500mg charted, 1g given

Documentation - Augmentin Forte® given, not signed for on chart

Shift 6 Wrong dose - sterculia granules 1 teaspoon charted, 2 teaspoons given

Wrong dose - diltiazem 120mg charted, 60mg given

Wrong dose - nifedipine 10mg tablet charted, 20mg tablet given

Documentation - beclomethasone inhaler given, not signed for on chart

Wrong dose - senna granules 2 teaspoons charted, 1 teaspoon given

Wrong dose - prednisolone 10mg charted, 15mg given

Shift 7 Wrong dose - Mylanta® 10ml charted, 15ml given

Wrong dose - prednisolone 40mg charted, 35mg given

Omission - nystatin oral suspension 1ml charted, not given

Documentation - paracetamol 500mg-1g charted, dose given not specified on chart

Documentation - theophylline SR 250mg given, not signed on chart

Table 3.31

Ward B - Ward Stock System

Shift No	Round No	Opp for Error	Timing Errors	Other Errors
12	43-45	8	4	0
13	46-49	23	12	2
14	50-51	14	2	3
15	52-56	31	11	2
16	57-59	23	8	1
17	60-64	25	15	2
20	71-75	24	6	7
22	80-81	20	12	5
23	82-83	31	6	6
24	84-85	22	2	2
25	86-88	26	3	3
Total		247	81	33

Description of non-timing "other" errors

Shift 13 Wrong dose - frusemide 40mg charted, 80mg given

Wrong dose - diltiazem 30mg charted, 60mg given

Shift 14 Wrong dose - metoprolol 25mg charted, 50mg given

Wrong dose - mianserin 20mg charted, 40mg given

Omission - potassium chloride SR 1200mg charted, not given

Shift 15 Documentation - paracetamol/codeine 1-2 charted, dose given not specified on chart

Documentation - paracetamol/codeine 1-2 charted, dose given not specified on chart

Shift 16 Wrong drug - ferrous sulphate 350mg given, ferrous sulphate/folic acid given

Shift 17 Omission - labetalol charted, not given

Documentation - salbutamol inhaler charted, signed but not given to patient

Shift 20 Wrong dose - ranitidine 150mg charted, 300mg given

Omission - paracetamol/codeine 30mg charted, not given

Omission - prochlorperazine 5mg charted, not given

Omission - nystatin oral lozenge charted, not given

Documentation - paracetamol 500mg-1g charted, dose given not specified on chart

Documentation - paracetamol 500mg-1g charted, dose given not specified on chart

Documentation - Bonjella® charted, signed for but not applied to patient

Shift 22 Wrong dose - sorbitol 30ml charted, 20ml given

Extra dose - paracetamol/codeine 30mg given before prescribed time interval

Wrong drug - metoprolol 100mg charted, ranitidine 150mg given

Omission - nystatin pessaries charted, not given

Documentation - metronidazole suppositories signed for, not given

Shift 23 Omission - frusemide 40mg charted, not given

Omission - ferrous sulphate/folic acid charted, not given

Omission - potassium chloride elixir charted, not given

Wrong dose - digoxin 125mcg charted, 62.5mcg given

Documentation - paracetamol 500mg-1g charted, dose given not specified on chart

Documentation - timolol 0.5% eye drops signed for, not given

Shift 24 Omission - salbutamol/ipratropium charted, ipratropium not given

Formulation - felodipine 5mg charted, 5mg SR given

Shift 25 Omission - atenolol 100mg charted, not given

Omission - captopril 12.5mg charted, not given

Documentation - cephalexin 500mg charted, given but not signed for

Table 3.32

Ward A - Unit Supply Individual Patient Dispensing System

Shift No	Round No	Opp for Error	Timing Errors	Other Errors
26	89-90	43	23	1
27	91-92	20	3	0
28	93-96	45	13	1
29	97-100	28	17	1
33	108-110	23	11	0
34	111-112	42	10	0
35	113-115	49	18	0
Total		250	95	3

Description of non-timing "other" errors

Shift 26 Omission - trimethoprim charted, not given

Shift 28 Wrong dose - potassium chloride SR 1200mg charted, 600mg given

Shift 29 Omission - metronidazole 200mg charted, not given

Table 3.33

Ward B - Unit Supply Individual Patient Dispensing System

Shift No	Round No	Opp for Error	Timing Errors	Other Errors
37	120-122	31	8	1
39	126-127	30	2	1
40	128-131	29	11	2
43	136-137	26	3	0
44	138-139	26	12	1
45	140-141	20	0	2
48	149-151	9	5	0
49	152-156	39	10	0
50	157-159	17	2	0
51	160-161	25	1	2
Total		252	54	9

Description of non-timing "other" errors

Shift 37 Omission - miconazole gel charted, not given

Shift 39 Omission - sorbitol charted, not given

Shift 40 Omission - sorbitol charted, not given

Documentation - bisacodyl tablets given, not signed for on chart

Shift 44 Wrong dose - felodipine SR 10mg charted, 5mg SR given

Shift 45 Documentation - salbutamol nebuliser given, not signed for on chart

Documentation - metronidazole 400mg given, signed for in wrong column

Shift 51 Omission - hydroxyzine 25mg charted, not given

Omission - cisapride 10mg charted, not given

3.1.6 Nursing opinion survey

The number of responses to the surveys at Time 1 (WS system) and Time 2 (USIPD system) were 38 and 41 respectively. The overall preference was for the USIPD system with 40 of the 41 respondents to the second survey preferring the USIPD system. One subject had no preference and no subject preferred the WS system. The total score of "satisfaction" with each system was derived by adding the score given to each of seven questions giving a range of possible scores between a minimum of 7 and a maximum of 49.

Results from each survey are shown in Table 3.34 and show that nurses were significantly more satisfied with the USIPD system ($t = -9.818$, $p = 0.0001$).

Table 3.34

Nursing satisfaction scores in ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

	Number of responses	Minimum	Maximum	Mean	Std Deviation
WS	38	19.0	40.0	29.26	± 4.6
USIPD	41	11.0	49.0	43.8	± 7.5

In examining each of the seven statements regarding medication related activity the responses were allocated into one of three groups. Given that 1 represented very

dissatisfied and 7 represented very satisfied, the results were grouped as follows; 1-3 dissatisfied, 4 ambivalent, 5-7 satisfied. Results are shown in Table 3.35.

Table 3.35

Responses to nursing satisfaction survey for ward stock (WS) and unit supply individual patient dispensing (USIPD) systems

1. How satisfied are you with the time it takes to administer oral medications?

	WS (%)	USIPD (%)
Dissatisfied	36.1	2.5
Ambivalent	36.1	10.0
Satisfied	27.8	87.5

2. How satisfied are you with the time taken for new orders of oral medication to arrive from pharmacy?

	WS (%)	USIPD (%)
Dissatisfied	33.3	2.8
Ambivalent	30.6	5.6
Satisfied	36.1	91.6

3. How satisfied are you with the availability of the keys to access drug trolleys/cupboards to administer oral medications?

	WS (%)	USIPD (%)
Dissatisfied	50.1	10.0
Ambivalent	16.6	15.0
Satisfied	33.3	75.0

4. How satisfied are you with oral medications being administered close to the time prescribed to be given?

	WS (%)	USIPD (%)
Dissatisfied	24.4	5.0
Ambivalent	18.9	2.5
Satisfied	56.7	92.5

5. How satisfied are you with prn oral medications being administered close to the time requested by the patient?

	WS (%)	USIPD (%)
Dissatisfied	10.8	2.5
Ambivalent	13.5	2.5
Satisfied	75.7	95.0

6. How satisfied are you with the amount of time that medication charts are away from the ward in pharmacy?

	WS (%)	USIPD (%)
Dissatisfied	36.1	2.8
Ambivalent	25.0	5.6
Satisfied	38.9	91.6

7. How satisfied are you with having enough time to administer oral medications?

	WS (%)	USIPD (%)
Dissatisfied	27.8	5.0
Ambivalent	36.1	0
Satisfied	36.1	95.0

3.2. Part Two - Error Probability

Over the 12 month period 343 errors were reported by nursing staff using the standard SCGH incident/accident report form. These error reports include all those submitted for all wards in the hospital and represent an average of 28.6 (range 15-47) reports per month or 1.3 reports per ward per month.

3.2.1 Error type

The number of errors made for each error category is shown in Table 3.36. The definitions of the eight types of medication errors are listed in Table 2.5.

Table 3.36

Errors reported by "self reporting" incident medication error system at SCGH over 12 months by error category

	Number of Errors	% of total errors
Omission	111	32.4
Wrong dose	63	18.4
Extra dose	47	13.7
Unordered drug	33	9.6
Wrong formulation	9	2.6
Wrong route	14	4.1
Documentation error	42	12.2
Timing - minor	3	0.9
Timing - major	21	6.1
Total	343	100

The greatest number of errors were reported in the omission category (32.4%), followed by wrong dose (18.4%) and extra dose (13.7%). In the omission category cardiovascular drugs (28.8%) were the largest drug group, followed by antibiotics (13.5%) and anticoagulants (12.6%) as seen in Tables 3.37 to 3.39.

Table 3.37

Drug groups involved in the omission, wrong dose and extra dose categories of errors self-reported by nursing staff at SCGH over 12 month period in the existing ward stock system

Drug Group	Omissions (%)	Wrong Dose (%)	Extra Dose (%)
Anticoagulant	14 (12.6)	22 (34.9)	4 (8.5)
Immunosupp/Chemo	2 (1.8)	0 (0)	1 (2.1)
Antidiabetic	9 (8.1)	2 (3.2)	1 (2.1)
Cardiovascular	32 (28.8)	6 (9.5)	5 (10.6)
Antibiotic	15 (13.5)	4 (6.3)	6 (12.8)
Electrolyte	2 (1.8)	4 (6.3)	0 (0)
Antiepileptic	6 (5.4)	6 (9.5)	1 (2.1)
Antipsychotic	4 (3.6)	2 (3.2)	8 (17.1)
Gastro	2 (1.8)	0 (0)	0 (0)
Sedative	0 (0)	1 (1.6)	1 (2.1)
Analgesic	5 (4.5)	8 (12.7)	13 (27.7)
Topical	2 (1.8)	1 (1.6)	0 (0)
Premedication	5 (4.5)	0 (0)	0 (0)
Others	13 (11.8)	7 (11.2)	7 (14.9)
TOTAL	111	63	47

Table 3.38

Drug groups involved in the documentation, unrecorded drug and timing categories of errors self-reported by nursing staff at SCGH over 12 month period in the existing ward stock system

Drug Group	Documentation (%)	Unrecorded (%)	Timing (%)
Anticoagulant	10 (23.8)	2 (6.0)	0 (0)
Immunosupp/Chemo	1 (2.4)	0 (0)	0 (0)
Antidiabetic	0 (0)	6 (18.3)	4 (16.7)
Cardiovascular	5 (11.9)	7 (21.3)	7 (29.1)
Antibiotic	6 (14.2)	3 (9.1)	3 (12.5)
Electrolyte	1 (2.4)	2 (6.0)	1 (4.2)
Antiepileptic	0 (0)	2 (6.0)	0 (0)
Antipsychotic	1(2.4)	3 (9.1)	0 (0)
Gastro	2 (4.8)	1 (3.0)	1 (4.2)
Sedative	0 (0)	0 (0)	0 (0)
Analgesic	10 (23.8)	4 (12.2)	3 (12.5)
Topical	2 (4.8)	1 (3.0)	0 (0)
Premedication	1 (2.4)	1 (3.0)	1 (4.2)
Others	3 (7.1)	1 (3.0)	4 (16.6)
TOTAL	42	33	47

Table 3.39

Drug groups involved in the wrong route and wrong formulation categories of errors self-reported by nursing staff at SCGH over 12 month period in the existing ward stock system

Drug Group	Wrong route (%)	Wrong form (%)
Anticoagulant	0 (0)	1 (11.12)
Immunosupp/Chemo	1 (7.14)	2 (22.22)
Antidiabetic	0 (0)	0 (0)
Cardiovascular	2 (14.29)	4 (44.44)
Antibiotic	4 (28.57)	0 (0)
Electrolyte	0 (0)	0 (0)
Antiepileptic	0 (0)	0 (0)
Antipsychotic	0 (0)	0 (0)
Gastro	0 (0)	0 (0)
Sedative	0 (0)	0 (0)
Analgesic	1 (7.14)	0 (0)
Topical	2 (14.29)	0 (0)
Premedication	0 (0)	0 (0)
Others	4 (28.57)	2 (22.22)
TOTAL	14	9

3.2.2 Drug group

The total number of errors made for each drug group is shown in Table 3.40. The fourteen drug groups are listed in Table 2.6.

Table 3.40

Errors reported by "self reporting" incident medication error system at SCGH over 12 months by drug group

Drug Group	Number of Errors	% of total errors
Anticoagulants	53	15.45
Immunosupp/Chemo	7	2.04
Antidiabetic	22	6.41
Cardiovascular	68	19.82
Antibiotic	41	11.95
Electrolyte	10	2.92
Antiepileptic	15	4.37
Antipsychotic	18	5.25
Gastrointestinal	6	1.76
Sedative	2	0.58
Analgesic	44	12.83
Topical	8	2.33
Premedication	7	2.04
Others	42	12.25
Total	343	100

3.2.3 Cause of error

The reason cited by the reporting staff member for the error occurring is shown in Table 3.41. Definitions of these reported causes are seen in Table 2.7.

Table 3.41

Errors reported by "self reporting" incident medication error system at SCGH over 12 months classified by reason for error (as reported)

Reason for Error	Number of Errors	% of Total Errors
Communication	30	8.75
Documentation	60	17.49
Knowledge Lack	24	7.00
Faulty Check	145	42.28
Workload	23	6.70
Lapse	61	17.78
TOTAL	343	

A faulty check was noted as the reason in 42.28% of error reports, followed by an unexplainable lapse (17.78%) and then by documentation difficulties (17.49%). A

faulty check was most commonly associated with a wrong dose being administered (26.20%) with 50% of these involving anticoagulant drugs. Extra doses (22.07%) and omissions (20.00%) were the next most common error types in the faulty check group.

Table 3.42

Percentage of errors for each reason given compared to the type of error made

(% of errors)

	Om	Dose	Extra	Unord	Form	Route	Doc	Time
Communication	46.8	10.0	3.3	13.3	0	3.3	10.0	13.3
Documentation	38.3	5.0	11.7	0	0	0	41.7	3.3
Knowledge Lack	12.5	41.7	4.2	0	20.8	20.8	0	0
Faulty Check	20.0	26.2	22.2	12.4	2.7	4.1	7.6	4.8
Workload	39.1	21.7	8.7	13.1	0	0	8.7	8.7
Lapse	54.1	6.6	6.6	13.1	0	3.3	1.6	14.7

The drug groups involved in each of the reasons cited for the error occurring can be seen in Tables 3.43 to 3.48.

Table 3.43

Drug groups involved in those self-reported errors, over the 12 month period at Sir Charles Gairdner Hospital, cited as communication errors

Drug Group	Number of Errors	% of total errors
Anticoagulants	3	10.0
Immunosupp/Chemo	0	0
Antidiabetic	3	10.0
Cardiovascular	4	13.3
Antibiotic	3	10.0
Electrolyte	1	3.3
Antiepileptic	4	13.3
Antipsychotic	0	0
Gastrointestinal	0	0
Sedative	0	0
Analgesic	4	13.3
Topical	1	3.3
Premedication	3	10.0
Others	4	13.3
Total	30	100

Table 3.44

Drug groups involved in those self-reported errors, over the 12 month period at Sir Charles Gairdner Hospital, cited as documentation errors

Drug Group	Number of Errors	% of total errors
Anticoagulants	9	15.0
Immunosupp/Chemo	1	1.7
Antidiabetic	3	5.0
Cardiovascular	15	25.0
Antibiotic	9	15.0
Electrolyte	2	3.3
Antiepileptic	2	3.3
Antipsychotic	1	1.7
Gastrointestinal	2	3.3
Sedative	0	0
Analgesic	9	15.0
Topical	2	3.3
Premedication	0	0
Others	5	8.3
Total	60	100

Table 3.45

Drug groups involved in those self-reported errors, over the 12 month period at Sir Charles Gairdner Hospital, cited as lack of knowledge errors

Drug Group	Number of Errors	% of total errors
Anticoagulants	3	12.5
Immunosupp/Chemo	1	4.2
Antidiabetic	0	0
Cardiovascular	6	25.0
Antibiotic	3	12.5
Electrolyte	0	0
Antiepileptic	0	0
Antipsychotic	0	0
Gastrointestinal	0	0
Sedative	1	4.2
Analgesic	4	16.6
Topical	1	4.2
Premedication	1	4.2
Others	4	16.6
Total	24	100

Table 3.46

Drug groups involved in those self-reported errors, over the 12 month period at Sir Charles Gairdner Hospital, cited as faulty check errors

Drug Group	Number of Errors	% of total errors
Anticoagulants	30	20.7
Immunosupp/Chemo	4	2.8
Antidiabetic	11	7.6
Cardiovascular	21	14.5
Antibiotic	15	10.3
Electrolyte	6	4.1
Antiepileptic	8	5.5
Antipsychotic	9	6.2
Gastrointestinal	3	2.1
Sedative	1	0.7
Analgesic	19	13.1
Topical	2	1.4
Premedication	2	1.4
Others	14	9.6
Total	145	100

Table 3.47

Drug groups involved in those self-reported errors, over the 12 month period at Sir Charles Gairdner Hospital, cited as workload errors

Drug Group	Number of Errors	% of total errors
Anticoagulants	5	21.8
Immunosupp/Chemo	0	0
Antidiabetic	4	17.4
Cardiovascular	4	17.4
Antibiotic	3	13.0
Electrolyte	1	4.3
Antiepileptic	0	0
Antipsychotic	2	8.7
Gastrointestinal	0	0
Sedative	0	0
Analgesic	2	8.7
Topical	0	0
Premedication	0	0
Others	2	8.7
Total	23	100

Table 3.48

Drug groups involved in those self-reported errors, over the 12 month period at Sir Charles Gairdner Hospital, cited as lapse errors

Drug Group	Number of Errors	% of total errors
Anticoagulants	3	4.9
Immunosupp/Chemo	1	1.6
Antidiabetic	1	1.6
Cardiovascular	18	29.6
Antibiotic	8	13.1
Electrolyte	0	0
Antiepileptic	1	1.6
Antipsychotic	6	9.9
Gastrointestinal	1	1.6
Sedative	0	0
Analgesic	6	9.9
Topical	3	4.9
Premedication	0	0
Others	13	21.3
Total	61	100

3.2.4 Probability ranking

The probability ranking of all errors reported is shown in Table 3.49. Definitions of the error probability ranking system are seen in Table 2.8. The scores shown represent an aggregate of three scores given for each error.[75] A maximum of ten points was given for each of the following; probability of occurrence of error, probability of detecting error and probability of error causing harm to the patient. A maximum score of thirty was possible, with a score of three being the minimum (minimal probability of error occurring, maximum probability of error being detected and minimal probability of causing harm to the patient) and thirty being the maximum (high probability of error occurring, minimal probability of error being detected and maximum probability of error being fatal to the patient). No error reported scored under 7 or over 24 with the majority (78%) scoring between 12 and 17. Of the 343 errors reported 71.7% scored 15 or more points while 28.3% scored less than 15 points.

Table 3.49

Errors reported by "self reporting" incident medication error system at Sir Charles Gairdner Hospital over 12 months by probability ranking (minimum score of three and maximum score of thirty possible)

Total Probability Ranking	Number of Errors	% of total errors
7	1	0.29
8	5	1.46
9	9	2.62
10	10	2.92
11	19	5.54
12	37	10.79
13	63	18.37
14	44	12.83
15	58	16.91
16	40	11.66
17	25	7.29
18	18	5.25
19	6	1.75
20	3	0.87
21	2	0.58
22	0	0
23	2	0.58
24	1	0.29
Total	343	

Approximately 10% of errors, seen in Table 3.50, scored 18 points or more. While the top 10% of errors was chosen as an arbitrary cut-off, these errors can be considered the most serious errors of those reported.

Table 3.50

Top 10% of errors, scoring 18 points or more, indicating error type, breakdown of score (score out of ten each for occurrence, detection and harm) and drug group involved

Score	Drug	Error Type	Reason	Occurrence	Detection	Harm
18	Premed	Omission	Communication	6	8	4
18	C'vasc	Documentation	Documentation	8	3	7
18	C'vasc	Extra Dose	Check	6	6	6
18	C'vasc	Unrecorded	Check	6	5	7
18	C'vasc	Extra Dose	Check	5	6	7
18	C'vasc	Wrong Dose	Workload	5	7	6
18	A'coag	Wrong Dose	Check	7	3	8
18	A'coag	Extra Dose	Documentation	7	6	5
18	C'vasc	Formulation	Lack	6	6	6
18	C'vasc	Omission	Communication	9	2	7
18	A'coag	Wrong Dose	Check	7	3	8
18	Analgesic	Extra Dose	Lapse	7	6	5
18	C'vasc	Formulation	Lack	7	4	7
18	Antibiotic	Route	Lack	5	6	7

18	Analgesic	Wrong Dose	Lack	5	4	9
18	Antibiotic	Omission	Check	5	5	8
18	Analgesic	Extra Dose	Check	7	6	5
18	Antibiotic	Major Timing	Check	7	2	9
19	A'diabetic	Extra Dose	Documentation	7	5	7
19	Antibiotic	Extra Dose	Check	7	3	9
19	C'vasc	Unrecorded	Check	6	6	7
19	Antibiotic	Extra Dose	Check	6	5	8
19	Immunosup	Omission	Check	7	4	8
19	C'vasc	Omission	Documentation	7	6	6
20	Antibiotic	Omission	Documentation	6	7	7
20	Other	Wrong Dose	Documentation	7	6	7
20	C'vasc	Formulation	Lack	6	7	7
21	C'vasc	Extra Dose	Documentation	8	7	6
21	A'coag	Wrong Dose	Check	6	7	8
23	C'vasc	Extra Dose	Documentation	8	8	7
23	C'vasc	Omission	Documentation	7	8	8
24	A'diabetic	Unrecorded	Check	8	8	8

Of the 32 errors submitted with ranking scores over 18 points, the predominant drug group was cardiovascular (43.8%), error type was extra dose (31.2%) and reason cited was checking error (43.8%). Table 3.51 shows the drug groups, error types and reason cited for the top 10% of errors according to probability ranking.

Table 3.51

Drug group, error type and reason for error cited for top ranking 10% of errors on self-reported medication error incident report forms submitted over 12 month period at Sir Charles Gairdner Hospital

	Number of errors (%)	
Drug Group	Error Type	Reason Cited
C'vasc 14 (43.8)	Extra Dose 10 (31.2)	Check 14 (43.8)
Antibiotic 6 (18.8)	Omission 7 (21.9)	Documentation 9 (28.2)
A'coag 4 (12.5)	Wrong Dose 6 (18.8)	Lack 5 (15.6)
Analgesic 3 (9.4)	Formulation 3 (9.4)	Communication 2 (6.2)
A'diabetic 2 (6.2)	Unrecorded 3 (9.4)	Lapse 1 (3.1)
Premed 1 (3.1)	Documentation 1 (3.1)	Workload 1 (3.1)
Immunosup 1 (3.1)	Route 1 (3.1)	
Other 1 (3.1)	Time-major 1 (3.1)	

3.3 Part Three - Failure Mode and Effects Analysis and No-blame Reporting

3.3.1 Failure Mode and Effects Analysis

Failures identified in the WS system are shown in Table 3.52. Breakdown of the WS system into individual steps is seen in Figure 2.1. Each of the steps was studied with potential errors, based on detailed knowledge of the system, highlighted. In addition, answers given by nursing staff during the nurses' opinion survey (Table 3.35) and in the informal comment section were considered.

Table 3.52

System Failures Identified in the Ward Stock (WS) system

A. Availability

a) Drug availability from pharmacy, other wards, outside pharmacy hours

b) Trolley availability at medication round times

c) Key availability to access imprest cupboard and drug trolley

B. Review/Double Check

a) No review of medication chart by pharmacist prior to first dose being given

b) No patient profile kept by pharmacy for review and costing purposes

C. Selection

a) Large number of drugs to choose from in imprest cupboard

b) Large number of drugs to choose from drug trolley

c) Drugs able to be given without order due to availability

d) Multiple strengths, formulations and drugs with similar names available

D. Patient Issues

a) Limited opportunity for patient education

E. Nursing Time Issues

a) Length of time required to attend to medication related duties

b) Interruption level

The limited availability of drugs from the pharmacy, from wards other than the study wards, and outside pharmacy hours was a potential source of errors because it increased the possibility of a dose being omitted or late and of time being wasted by nurses trying to locate drugs rather than attending to other duties. The solution proposed was access to pharmacy dispensed drugs for extended hours. Lack of ready access to both the drug trolley and the imprest cupboard in the WS system had the potential to cause both omission and timing errors. This was addressed in the USIPD system by issuing a master key to all bedside drawers on the ward to each nurse at the start of each shift.

Data for both study wards indicate a reduction in the number of timing errors in the USIPD system (Table 3.29). This result is to be expected, given the improvement in access (each nurse was able to administer medications to patients without having to wait for the drug trolley or keys).

The problem of lack of review and double checking in the WS system was addressed by changing the method of drug distribution to the wards to an individual-patient system. In the WS system, there was no mechanism for the chart to be reviewed by a pharmacist before a nurse gave the first dose of a medication. Charts were routinely reviewed by pharmacists during their daily ward rounds Monday to Friday but would not be seen over the weekend or after 1700 (depending on when the patient was admitted). Similarly, no patient profile was kept by pharmacy for review or cost analysis purposes. These factors could contribute to the wrong drug or formulation being given to a patient and to omission errors if nurses do not notify the pharmacist of drug requirements after they have completed their drug administration round.

Omission errors may, however, be less likely in the WS system because of the ready availability of a large stock (provided the nurse can locate the required drug). In the USIPD system, all medication charts were reviewed by a pharmacist, and drugs were then dispensed to the individual patients (except for a few patients admitted before 0800 or after 2000). The nurse administering the medications would choose them from the patient specific supply provided by the pharmacy, thus enabling a double check by dispenser and nurse. A patient profile was kept in the satellite pharmacy to provide a record of the drugs dispensed and make it easier to track the drugs' cost.

The selection of drugs available on the ward was also identified as a potential problem area. During the two-week study period of the WS system, an average of 63 items (range 46-87) were stored in each trolley on the medical ward and an average of 58 items (range 38-74) in each trolley on the surgical ward. A large number of items present on trolleys and in cupboards can lead to omission errors (since it may be difficult to find the correct drug) and to the administration of wrong doses, extra doses, unordered drugs and wrong formulations.

The quantity of drugs available in the imprest cupboard was reduced and the drug trolley was removed, thus limiting the number of drugs, strengths and formulations available, increasing security and reducing the possibility of administering a drug without a physician's order.

The storage of drugs for individual patients in bedside drawers limited the number of drugs to select from and, if the drawers had been correctly filled by the pharmacy, ensured the correct drug, strength and formulation.

During the trial of the USIPD system, each ward had an average of 6 items per bedside drawer (range 1-14 for the medical ward and 0-12 for the surgical ward). The USIPD system reduced the number of drugs in the imprest cupboard to the minimum for after-hours emergency use and reduced the number of drugs the nurse had to select from to give a patient (the stock in the bedside drawer was smaller than that in the drug trolley).

Patient issues identified as failure modes of the WS system were not specifically addressed in the design of the USIPD system and were considered beyond the scope of this study. Increased opportunities for patient education may be possible, however, if more time is available to nursing and pharmacy staff.

3.3.2 No-blame self-reporting in existing system (Phase One) and Failure Mode and Effects Analysis system (Phase Two)

The control ward, Ward D, had two reports submitted during Phase One of the study on Ward C and one report submitted during Phase Two of the study on Ward C.

The no-blame errors reported on Ward C during Phases One and Two are seen in Table 3.53.

Table 3.53

Self-reported medication errors in Ward Stock (WS) System and Failure Mode and Effects Analysis (FMEA) System and Extrapolated in Disguised-Observer Ward Stock (DO-WS) System

	Number of Errors (% of errors)		
Error Type	WS System (23 days) Reported	FMEA System (31 days) Reported	DO-WS[a] (31 days) Extrapolated
Omission	66 (36.3)	47 (27.6)	358 (10.5)
Wrong dose	3 (1.7)	4 (2.4)	209 (6.1)
Extra dose	2 (1.1)	2 (1.2)	30 (0.9)
Unordered drug	1 (0.5)	1 (0.6)	60 (1.8)
Wrong formulation	1 (0.5)	1 (0.6)	30 (0.9)
Wrong route	0	0	0
Inadequate documentation	39 (21.4)	67 (39.4)	298 (8.8)
Wrong time (minor)	24 (13.2)	15 (8.8)	1997 (58.7)
Wrong time (major)	46 (25.3)	33 (19.4)	417 (12.3)
TOTAL ERRORS	182[b]	170[b]	3398

[a] Extrapolated from data from Part One of the study (estimated 237 opportunities for error per ward per day for 30 bed ward at SCGH)

[b] Significantly different ($\chi^2 = 11.91$, $p < 0.001$)

Omissions, inadequate documentation and timing errors (minor and major) constituted the majority of errors in both reported phases. The number of errors reported over 31 days in Phase Two of the study was significantly different to those reported in Phase One ($\chi^2 = 11.91$, $p < 0.001$). Data collected over the first 23 days of Phase Two of the study were also analysed and found to be significantly different to Phase One, indicating no period effect.

Extrapolating the number of observations made during each nursing shift observed in Part One of the study, it is estimated that approximately 237 opportunities for error occur on each ward each day (for 30 bed ward at SCGH). Approximately 660 non-timing errors would be made during a three week period at SCGH. In this section of the study 112 non-timing errors were reported over 23 days using no-blame self-reporting in existing drug distribution system and 122 non-timing errors over 31 days in the FMEA designed phase.

A variable number of reports were submitted each day through both phases of the study (Table 3.54).

Table 3.54

Number of "no-blame" error reports submitted each day in Phase One ward stock system and Phase Two Failure Mode and Effects Analysis designed system

	Number of error reports submitted	
Day	Phase One	Phase Two
1	2	4
2	7	11
3	18	3
4	9	0
5	16	2
6	5	2
7	4	8
8	8	8
9	16	4
10	6	3
11	10	1
12	24	4
13	1	8
14	4	7
15	15	11
16	8	4
17	6	8
18	12	4
19	5	3
20	0	3
21	3	10
22	2	12
23	1	10
24		5
25		4
26		3
27		3
28		5
29		9
30		7
31		4
TOTAL	182	170

Regression analysis of this data indicated a slope of -0.308 ± 0.378 for Phase One (over 23 days) and 0.0307 ± 0.138 for Phase Two (over 31 days). The slope value for Phase Two from 0 to 23 days was 0.193 ± 0.220. None is significantly different from zero.

For comparative purposes data extrapolated from Part One of the study are also seen in Table 3.55. The most commonly documented errors observed using the disguised-observer technique were omissions, wrong doses, inadequate documentation and timing errors. A summary of errors detected and reported in all three parts of the study can be seen in Table 3.55.

Table 3.55

% errors detected using direct-observer (DO) technique, self-reported incident (SR) technique and "no-blame" (NB) reporting technique.

	% errors detected						
	System Tested*						
	1	2	3	4	5	6	7
Omission	0.6	10.5	2.1	7.9	32.4	36.3	27.6
Wrong dose	8.4	6.1	1.0	1.6	18.4	1.7	2.4
Extra dose	0	0.9	0	0	13.7	1.1	1.2
Unordered drug	0.6	1.8	0	0	9.6	0.5	0.6
Wrong form	0.6	0.9	0	0	2.6	0.5	0.6
Wrong route	0	0	0	0	4.1	0	0
Documentation	3.2	8.8	0	2.6	12.2	21.4	39.4
Timing - minor	81.3	58.8	88.8	79.4	0.9	13.2	8.8
Timing - major	5.1	12.3	8.2	6.3	6.1	25.3	19.4

* Systems tested

1. DO-WS (A) - direct observer technique, ward stock system Ward A (Part One)
2. DO-WS (B) - direct observer technique, ward stock system Ward B (Part One)
3. DO-USIPD (A) - direct observer technique, unit supply individual patient dispensing system Ward A (Part One)
4. DO-USIPD (B) - direct observer technique, unit supply individual patient dispensing system Ward B (Part One)
5. SR-SCGH - Self-reported medication error incident reporting, ward stock system, all wards SCGH over 12 months (Part Two)
6. NB-WS (Phase One) - "no-blame" medication error reporting, ward stock system, Phase One Ward C (Part Three)
7. NB-WS (Phase Two) - "no-blame" medication error reporting, ward stock system Phase Two (interventions) Ward C (Part Three)

4. DISCUSSION

Research into the occurrence, detection and reduction of medication administration errors has been reported in the literature over the past thirty five years. Initial research reported by Barker and McConnell [1] in 1962 alerted the pharmacy community and wider hospital community to the incidence and possible consequences of medication errors. This work contributed to the development of unit dose drug distribution aimed at reducing these errors. Unit dose drug distribution was found to reduce the rate of medication administration error rate as well as reduce drug costs and nursing time. There has been little research into the error rate in ward stock distribution systems. Similarly, little has been reported regarding direct comparison between the error rate and other parameters in ward stock and individual patient dispensing systems within the same hospital setting. This study prospectively compared two methods of drug distribution in terms of nursing and pharmacy time, drug costs and medication errors. Approximately 1000 opportunities for error were observed during the study.

Failure mode and effects analysis has not been widely used in the medical setting though it is used extensively in many other industries. Analysis is directed at the identification of problem areas with the potential to cause an error within a system. FMEA was employed in this study to design a medication distribution system, with the specific aim of reducing error occurrence. This research is the first in Australia and one of the first in the world to apply systems analysis to a ward stock medication system distribution in hospitals.

The development by Barker and McConnell [1] of the disguised-observer technique for the detection of medication errors has become the bench-mark method for identifying the rate of occurrence of medication errors within a distribution system. This method,

while the most accurate, is labour intensive to administer and cannot be used on a continuous basis. The problem of detecting the occurrence of errors on an ongoing basis, for quality assurance and safety reasons has remained. Other workers have assessed the viability of various methods of reporting medication errors such as anonymous self-reporting and incident/accident reporting. This study uses the disguised-observer technique to assess the error rate, analyses those errors reported by staff under the existing incident report scheme and also assesses the use of a no-blame self-reported method. This research is the first of its kind in Australia. The advantages and issues associated with the disguised observer technique were discussed in the introduction (Pages 33-35).

The clinical significance of the medication errors has been studied elsewhere.[18,53,63] Since such research has been documented in the literature errors detected in this study were not evaluated with respect to the adverse effect on the patient.

This study contributes to the literature on the topic of medication errors by providing current information in three areas; comparison of the WS and USIPD methods of drug distribution in terms of medication errors, nursing time, pharmacy time, drug costs and the opinion of nursing staff was made; use of FMEA to detect problem areas with the potential to cause errors in the existing WS system; and the use of no-blame error reporting to assess the rate and nature of error reporting achievable in a non-punitive setting.

4.1 Part One - Ward Stock versus Unit Supply Individual Patient Dispensing

4.1.1 Ward comparisons during ward stock and unit supply systems

A comparison of the two wards during each method of drug distribution (WS and USIPD) was undertaken to assess whether the wards were unusually busy or quiet at any time during the study period. Staff workload is altered appreciably depending on the number of patients present on the ward, the number of admissions and discharges daily and the number of bed changes within the ward. No attempt was made to compare the case-mix of patients on the wards under each distribution system. Table 3.1 shows a similar throughput of patients for each ward in the WS and USIPD systems. Patient numbers and movements seen during the study period would, therefore, not be expected to have a significant influence on nursing workload.

4.1.2 Observers

Correlation between the two observers was found to be high for simultaneous observations of nursing time made. A correlation of 89.2% was found at the start of data collection for the WS system and 91.2% correlation at the start of the USIPD data collection. As seen in Table 3.2, more shifts were observed by observer one. This was because observer one (pharmacist observer) was involved in the observation of nursing staff for timing purposes and for medication error purposes. It was considered that observer two (nurse observer) was not sufficiently familiar with the details of medication formulation, dose and identification to make observations suitable for the detection of medication errors. Therefore the required number of

opportunities for error to be observed necessitated additional shifts being monitored by observer one.

A greater number of rounds were observed for Ward B in both the WS and USIPD systems as seen in Table 3.2. This was due to the nature of patient allocation. Nurses on Ward B were allocated 6 patients to care for, including administration of medications, during the shift. Ward A used a system whereby three nurses on the ward were allocated ten patients to administer medications to during the shift. As such, the predetermined number of observations required took longer to accumulate on Ward B than Ward A, necessitating a greater number of rounds and shifts being observed.

4.1.3 Nursing volunteers

Fourteen nurses were observed during the study. On Ward A, six nurses (24% of nursing staff) volunteered to be observed during the study. Eight nurses (33% of nursing staff) volunteered on Ward B. Due to requirements for ethics approval of this study, only those nurses who volunteered could be observed. The voluntary nature of the nursing staff observed can be considered a limitation of the study since those nurses with the best practice, most experience or highest confidence may have been the only ones who felt comfortable volunteering. This could possibly reduce the number of errors made and also minimise the time spent undertaking medication related activities. In addition, using timing as the "disguise" to detect medication errors may have caused the nurses to rush somewhat which may have affected the

error rate. However, the same techniques were used to evaluate both systems on both wards with each ward acting as its own control. Allan and Barker discussed the issue of observer influence and stated that concern that observers make a subject either more nervous or more careful seem unfounded with normal behaviour resuming within one to three hours of the initial observation.[6] Barker [70] also stated that evidence indicates that, with respect to disguised observation, the observers' presence does not affect most research very much.

4.1.4 Nursing time

The number of times each of the fourteen nurses were observed along with the time spent during those shifts on medication related activities is seen in Table 3.3 and in Appendices 1 to 4. Variability in the number of shifts and involvement in one or both phases of the study was due to rostering and other commitments of the nursing staff.

Nursing time required to undertake medication related activities is seen in Tables 3.4 to 3.9. Table 3.4 shows the mean time spent by nursing staff on all medication related activities for both wards in both systems. Differences in total time between the two wards may be accounted for by the variation in patient allocation to nursing staff for medication administration purposes as previously described. A statistically significant ($p = 0.02$) time saving was seen on Ward A. A 27.2 minute saving per shift was noted which represents a 29.8% reduction in time spent by nursing staff on all medication-related activities in the USIPD compared to the WS system. For Ward B, a 15.9 minute per shift time saving was detected. This represents a 28.8%

reduction in time spent by nurses in the USIPD system but was not found to be statistically significant ($p = 0.07$). The method of patient allocation to nursing staff for medication administration purposes may account for this finding.

Time taken by nursing staff to undertake the various medication related activities is shown in Tables 3.5 to 3.9. Table 3.5 presents the mean time taken by nurses to administer individual medications during the usual medication rounds. Time taken was reduced by 21.7 seconds (20.2%) on Ward A and 14.0 seconds (15.6%) on Ward B in the USIPD system. This result is expected since the number of items (medication bottles or packets) was limited in the USIPD system to those prescribed for the patient, compared to the drug trolley used in the WS system. As such the number of items to choose from was less in the USIPD system, therefore reducing the time taken by nurses to identify and prepare the individual medication for the patient.

Table 3.6 shows the mean time taken by nurses to administer all medications to each patient during the usual medication rounds. As seen in Table 3.5, the time taken was reduced in the USIPD system by 7.7 seconds (3.9%) on Ward A and 25.8 seconds (14.7%) on Ward B compared to the WS system. The primary reason for the time reduction seen is, again, related to the identification and preparation of the medication in the USIPD system since all medications required for the patient were readily available in the bedside drawer.

Table 3.7 presents the mean time taken by nurses to administer individual medications outside usual medication rounds. This table depicts the time taken outside the regular rounds and therefore includes medications prescribed to be given

at unusual times and also those "as required" medications requested at various times by the patients themselves. Time taken was reduced by 80.0 seconds (53.1%) for Ward A and 54.0 seconds (62.1%) on Ward B in the USIPD system compared to the WS system. The reason for this time reduction mainly relates to the time taken in the WS system to walk from the nurses' station to the patient, identify the patients' requirements, walk back to the drug trolley, obtain the medication, walk back to the patient to then administer the medication. In the USIPD system the nurse was able to administer the medication directly from the patients' bedside drawer, eliminating the need to walk back to the drug trolley and then return.

Similar reasons are likely for the results seen in Table 3.8. In this table the mean times taken by nurses to administer all medications to each patient outside the usual rounds is presented. Time taken was reduced by 183.7 seconds (70.7%) for Ward A and by 72.1 seconds (60.5%) for Ward B in the USIPD system.

Table 3.9 shows the mean time taken by nurses to perform all other medication related activities. These data are divided into the time taken during and outside the usual rounds. In the USIPD system, there was a 231.9 second (37.8%) time saving on Ward A and a 477.9 (76.2) second saving on Ward B during the usual rounds. Outside the usual rounds there was a 475.3 second (98.3%) saving on Ward A and a 352.0 second (98.5%) saving on Ward B for the USIPD system. The difference in time taken to perform all other medication related activities in the USIPD system was the largest contributor to the time difference between the two systems of drug distribution. These other duties included ordering drugs, replenishing drug trolleys, tidying drug trolleys and locating drugs after pharmacy hours. These functions were

essentially eliminated from the nurses' duties in the USIPD system, thus creating the overall nursing time saving.

Analysis of the data, by t-test, for Ward A is shown in Table 3.10. Differences between the WS and USIPD system on Ward A for the total time taken to administer drugs and the time taken to perform all tasks was found to be not statistically significant. The difference in time taken to perform all tasks relates to the change in work pattern in the USIPD system with respect to the ordering, storage and disposal of medications. As seen in Tables 3.4 and 3.9 all other medication related activities constituted 20.0% of the time spent by nurses in medication related activities per shift in the WS system, compared to 10.2% in the USIPD system. Large variations in the standard deviations were associated with the inconsistent work patterns of the nursing staff in relation to the nature of medication administration. While there is a trend towards time savings in the USIPD system, a larger study would be required to demonstrate statistical significance.

Table 3.11 presents the analysis, by t-test, of data for Ward B. As seen for Ward A, there was no statistical difference in the total time taken to administer drugs but there was a difference in the time taken to perform all tasks. Time taken to perform all other medication related activities constituted 30.22 % of the time spent by nurses in medication related activities per shift in the WS system, compared to 6.55% in the USIPD system.

Also tested, using the t-test, was any difference between the two drug distribution systems as seen in Table 3.12. Differences between the WS and USIPD systems were

found to be not significant for the time taken to administer drugs, but were found to be significantly different for the time taken to perform all tasks.

The Mann-Whitney test was also used to identify differences between the ward and the system on the total time taken to administer drugs and the total time taken to perform all medication related tasks for Wards A and B. As seen in Table 3.13, an association with the system (WS or USIPD) was found for the total time taken to perform all tasks ($p = 0.000$) but not for the total time taken to administer drugs ($p = 0.637$). Table 3.14 shows an association with the wards tested (Ward A and Ward B) was found for both the total time taken to perform all medication related tasks ($p = 0.001$) and the total time taken to administer drugs ($p = 0.000$).

Tables 3.15 and 3.16 show differences between Wards A and B in the time taken to administer drugs and time taken to perform all tasks in the WS and USIPD systems using one way analysis of variance. There was a significant difference in the time taken to administer drugs and in the time taken to perform all medication related tasks between the two wards.

Tables 3.17 and 3.18 show differences between the WS and USIPD systems in the time taken to administer drugs and the time taken to perform all medication related tasks on Wards A and B using one way analysis of variance. The time taken to administer drugs was found not to be significantly different in the two systems but the time taken to perform all tasks was found to be significantly different.

Two way analysis of variance, using natural log transform, was also undertaken to assess differences between the wards (Ward A and B) and the drug distribution systems (WS and USIPD) simultaneously. Table 3.19 shows a significant difference

between the wards (p = 0.000) but not the systems (p = 0.568) with respect to the total time taken to administer drugs. Table 3.20 shows a significant difference between the wards (p = 0.005) and the systems (p = 0.000) with respect to the time taken to perform all medication related tasks. The model is seen to have predictive power.

Differences between the groups was also studied. Groups were designated as Ward A-WS system, Ward B-WS system, Ward A-USIPD system, Ward B-USIPD system. Results found using the contrast coefficient matrix showed no difference in the time taken to administer drugs between Ward A-WS system and Ward B-WS system or between Ward A-USIPD system and Ward B-USIPD system. There was, however, a significant difference between the WS system (Ward A-WS system and Ward B-WS system combined) and the USIPD system (Ward A- USIPD system and Ward B-USIPD system combined) for the total time taken to administer drugs. This demonstrates that the total time taken to administer drugs is reduced in the USIPD system compared to the WS system.

Also studied was the time taken to perform all tasks. Using the contrast coefficient matrix it was found that there was no significant difference between Ward A-WS system and Ward B-WS system but there was a significant difference between Ward A-USIPD system and Ward B-USIPD system. There was also a significant difference found between the WS system (Ward A-WS system and Ward B-WS system combined) and the USIPD system (Ward A-USIPD system and Ward B-USIPD system combined).

The time taken for nursing staff to give each medication related to the number of medications given is seen in Table 3.21. The number of drugs given to a patient during a single medication round ranged from zero to nine. The mean time taken to give each medication ranged from 13.86 seconds to 32.00 seconds. The minimum time taken to give a medication was 2 seconds and the maximum time was 269 seconds. The time taken relates to the number of other medications present for the administering nurse to choose from, the nurses' interpretation of the orders on the medication chart and the ease of removal of the tablet/capsule from the packaging.

Time taken by nursing staff to perform all other medication related activities during the observed medication rounds is shown in Table 3.22. The possible contributors to time taken such as patient requirements, interruptions, walking to the cupboard, locking the trolley etc were variable for each drug administered and ranged widely from 13.37 seconds (locking trolley/drawer) to 620.91 seconds ("others" ie; cleaning out drug trolley, returning stock). The medication administration rounds undertaken by nursing staff were often disjointed in nature due to multiple interruptions by patients, medical staff, relatives etc combined with a variety of other tasks such as restocking the drug trolley when an item has "run out", finding the drug chart and tending to patients requests. The unpredictable nature of the rounds prolongs time spent involved in medication related activities and also contributes to the occurrence of medication administration errors. The USIPD system addressed a number of nursing time related issues by reducing the amount of time spent locating keys, drug charts and drug trolleys, eliminating time taken to wheel the drug trolley, order drugs

and restock the drug trolley and also by eliminating the need to clean out the drug trolleys and return unwanted stock to pharmacy for salvage or destruction.

A reduction in total time taken by nurses in all medication related activities of 29.8% on Ward A and 28.8% on Ward B was seen in the USIPD system (Table 3.4). Schnell [92] reported a reduction in nursing time in a unit dose distribution system of 12%, 27%, 38% and 41% compared to the ward stock systems of four Canadian hospitals. Rivers et al [38] demonstrated a 34% decrease in nursing time between a ward stock system and a controlled dosage distribution system. Simborg et al [93] reported a reduction of 22.2%, from 39.9% to 17.7%, when comparing nursing time in a ward stock system to a unit dose distribution system. Direct comparison is difficult given the variation in drug distribution systems reported, however this study demonstrates a reduction in nursing time comparable to other work. Wide variability seen in the data seen in nursing time taken to perform medication related activities indicate that very large studies, beyond the scope of this one, are necessary to reach statistical differences.

4.1.5 Pharmacy time

Pharmacy time spent on drug distribution in the two methods of drug distribution was variable according to the function of the staff (Table 3.23). The USIPD system was more pharmacy labour intensive than the WS system in all areas except the junior technician whose role was not required during the USIPD system study. Time spent on drug distribution by both the senior pharmacy technician and pharmacist

were significantly increased in the USIPD system due to the more labour intensive nature of individual patient dispensing and the extension of pharmacy hours of service. The effects of the extension of pharmacy hours and the installation of the satellite was not isolated. The satellite pharamacy and increased pharmacist availability was, however, integral to the USIPD system.

The junior pharmacy technician, whose main role was to assist with dispensing in central pharmacy and deliver medication to the wards, was not required in the USIPD system in terms of the day to day running of the satellite pharmacy.

The role of the senior pharmacy technician was integral to the USIPD system. In the WS system the senior technician was responsible for restocking the imprest cupboard. In the USIPD system, the senior technician was involved in the daily functions of the satellite pharmacy, ie. stock control, collection of medication charts, dispensing support, placement of dispensed medications into the bedside drawer and patient profile maintenance. Accordingly, the time taken by the senior technician in the USIPD system was increased by 415% (20.5 minutes per ward per day in the WS system versus 105.7 minutes per ward per day in the USIPD system). Much of the work undertaken by the senior technician and satellite pharmacist directly reduced the work of nursing staff with respect to medication administration related activities. These factors contributed to nursing time saving but correspondingly increased pharmacy time. Much of the routine satellite work could be done by the senior technician with final checks done by a pharmacist. From a hospital perspective, a senior pharmacy technician costs less to employ than a registered nurse. Possible

outcomes could be either a reduction in nursing staff numbers or an increase in the time available to nurses to perform other non-medication related duties.

The pharmacists' time required to perform medication distribution-related activities was increased by 38.5% on Ward A and by 57.7% on Ward B in the USIPD system compared to the WS system. This is a combination of the time taken for clinical activities and time taken for dispensing activities. The time taken by the clinical pharmacist to perform clinical functions (medication chart review, liaising with medical and nursing staff, review of patients notes etc) was reduced for both wards in the USIPD system. This may have been due to the availability of medication charts which were consistently kept by the patients' bedside in the USIPD system, compared to various locations in the WS system. Another factor that may have contributed to the clinical time saving was the fact that all charts were reviewed by the satellite pharmacist when the drugs were dispensed, allowing any obvious problems or errors to be dealt with at the time. The time saving for the clinical pharmacist was, however, taken by the increased time taken to check stock requirements since stock control issues remained a part of the clinical pharmacists' role. In the USIPD system this involved checking the bedside drawers to monitor the "prn" drugs, review patients own medications, or retrieve medications that had be discontinued. The time taken to perform dispensing activities was increased for both wards in the USIPD system. Time was increased by 26.4 minutes per day for Ward A and by 31.5 minutes per day on Ward B in the USIPD system (Table 3.23). These increases relate to the individual dispensing for each patient and delivery to the bedside drawer, and with the quantity of drugs returned to the satellite for salvage or destruction.

Overall, there was a 64.5% increase in the time taken for pharmacy staff to perform medication distribution related activities in the USIPD system compared to the WS system.

Individual patient dispensing can also be conducted from a central pharmacy area rather than using the decentralised satellite approach. In some hospitals the geographical layout of the hospital makes a central pharmacy logical. Staffing considerations are probably more easily addressed in a central pharmacy situation since each satellite requires the physical presence of staff including those times that are "quiet". Fluctuations in work patterns in the satellite could be reduced in a larger central pharmacy. Proximity to the ward areas and turn around time for medication charts and medications are advantages of the satellite pharmacy system.

Study of the effect on pharmacy time on implementation of a patient specific medication distribution system has not been extensive. Greenhill[15] found that an extra 2.1 full-time equivalent pharmacy personnel were required to provide a modified ward stock system for a 370 bed hospital. Although drugs were stored in bedside drawers, nursing staff were required to place drugs into the drawers from the imprest cupboard at the nurses' station. In a trial of the ATC-212 machine, an automated unit dose distribution device, an increase in pharmacy labour of approximately 30% was noted, compared to the ward stock system.[94]

This study found an overall increase in pharmacy staff time of 64.5% (Table 3.23) for the USIPD system compared to the WS system.

4.1.6 Drug costs and security

Advantages of a modified unit dose drug distribution system have been reported to include a reduction in drug inventory and wastage.[4] This includes an increase in drug control since minimal quantities of medications are kept on the ward for out-of-hours use. Additional contributing factors to the savings may, therefore, include the increased security of medications in the USIPD system which reduced the possibility of pilferage by staff and the distribution of ward stock medications to patients being discharged from the hospital.

Compared to the WS system drug costs were reduced in the USIPD system by $327.57 over two weeks on Ward A and $542.48 over two weeks on Ward B. Extrapolating this over a one year period, approximately $ 8500 on Ward A and $14100 on Ward B would be saved. As seen in Table 3.20, this was primarily due to the increased salvage and reduced wastage in the USIPD system since relatively small quantities were dispensed for each patient. The value of the stock salvaged is large compared to the stock issued in the USIPD system. This is due to the number of days supply of drugs chosen to dispense for each patient at the start of the study. A five day supply was chosen to reflect the average length of stay for all patients at SCGH. A significant number of patients remained in these wards for more than the five days indicating that a seven day or ten day supply may have been more appropriate. Another approach may be to tailor the supply of medications to the average bedstay for each ward or to review the possible length of stay on a patient by patient basis, especially for those where it is anticipated will be admitted for an extended period.

The cost of drugs kept as imprest holdings and in drug trolleys was reduced in the USIPD system. In the WS system the value of non-injectable imprest stock held on Ward A accounted for 3.39% of the total hospital imprest holdings, while Ward B accounted for 5.85%. During the USIPD phase of the study, the non-injectable imprest stock held on Wards A and B was negligible. In addition to the increased security, there is reduced potential for stock on the ward reaching or passing its expiry date.

The stock held in drug trolleys was also an additional cost seen in the WS system and not in the USIPD system. The mean value of drugs held in the drug trolleys was $671.41 which, if extrapolated, reflects a value of almost $15,000 hospital wide. While drug quantities in the imprest cupboards were monitored twice a week by the senior pharmacy technicians, stock stored in the trolleys was not formally checked by pharmacy staff. Instead the clinical pharmacist would check the trolley, as required, to determine whether repeat supplies of non-imprest medications were needed. Large quantities of drugs were often stored in the trolleys, representing both a cost and also a potential source for error by increasing the range of medications the nurse had to choose from.

During the USIPD portion of the study, drugs were stored in the pharmacy satellite. The average value of stock held in the satellite was $1981.93. This figure was calculated over four weeks and, due to the experimental nature of the satellite, may not reflect the realistic value if the satellite was to exist long term. By way of comparison, the ward imprest lists had evolved over many years to reflect patient case-mix and turnover.

Patients are encouraged to bring their own medications with them to hospital to assist the medical staff in diagnosis and treatment procedures. A complaint of the WS system, both by patients and nursing staff, was that the patients own medications were often "mislaid" and left behind in hospital. This caused inconvenience and an additional cost to the patient, wasted nursing staff time trying to locate the items and also wasted pharmacy staff time eventually to destroy the medications. As seen in Table 3.25 the USIPD system eliminated this problem. The storage of patients own drugs in their bedside drawer facilitated return to the patient on discharge and also facilitated a review of medications during the admission. The significance in relation to patient outcomes was not able to be quantified but was reported informally during the nursing satisfaction survey. The storage of medications in the bedside drawer could also be utilised as an education tool, to inform and counsel patients about new medications or those being taken long term. This aspect was not included as part of the study.

The cost of medications consumed by each patient during their inpatient stay is of interest from both a financial and also drug use evaluation (DUE) point of view. The value of medications is important to calculate the total cost of a patient's admission to hospital and for ongoing review of the pharmacy drug budget. DUE is used to ascertain trends in drug use throughout a hospital or a section of a hospital. DUE surveys may target a specific drug, a group of drugs or a specific group of patients. Information from a DUE can be used to modify prescribing habits both from a cost-benefit or a best practice perspective. The cost of drugs consumed by each patient during the WS phase of the study was not studied. The WS system does not avail

itself to data collection for either cost calculation or DUE purposes. Any data collected in this system requires labour intensive manual recording of each tablet or capsule consumed.

While this study was not intended to collect such data, the USIPD system has a ready-made database of all medications taken by each patient as part of the dispensing function of the system. As such, information on the cost of drugs or any drug or drug group is easily retrieved. The mean number of medications as well as the mean cost of medications taken during the USIPD system is seen in Table 3.26. The mean number of drugs taken was similar for the two wards (Ward A 6.00, Ward B 5.56) with the medical ward, consisting of patients who are traditionally considered to take more drugs than surgical patients, slightly greater. The mean cost of medications for the two wards was more disparate. The mean cost of drugs on Ward B was almost twice that of Ward A. The major contribution to this difference was the type of drugs taken by the six renal patients on Ward B. Many of these, during the course of the study, were taking immunosuppresive agents (eg; cyclosporin, azathioprine), antihypertensives (eg; enalapril, captopril, atenolol) and antibiotics (eg; ciprofloxacin), often in large doses. Collection of these data was done as part of the initial dispensing of the medications with any returned medications "credited" to the patients' profile. Calculation of the cost for each patient was done at the time of the patients discharge from hospital.

Previous studies of codeine containing analgesics in the existing WS system at SCGH had found an ongoing problem with differences in the amount of stock sent to the ward and that known to be administered to patients. This phenomenon is significant

since the codeine content in Panadeine Forte® is 30mg per tablet, a dose which is considered a narcotic when provided as a single ingredient. Pilferage by staff, administration to patients without medical orders, documentation errors or supply of drugs to patients on discharge from the hospital are possible explanations, all of which are against hospital policy. As seen in Table 3.27, almost 100% of doses could be accounted for in the USIPD system compared to results ranging from 42% to 75% in the WS system. The smaller quantity of medications dispensed for each patient rather than bulk supply boxes kept in the imprest cupboard made the unauthorised use of codeine-containing analgesics less possible in the USIPD system. The nature of the system ensures drugs are more secure and accounted for in the USIPD system.[1] This group of medications was the only one studied from a security perspective during the study, although this phenomenon may also occur with other drug groups for example benzodiazepines and antibiotics.

Over the two week study period, $327.57 (25.9%) was saved on Ward A and $542.48 (28.8%) on Ward B in the USIPD system. These savings relate to wastage and pilferage of stock. Further savings were also seen in the reduction in ward stock stored at ward level and that stored in drug trolleys.

Pilferage and wastage issues were studied by Oldnall[12] who reported losses due to waste and pilferage of 25-50% in a ward stock system compared to 9-12% in a unit dose system, a reduction of 16 to 38%. Roberts [29] reported the effects on drug costs of implementing a decentralised unit dose drug distribution system compared to a centralised ward stock based system. Results showed a reduction in drug costs per day of 18% in the unit dose system.

The differences in the overall costs between the WS and USIPD systems can be seen in Table 4.1 below. Results for pharmacy time were calculated for the entire study period, therefore values are the same for each ward.

Table 4.1

Differences in costs between the ward stock (WS) system and the unit supply individual patient dispensing (USIPD) system

	Ward A	Ward B
Nursing Time	-29.8%	-28.8%
Pharmacy Time	+64.5%	+64.5%
Drug Costs	-25.9%	-28.8%

4.1.7 Medication errors

Administration based error rates, as detected by observation, are an outcome measure of the quality of a drug distribution system. [6] The medication error rates observed in this study are comparable to those reported for other institutions with similar drug distribution systems. Error rates, excluding timing errors, for a number of systems have been reported to range from 6.7% to 20.7% of opportunities for error in ward stock systems and from 0.5% to 7.23% of opportunities for error in unit dose systems.[1-3,6,11] The non-timing error rates in the two study wards were 8.5% and 13.4% with the WS system and 1.2% and 3.6% with the USIPD system. Barker

et al [60] found the mean error rate for an automated bedside dispensing machine to be 10.6%, compared with 15.9% for the control unit dose system; the difference was significant and was due to fewer timing errors and dose omissions.

In comparing error rates among hospitals in different countries and over several decades in the literature, a number of points must be considered. These include issues such as differences in error definition, observation techniques, number of opportunities for error observed, changes in medical technology and the number and types of drugs.

The disguised-observer technique was used to prevent behaviour modification as much as possible. This technique of observation has been reported to have little effect on the subject; if the observer is unobtrusive and nonjudgmental the subject will return to his or her usual work patterns after one to three hours.[70]

The method of prescribing medications in most Australian and British hospitals differs greatly from the order-transcription method used in US hospitals.[21] In Australian hospitals the physician writes all orders directly on a medication chart and rewrites the chart after 10-14 days, if necessary. Each chart has space to allow, for example, a 14 day supply of medication to be given and is used by nurses to document doses administered. The medication chart is also directly reviewed and annotated if necessary by clinical pharmacists during their routine ward rounds. Errors in transcription are therefore eliminated from the drug distribution system in Australia.

In the USIPD system, a five-day supply of medication was dispensed by the pharmacy for each patient. Many US hospitals dispense only a 24-hour supply, thus

reducing the quantity of stock available to give the patient and therefore the potential for a number of types of errors.[5] This is partly influenced by the requirement to charge patients for medication, a need that does not exist in public hospitals in Australia.

The number and type of administration errors for each ward in each system can be seen in Table 3.28. By reducing the quantity and range of medications the nurse had to choose from in the USIPD system, it would be expected that the number of omissions, wrong dose, unrecorded drug, wrong formulation, wrong drug and wrong route administrations would be reduced. In addition, the need for the nurse to wait for the drug trolley and keys was eliminated and therefore should reduce the number of timing errors in the USIPD system. With the exception of omission errors on Ward A, the incidence of errors in all error categories was reduced in the USIPD system

The difference in the prevalence of medication errors could be due to a number of factors in the USIPD system including; the reduction in the number of medications to choose from (drawer versus trolley); availability of individually dispensed drugs between the hours of 0800 and 2000 hours daily; ease of access to the medication drawer rather than waiting for the drug trolley; reduced quantity and range of drugs available in the imprest cupboard therefore reducing the possibility of the administration of unordered drugs; multiple strengths and formulations clarified by the pharmacist; and medication rounds taking less time therefore reducing the need to "rush".

The greatest contributor to the medication errors for both wards in both systems was timing errors. Timing errors were divided into those less than and those more than

two hours before or after the time they were prescribed to be given. For many medications, especially those given once daily, the timing may, within reasonable limits, not be important. For others, including those where a drug assay has been performed and where multiple daily doses must be given, timing errors may be serious.

The individual non-timing errors are described in Tables 3.30 to 3.33. These covered a number of error groups including omission, wrong dose, documentation error and wrong drug administration. Each of these categories has the potential to have serious or lethal consequences for the patient. Documentation errors can lead to a dose which has been given but not signed for by the first nurse being given again by a second nurse. Conversely, a dose may be signed for but not given by the first nurse and therefore would be omitted. The greatest danger with either of these scenarios is that the medical team may reduce the dose, increase the dose, cease a drug or instigate some measure to treat a new symptom based on erroneous information.

Medication error rates for various distribution systems have been reported in the literature. The non-timing error rate in the WS system was found to be 8.5% on Ward A and 13.3% on Ward B. These results are comparable to other work published. Lepinski et al [24] reported an error rate of 8.53%, Simborg et al [93] a rate of 7.35% and Goodman et al [17] a rate of 13%.

The literature for non ward stock systems is more difficult to compare to the USIPD system since systems range from unit of use to modified unit dose to unit dose systems. The patient specific nature of all these methods is, however, a common feature. Goodman et al [17] reported an error rate of 3.2% in a unit-of-use system.

Lepinski et al [24] found an error rate of 0.97% in a modified unit-dose system and Simborg et al [93] reported an error rate of 1.62% in a unit dose distribution system. In this study a non-timing error rate of 1.2% was detected on Ward A and 3.6% on Ward B. This study provides current Australian data on medication administration error rates in two drug distribution systems in the same hospital setting.

4.1.8 Nursing opinion survey

There was a positive response by nursing staff to the USIPD system. This was found despite the relatively short time frame of the study. The satisfaction of staff in the evaluation of different drug distribution and administration systems has not been reported in the literature. The results of the satisfaction survey support the main findings of the efficiency and safety of the USIPD system. They also suggest additional benefits such as the increased opportunity to educate patients about their medications due to the nature of the bedside drawers. The limitations of the survey are acknowledged, in particular that validity reliability of the survey was not tested. However, the open ended comment section provided unstructured opportunity to comment on aspects not included in the seven questions. Comments made were used to help design the interventions made in Part Three of the study.

A study by Jacobsen[13] reviewed nurses' opinions before and after the implementation of a unit dose system. In the existing ward stock system nearly one half of nurses stated they thought medication errors occurred frequently and half believed they spent more than four hours each shift in medication distribution activities. Their early

evaluation of the unit dose system indicated 75% believed the new system was valuable with the percentages increasing as experience with the system increased.

This study gave nurses the opportunity to comment on a number of points with their responses of great importance in the application of FMEA to the WS system.

4.2 Part Two - Error Probability

It has been estimated that self-reporting of medication errors in hospitals typically identifies only about 5% of events.[40] Two possible reasons for low rate of self-reporting of administration errors can be considered.[89] Firstly the nurse may be unaware that an error has been made. In this situation direct observation by a second party is the only method that will detect the error. A suspicion that an error has occurred may arise if a patient either fails to respond to treatment or exhibits signs of toxicity but these could rarely be proven. Many of the error categories (Table 2.4) used in this study would never be detected without direct observation techniques.

Secondly, the nurse may be aware that an error has occurred but decide not to report it. For a medication administration error to be reported, the nurse must feel compelled to do so. Reasons for not reporting an error may include lack of familiarity with the reporting mechanisms of the hospital, difficulty or time constraints associated with completing the report form, fear of possible ramifications for the individual and the institution, lack of feedback to staff, lack of motivation, feeling that the error is not important or significant enough to report and fear of widespread knowledge of the error with subsequent reduction in professional respect. There is also the possibility that a second party (another nurse, pharmacist, doctor or patient) may detect the error sometime later. In this situation the nurse may be forced, directly or indirectly, to report the error.

The documentation of errors may only occur in this system when the nurse feels the error is important enough to report. This may account for the rate of reports for drug

groups associated with low therapeutic index drugs such as cardiovascular drugs and anticoagulants as opposed to drugs seen as mild or relatively non-toxic (eg; laxatives).

The number of errors reported by nursing staff using the standard SCGH incident/accident report forms averaged 28.6 per month for the entire hospital campus or 1.3 reports per ward per month. This rate of reporting is low compared to the number of errors detected by direct observation during Part One of the study and that reported in the literature from other institutions involving direct observation. The study of these reported medication errors was done retrospectively and did not coincide with any type of interventions such as an education program or awareness campaign. Therefore the results reflect the baseline level of reporting by nursing staff.

In a study by Barker et al [1] only six anonymous reports of medication errors were filed over a seven month period in a teaching hospital. The authors noted that 40% of nurses in the study were opposed to the use of this reporting system, contributing to the low number of reports submitted. In the same study Barker et al reported that thirty six errors were documented during the year studied using an incident report scheme.

Each of the 343 errors reported over the 12 month period was studied and classified by error category, drug group, cause of error and probability ranking.

4.2.1 Error group

As seen in Table 3.36, of the 343 errors reported, 32.4% were omissions, 18.4% were wrong dose, 13.7% were extra doses and 12.2% were documentation errors. These four categories contributed 76.7% of all reported errors.

In this "self-reported" system the nurse who has made the error is often compelled to complete an incident/accident report form because a second nurse detects the error and alerts the first nurse. In this situation the system is ensuring a report is completed but can not be called a true "self-reporting" system. From this perspective it is logical that the omission category is the most common since the nurses' signature on the drug chart is missing. This very visible sign alerts the second nurse that an error (either as an omission or documentation error) has occurred. Similarly the documentation error category was common as was the extra dose category which also has a very visible cue that an error has occurred.

Tables 3.37 to 3.39 indicates each of the error categories compared to the drug groups involved. For the omission category, cardiovascular drugs represented 28.8% of errors reported. These along with antibiotics (13.5%), anticoagulants (12.6%) and others (11.7%) constituted two thirds of omission errors documented. Omission of drugs from the cardiovascular, antibiotic and anticoagulant groups are potentially dangerous and could lead to doses being incorrectly increased or treatment failures in the case of antibiotics. Whilst these drug groups were the most commonly reported, the true incidence of errors for each drug group cannot be calculated since the total number of drugs administered from each drug group (denominator) is unknown.

Wrong doses reported constituted 18.4 % (63 of 343 errors) of errors reported over the twelve month period. Of these errors 34.9% were from the anticoagulant group which includes warfarin and heparin. This finding is of great importance given the low therapeutic index and the potential side effects of this group. Again many of

these errors were detected by a second nurse especially in the case of continuous intravenous infusions of heparin where the medication ordered can be checked against the infusion that is in progress. The label indicating the contents of the infusion bag are visible and errors can be detected if the dose documented is incorrect. Analgesics (12.7%), others (11.1%), cardiovascular (9.5%) and antiepileptics (9.5%) were also documented as wrong doses.

For those errors documented as extra doses (13.7%), almost one third were from the analgesic category (27.7%). This finding is not unexpected since the majority of analgesics are given on an "as required" basis and are given to patients needing analgesia for pain. Most extra doses reported related to doses being given at a shorter interval than that specified by the medical staff and included cases where prescriptions for paracetamol 500mg and paracetamol 500mg/codeine 8mg and paracetamol 500mg/codeine 30mg were current. The possibility that the nurse did not notice the prescription for all items may explain this finding. Other common drug groups involved in extra dose reports included antipsychotics (17.0%) and others (14.9%).

The documentation error category was the fourth most common error category (12.2%). Of these anticoagulants (23.8%) and analgesics (23.8%) were the most common drug groups. This may reflect the importance that nursing and medical staff place on the correct administration of anticoagulant drugs. The prevalence of analgesic related errors indicates the high proportion that are prescribed to be given "as required". In this situation doses may be given and not signed for on the chart.

Unrecorded drugs constituted 9.6% (33 out of 343) of the documented errors. Of these 21.2% (7 out of 33) were cardiovascular agents and 18.2% were antidiabetic drugs. The administration of an unrecorded drug primarily relates to the incorrect drug being chosen from the stock available in the drug trolley. In the case of antidiabetic drugs, a number (eg; gliclazide, glibenclamide, glipizide) have somewhat similar sounding names, leading to a degree of confusion. Similarly, a number of insulin injections have similar sounding names with similar looking bottles. These errors are usually detected after the event by the nurse making the error or by the patient when they receive the next dose and realise the previous dose was different.

Timing errors, both major and minor, were responsible for 7% of documented errors during the 12 month period. Most timing errors reported were classified as major (87.5% of timing errors reported), however results from Part One of the study would support the notion that most timing errors are minor (ie; more than 30 minutes but less than two hours deviation from the time prescribed to be given). It would be expected that most nursing staff would deem most timing errors as an everyday part of drug administration rather than an error, as supported by the low occurrence of timing errors reported.

Wrong route (4.1%) and wrong formulation (2.6%) were the least reported medication administration errors in this section of the study. For the wrong route category almost one third were antibiotics (28.6%) which is probably due to the fact that many antibiotics are initially charted to be given intravenously then changed to oral after a few days. Inappropriate familiarity with the patients' medications, rather than proper attention to the medication chart, may contribute to this type of error.

Wrong formulation errors were predominantly associated with cardiovascular medications (44.4%). The use of a number of sustained release preparations from this group may be the reason for this result.

4.2.2 Drug group

The drug group involved in the errors reported may have important implications as to whether the nurse will report the error or not. The possibility that an error may be serious coupled with the likelihood that the nurse will be "found out" is most likely a major motivating factor. As such it would be expected that drug groups such as cardiovascular drugs, anticoagulants, antidiabetic drugs and analgesics would be among the most commonly self-reported drug errors. As seen in Table 3.40, this seems to be the case. Cardiovascular drugs (19.8%) are the most commonly reported drug group, followed then by anticoagulants (15.4%), analgesics (12.8%), others (12.2%), antibiotics (11.9%) and antidiabetic drugs (6.4%).

Four of the above groups are associated with parameters that are regularly and readily tested objectively on patients. Blood pressure, blood sugar levels, coagulation profile and temperature are all measured on a regular basis to monitor progress of the patient and treatment. Subjectively, pain experienced by the patient is also a measure of the patients' progress.

The potential to monitor these drugs may have some influence on the rate at which these administration errors were reported.

4.2.3 Cause of error

The cause of the error reported by nursing staff is useful information when studying a system from a failure mode and effects analysis perspective. One advantage of FMEA is that deficiencies in the system are highlighted by staff who are working in that system on a day to day basis. While many problem areas are obvious, a number are harder to elucidate since experienced staff are practised at "working around" or compensating for the problem. Documenting the perceived reason for the error occurring may help bring to light this second layer of failure modes.

In this part of the study, the majority of errors were reported as being due to a faulty check (42.3%). This refers to an inadequate check of the drug chart for orders, inadequate check of drugs prior to administration, inadequate supervision of the patient actually taking their medication, inadequate checking of the patients nameband prior to administration and not checking that the patients own medications were stored at the nurses station (to prevent the patient self-medicating). Most of these resulted from the nurse "not checking properly" and ignoring hospital policy. From the faulty check category as seen in Table 3.42, 26.2% caused an incorrect dose to be given, 22.2% an extra dose and 20.0% caused an omission. Of the drug groups involved in faulty check errors, 20.7% were associated with anticoagulants, 14.5% with cardiovascular agents and 13.1% with analgesics.

The next most commonly cited reason for errors, as seen in Table 3.41, was an inexplicable lapse in concentration and usual work practices (17.7%). In this situation the nurse gave no reason other than a lapse from usual. The majority of lapses, as seen in Table 3.42, were associated with an omission (54.1%), followed by timing

errors (14.7%) and then by unordered doses (13.1%). Approximately one third of lapse errors involved cardiovascular drugs.

Documentation of orders by medical staff that were not clear or easy to interpret by the nurse and doses not signed for requiring follow up by the second nurse were categorised as documentation failures. This group accounted for 17.5% of errors as grouped by causes of error (Table 3.41). Of these 41.7% were responsible for a documentation error and 38.3% caused an omission to occur (Table 3.42). Orders that are unclear or ambiguous would be expected to most commonly cause an omission since nurses should not administer a medication which is unclear as to the dose, drug or interval. Cardiovascular drugs contributed 25.0% to this group of errors, followed by anticoagulants 15.0%, antibiotics 15.0% and analgesics 15.0% (Table 3.44).

Lack of communication or inadequate communication was another cause of errors cited by nursing staff. This could have been associated with communication between the nurse and the doctor, patient, pharmacist or another nurse. As seen in Table 3.41, this category constituted 8.75% of error causes with most (46.8%) linked with omissions (Table 3.42). There was an even spread of drug groups involved in this category with cardiovascular agents, antiepileptics, analgesics and others all scoring 13.3%.

Lack of knowledge was reported as the cause of the error in 7.0% of cases (Table 3.41). This category was defined as a lack of knowledge on the part of the nurse in the drug therapy, the equipment being used to administer the drug or in the hospital policy regarding drug administration. Of this classification 41.7% were incorrect

doses administered, 20.8% were wrong formulations and 20.8% were wrong route (Table 3.42). As seen in Table 3.45, cardiovascular drugs accounted for 25.0% of lack of knowledge errors.

Workload considerations were also documented as the reason for a number of errors occurring. A number of nurses described their workload as excessive at the time the error occurred. This would be expected to lead to a variety of errors and omissions were the most common as seen in Table 3.42 (39.1%). Incorrect dose was the second most common (21.7%). As seen in Table 3.47, anticoagulants were involved in 21.8% of workload associated errors, followed by antidiabetic agents (17.4%) and cardiovascular drugs (17.4%). From a failure mode and effects analysis point of view, any excessive workload can potentially cause a problem since staff are invariably unable to complete one task (for example administering medication) before another one is started. Lack of staff, a number of acutely unwell patients, new or inexperienced staff and a variety of other factors can lead to an increase in the nurses' workload.

There are no reports in the literature detailing medication errors in terms of error category, drug group and causes of error.

4.2.4 Probability ranking

Ranking of each of the 343 errors self-reported over the 12 month period was done using a point scale (out of ten) for probability of occurrence, probability of detection and probability of harm to the patient. A maximum score of thirty could be allocated (high chance of occurrence, remote chance of detection and maximum chance of

harm to the patient) with a minimum score of three (remote chance of occurrence, high chance of detection and no chance of harm to the patient). Definitions of each of the points that could be allocated is seen in Table 2.8. Allocation of the points was undertaken using these definitions based on the work of Williams and Talley.[75]

The errors reported can be seen in Table 3.49. The lowest ranking given to an error was 7 points and the highest 24 points. Approximately 25% scored less than 12 points and approximately 90% scored below 18 points. Three quarters of the errors scored between 12 and 17.

Approximately 10% scored over 18 points as shown in Table 3.50. This table presents the drug group involved, the error type, the reason cited and the breakdown of points scored by each probability category. As shown in Table 3.51, of the top 10% of errors reported, 43.8% was from the cardiovascular group, 18.8% were antibiotics and 12.5% were anticoagulants. This result could reflect a combination of drugs that are most commonly used (eg; cardiovascular agents and antibiotics) and those perceived by nursing staff to have serious consequences if given incorrectly (eg; anticoagulants). However, no baseline data for this assumption exists since the denominator value for the number of doses of each drug group given to patients over the one year period could not be calculated. Whether the incidence of errors reported was related to the frequency of doses given, with commonly used drugs representing the largest group of reported errors is unknown.

The most common error type in the top 10% group was extra doses (31.2%) followed by omissions (21.9%) and wrong doses (18.8%). The reason cited was a

faulty check in 43.8% of errors, followed by documentation errors (28.2%) and lack of knowledge (15.5%).

In a study by Ogden et al [91] errors directly observed over 56 drug administration rounds were given a severity index, where one indicated that an error had occurred but had no potential harm for the patient and six indicated that the error occurred that contributed to the death of the patient. Of the 131 non-timing errors observed 49% were given a severity index of one, 10% and index of two, 7% and index of three and 15% and index of four (19% of reports were not evaluable as to the impact on the patient). No error scored above four and the median was an index of one. This study evaluated the error type, but did not assess the drug group or cause of the error.

In a study by Williams and Talley [75] review of the drug distribution system revealed the top five criticality indices associated with errors. These were having lethal drugs available as ward stock, mistakes in maths when calculating doses, doses or flow rates calculated incorrectly, not checking arm name bands before drug administration and excessive drugs available as ward stock. This study reviewed causes of errors but did not assess drug groups involved, error types or causes of errors.

4.3 Part Three - Failure Mode and Effects Analysis and No-blame Reporting

4.3.1 Failure Mode and Effects Analysis

The failure mode and effects analysis of the existing WS system at SCGH identified a number of issues that could contribute to the occurrence of medication administration errors. Identification of these issues was done by breaking down the WS system into steps as seen in Figure 2.1. Areas of potential error were identified by pharmacy and nursing staff, who had expertise in the daily running of the system. As seen in Table 3.52, these were categorised as availability, review/double check, selection, patient issues and nursing issues.

As a result the review of these categories the USIPD system, as tested in Part One of the study, was devised. The aim of the USIPD system was to increase the safety of the medication administration system at SCGH.

A number of identified sources of medication errors were eliminated or reduced by moving from the ward stock to the USIPD system. Individual patient dispensing would be expected to eliminate administration of wrong drug formulations and unordered drugs, since only the drugs in the bedside drawer were available for selection. This assumes that the pharmacy has dispensed the correct medications and placed them in the correct bedside drawer.

Other types of errors were also be expected to be reduced in the USIPD system, such as omissions, wrong routes and wrong time (by eliminating queuing for drug trolleys and keys). Administration of drugs by the wrong route did not occur in this study, but the number of timing errors was reduced for both wards. The rate of omissions

increased in the USIPD system on the medical ward (from 0.4% to 0.8%). The usual practice of nurses in the ward stock system was to leave all drug charts with outstanding doses on the drug trolley at the nurses' station as a reminder. In the USIPD system, all drug charts were left by the patient's bedside.

No difference in the rate of wrong or extra doses or of documentation errors would be expected in the USIPD system, since, unlike the unit dose system in which a 24 hour supply is available for a given drug, the USIPD system provided a five-day supply in the bedside drawer. However, the results showed a reduction in the frequency of wrong doses for both wards in the USIPD system. There was a small reduction in extra doses in the surgical ward. The number of errors observed was not sufficient to detect statistical significance between the systems. A larger sample size, beyond the scope of this study would be required.

In this study only one error could occur per opportunity. However, from an FMEA point of view, for each opportunity there are a number of possibilities for error that may or may not be mutually exclusive. For example, a documentation error may be made and the wrong drug formulation given. In the ward stock system there are eight possible errors that could be induced for any given administration event, and six of these could occur at the same time.

In the USIPD system, two types of errors (unordered drug and wrong formulation) were reduced. However, unordered drugs and wrong formulations were not major influences on the error rate in the ward stock system in this study. A notable reduction in the rate of wrong doses was seen for both wards. This may have been due to the provision of a five-day supply of medication in an individual package in the

USIPD system rather than administration from the bulk package used in the ward stock system. The smaller quantity may have provided a subconscious alert to the nurse administering the dose. The number and availability of drugs and the potential for selection errors were both factors identified by FMEA.

The analysis of the medication administration and distribution system identified 12 system errors as seen in Table 3.52. The drug availability element was addressed in the USIPD system by ensuring that all drugs ordered for each patient were readily obtainable in a manner that allowed the nurse to access the medications without key or trolley availability problems. The small quantity of imprest stock left for emergency use reduced the possibility of pilfering, administering unordered drugs and supplying take-home medications to patients when they were discharged.

The extended pharmacy hours, along with the review of all orders by a pharmacist before administration of a drug, allowed a double check not available in the WS system.

Selection of drugs from the imprest cupboard or drug trolley in the ward stock system can lead to the wrong drug, wrong dose, or wrong formulation being given. The number of drugs is greatly reduced in the USIPD system and only those prescribed to the patient are available.

The major contribution to medication errors as defined by this study was variations in administration times from the charted times. While the USIPD system did reduce this type of error, it did not eliminate it, indicating that factors other than the drug distribution system are also involved. The time taken to obtain drugs and the time spent waiting for trolleys and keys was reduced. As such, the impact of the USIPD

system on minor and major timing errors was principally due to the increase in access to medications afforded by the individually dispensed medications being available for each patient in the bedside drawer. The clinical significance of the medication errors was not assessed. This aspect has been previously examined by several authors. [18,53,63]

4.3.2 No-blame error reporting

As seen in Table 3.53, the number of self-reported medication errors in a no-blame environment was significantly different for the NB-WS system between Phase One and Phase Two. Omissions, documentation errors and timing errors form the majority of errors for both phases.

In conjunction with FMEA, the use of a no-blame system of error reporting may be part of an approach to elucidate systemic problems in a drug distribution system. Highlighting common errors that are considered routine is important since these problems are usually "worked around" or accommodated for by staff. Using a non-punitive approach to error-reporting can reinforce the notion that reporting is a positive process aimed at improving the system. While the incidence of errors reported in this section was not as high as that found in Part One, this low-cost method did have a much higher reporting rate than the incident report system currently in place (Part Two). No-blame assurances, extra interest and input from the researcher and easy to use report forms may have contributed to the higher rate of reporting seen.

The type of error reported under the no-blame scheme differed from that detected by the disguised-observer technique used in Part One. The most notable non-timing

differences include the rate of omissions (36.3% in NB-WS system compared to 10.5% in DO-WS system) and for inadequate documentation (21.4% in NB-WS compared to 8.8% in DO-WS). There was also variance in timing errors, both minor and major. The difference in error rates relate to the ease of detection for the nurse administering the medication in the no-blame system. The standard practice of the nurse checking all medication charts prior to the end of the shift would most commonly lead to the detection of omitted doses and documentation errors. Similarly, review of the chart would highlight a timing error (and with appropriate dosing of the patient would prevent it from becoming an omission). The nurse must know that an error has occurred in order to report it. In contrast, the disguised observer method will detect those errors that are made without the nurses' knowledge.

The rate of error reporting was significantly less in Phase Two. This can only be explained as due to the FMEA designed interventions. The possibility that the nurses reported less as the study progressed was not evident from linear regression where in all cases the slope values over the reporting period were not significantly different from zero.

The use of no-blame error reporting may be one approach used to monitor medication errors in hospitals. Once the rate of medication errors in a hospital has been determined using both the disguised-observer method and the no-blame reporting method and presuming the rate of errors and rate of reporting are constant, a dual approach may be considered. Ongoing hospital review of medication errors may include the routine use of no-blame error reporting with the disguised-observer

method used on a short-term basis at regular intervals to assess the validity of the no-blame reporting rate.

Key measures to facilitate self-reporting of medication administration errors have been considered to include making report forms as simple and quick to use as possible, training staff to report and identify errors, fostering an ethos in staff that a systems approach is being used rather than blaming the individual, feedback of errors that have occurred with possible strategies to prevent recurrence, provision of sufficient staff to process and evaluate reports and making medication errors a priority area rather than an "extra job".[48,56,59]

The legal situation regarding self reported errors has not been considered as part of this study.

Barker and Connell[1] have stated that the use of incident reports as source material for error incidence was flawed since reports cannot be produced unless it is known an error has been made and then the individual must feel compelled to complete a report form. A study by Hartwig et al evaluated the use of a self-reporting program whereby staff were encouraged to report errors in a non-threatening environment.[63] The program was designed to identify problem areas and trends in the system so that quality assurance and medical committees could implement measures to improve drug use. The reporting rate increased throughout the study period which the authors attributed to increased emphasis and information provided by the administrators. While recognising that the error rate was probably well below the actual error rate,

the authors placed more emphasis on the quality of the reporting system rather than the quantity of error reports.

A multidisciplinary expert panel discussing the prevention of adverse drug events stated that hospitals should focus primarily on systems and continuous quality improvement activities instead of on individuals.[59,90] In this manner the problems inherent in a medication distribution and administration system may be highlighted and the system subjected to failure mode and effects analysis in an attempt to overcome them.

Table 3.55 summarises all errors detected during the study using the three reporting methods; direct observation, incident reporting and no-blame self-reporting. Percentages for each error type seen in this table reflect the proportion of the total number of errors, rather than opportunity for error. The percentage of errors seen is variable between the different reporting methods. Omissions range from 0.6 to 10.5% using direct observation but rates using self-reporting techniques, both incident and no-blame, range from 27.6 to 36.3%. Omissions are easily detected by nursing staff under usual ward conditions since the medication chart, without a signature documenting the drug has been given, is a visual identification. The possibility exists, in a self reporting system, that a drug is "missed" and reported as an omission but is actually a documentation error. This cannot be accounted for in a self-reporting system.

Wrong dose errors were most commonly reported in the self-reported incident system (18.4%). The next most commonly reported wrong dose category was using

the direct observation method in the ward stock system (8.4% and 6.1%). The detection of a wrong dose error would be most commonly expected in a direct observation system since most of these errors are unknown to the nurse. The incidence of wrong doses in the self-reporting incident system may be explained by the results in Table 3.37. Of the wrong doses reported, 34.92% were anticoagulants which are easily monitored and may have serious haematological effects if the patient is either underdosed or overdosed.

Documentation errors ranged from 3.2 to 8.8% in the direct observation method to 12.2 to 39.4% in the self-reporting schemes. As with omission errors, nurses have the medication chart as a reminder.

The most variable results occur with the reporting of timing errors. Minor timing errors range from 58.8 to 88.8% using direct observation to 0.9% in the self-reporting incident system and 8.8 to 13.2% in the no-blame system. Major timing errors are less variable with the two highest rates of reporting in the no-blame system. This is explained by the nurses' perception of the importance of timing errors. The direct observation method confirms that timing errors occur very frequently. The rate reported in the no-blame system represents the presence of the investigator and the continued reminder to complete forms for all errors noticed.

5 CONCLUSIONS

5.1 Part One - Ward Stock versus Unit Supply Individual Patient Dispensing

Research reporting the direct observation of a significant number of opportunities for error has been lacking in the recent literature. Australian data studying the medication error rate in the commonly used ward stock system is similarly lacking. This study provides these data and compares the ward stock system to a modified unit dose system (USIPD). The WS error rate elucidated using the disguised observer technique described by Barker and McConnell [1] was found to be within the range reported in the literature. Similarly, the rate detected in the USIPD system, was within the range reported for individual patient dispensing systems.

Nursing time was found to be reduced by approximately 27 minutes per shift on Ward A and 16 minutes on Ward B in the USIPD system. This translates to almost 30% reduction in the time spent by nurses on medication related activities. This time saving can be viewed as either an opportunity to reduce nursing staff numbers with a corresponding increase in pharmacy technicians or the chance for nurses to expand their role. The greatest time saving for both wards was found to be the time taken to perform "all other" medication related activities which included duties such as ordering drugs, replenishing drug trolleys, tidying drug trolleys and locating drugs after pharmacy hours. These tasks were essentially eliminated in the USIPD system.

Pharmacy time was correspondingly increased in the USIPD system, since the system is more pharmacy labour intensive. Overall, there was a 64.5% increase in pharmacy time in the USIPD system compared to the WS system. Pharmacists' time increased by 38.5% on Ward A and by 57.7% on Ward B in the USIPD system. While the time taken to undertake clinical duties was reduced, the time taken for dispensing

activities was increased. The role of the pharmacy technician was significantly altered in the USIPD system with the junior technicians' role eliminated. However, in the full scale implementation of the USIPD system to a teaching hospital a degree centralisation of certain functions may occur and include the junior technician. Procedures such as repacking of drugs into individual patient sized quantities could facilitate dispensing at satellite level. The time taken by the senior pharmacy technician was increased by 415% in the USIPD system.

The number of extra staff that would be required to implement the USIPD system hospital wide would depend on a number of factors such as the hours the pharmacy was open, proximity of the satellite pharmacy to the ward and to the central pharmacy and the number of wards covered by each satellite.

Drug costs were found to be reduced in the USIPD system in terms of the stock held at ward level in the imprest cupboard and drug trolleys, increased salvage of returned drugs and reduced waste. For the two wards studied, a once off saving of approximately $5000 could be expected (imprest cupboard and drug trolleys) if the USIPD system was implemented. In addition an annual saving of approximately $8500 on Ward A and $14100 on Ward B would occur, due to reduction in wastage.

The security of medications was assessed using a paracetamol-codeine survey. Pilferage by staff, administration to patients without medical orders, documentation errors or supply of drugs to patients on discharge from hospital are possible explanations between the amount of stock supplied to the ward and that documented as administered to patients. Almost 100% of doses were accounted for in the USIPD system compared to 42 to 75% in the WS system.

Medication error reduction is reported to be the greatest advantage of patient specific dispensing systems.[4] Error rates reported for WS systems, excluding timing errors, are between 6.7 and 20.7%.[1-3,6,111] Error rates detected in this study were 8.5% for

Ward A and 13.4% for Ward B. Error rates reported for unit dose systems are between 0.5 and 7.23%.[1-3,6,11] The error rate detected in the USIPD system, while not identical to a unit dose system, were still within this range. An error rate of 1.2% was detected on Ward A and 3.6% on Ward B. The USIPD system reduced medication administration errors compared to the WS system.

The opinion of nursing staff in the evaluation of different drug distribution systems has not been reported. The survey undertaken indicated an overall preference for the USIPD system.

5.2 Part Two - Error Probability

The disadvantages of the self-reported incident method of error detection have been discussed by Allan and Barker. [6] The nurse must know that an error has occurred and then feel compelled to report it. While the incident method is not optimal, it is cheap and easy to administer. The incident report system is the method currently operating at SCGH, enabling analysis of the types of errors submitted over a one year period. Each of the 343 errors reported by staff over a one year period were analysed according to error type, drug group, cause of error and error probability ranking. The most commonly reported error type was omissions (32.36%), most common drug group was cardiovascular (19.82%), and most common cause cited was faulty check (42.28%). The ranking scale had a minimum score of three and a maximum of thirty points, with 78% of errors scoring between 12 and 17. Approximately 10% of errors scored 18 points or more. Of the top 10% of errors, 43.8% were cardiovascular agents, 31.2% were extra doses and 43.8% were due to a faulty check.

In comparing these data, the main difference between the most common categories for all errors reported and the top ranking 10% of errors is associated with the type

of error. "All" reports consisted most commonly of omission errors compared to extra doses in the top ranking errors. While cardiovascular drugs were the most common drug group for both, the rate (19.82% compared to 43.8%) can be seen. The reason cited for the error, faulty check, was the same for both groups.

This information can be valuable in assessing medication errors that have occurred in a hospital and that were reported by staff. Certain target drugs could be identified or better checking systems devised. Further study on the types and causes of drug errors along with the severity ranking would be a useful addition to the literature.

5.3 Part Three - Failure Mode and Effects Analysis and No-blame Reporting

The existing ward stock system was subjected to FMEA with a number of system failures exposed. These were availability of medications, review or double check procedures, quantity of drugs available causing selection errors, patient issues, and nursing time issues. The USIPD system was devised in an attempt to overcome a number of these potential problems. Availability of drugs was increased, all charts were reviewed by a pharmacist before the first dose was given, the number of drugs available to choose from was limited and the time taken by nurses to perform medication related activities was reduced.

Ongoing study of distribution systems using FMEA is necessary. This method uses staff that are expert in the area with the aim of preventing a problem before it happens. A multidisciplinary team consisting of physicians, pharmacists and nurses is considered the optimum approach.

The disguised-observer technique of medication error detection is recognised as the most accurate method of determining error prevalence, however the labour intensive nature and therefore cost of the method precludes its routine use for most institutions. In Part One of this study an error rate of 8.5% for Ward A and 13.3%

for Ward B in the ward stock system was observed. Part Two of the study revealed an error reporting rate in the existing hospital incident accident scheme of 1.3 reports per ward per month. In Part Three of the study the no-blame self-reporting method studied revealed an error rate of 2.1% in Phase One (existing system) and 1.7% for Phase Two (intervention), excluding timing errors. The rate of no-blame self-reporting was approximately 16% of that detected using the disguised-observer technique in Part One. The no-blame system tested was low cost and easy to administer with an error reporting rate greater than that of the existing incident reporting scheme.

Use of the direct observation method to ascertain the baseline error rate with subsequent periodic measurements may provide a feasible alternative. The true nature of the data collection would, however, become exposed over time. A combination system using this and a self reporting system may provide useful data. While incident reports have been widely used, the rate of reporting has been relatively low. Fear of discipline is one reason cited. A no-blame non-punitive method may provide an acceptable method for staff to report errors.

Medication administration errors in pharmaceutical distribution systems have been studied and reported in the literature over the past 35 years. Recent systematic studies have, however, been sparse. This study identifies a number of issues pertinent to the pharmaceutical care of the hospitalised patient in Australia. The medication error rate detected in the ward stock system at this major teaching hospital was significantly greater than that seen in the unit dose individual patient dispensing system. Ward stock drug distribution is still widely used in Australian hospitals. The medication error rate detected in this study was higher in the WS system in place at SCGH than the USIPD system trialed at the same hospital. If medication

administration error rates for alternative distribution systems in operation elsewhere have been demonstrated to be lower than those detected in the WS system in this study, the legal and ethical implications of continuing to use an inferior system should be contemplated. Patient specific dispensing along with ongoing systematic detection, reporting and analysis of administration errors is a priority area for hospital pharmacists in order to fully embrace the pharmaceutical care of patients.

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APPENDICES

Appendix 1

Ward A Ward Stock System (Shifts 1-10)

Round	Time	Mins	Patient	Day am/pm	Observer	Obs No	Nurse
Shift 1							
1	0800	35	1-10	Tues pm	1	1	1
2	1200	5	11-12				
3	1400	10	13				
4	X	17	14-16				
Shift 2							
5	0800	34	17-24	Thurs am	1	2	
1							
6	1200	10	25-29				
7	1400	7	30-32				
8	X	11	33-34				
Shift 3							
9	0800	36	35-42	Thurs am	2	1	2
10	1200	30	43-46				
11	1400	40	47-51				
12	X	24	52				
Shift 4							
13	0800	45	53-62	Mon am	1	2	2
14	1200	15	63-65				

15	1400	26	66-69				
16	X	11	70-73				
Shift 5							
17	0800	40	74-83	Sat am	2	1	3
18	1200	14	84-86				
19	1400	25	87-91				
20	X	22	92-94				
Shift 6							
21	1400	21	95-101	Sat pm	1	2	3
22	1600	22	102-109				
23	1800	11	110-113				
24	2000	19	114-119				
25	X	35	120-121				
Shift 7							
26	1400	43	122-127	Fri pm	1	1	4
27	1600	25	128-133				
28	2000	38	134-139				
29	X	9	140				
Shift 8							
30	0800	50	141-147	Sat am	2	2	4
31	1200	30	148-154				
32	X	8	155-156				
Shift 9							
33	1600	35	157-162	Fri pm	2	1	5
34	2000	25	163-168				
35	X	7	169				

Shift 10

36	1400	15	170-173	Sun pm	2	2	5
37	1600	17	174-176				
38	2000	35	177-185				
39	X	10	186-188				

Appendix 2

Ward B Ward Stock System (Shifts 11-25)

Round	Time	Mins	Patient	Day am/pm	Observer	Obs No	Nurse
Shift 11							
40	0800	14	189-193	Tues am	2	1	7
41	1200	7	194-197				
42	X	13	198-201				
Shift 12							
43	0800	11	202-205	Thurs am	1	2	7
44	1200	10	-				
45	X	14	206				
Shift 13							
46	1400	19	207-210	Mon pm	1	3	7
47	1600	11	211				
48	1800	15	212-215				
49	2000	14	216-220				
Shift 14							
50	0800	12	221-224	Thurs am	1	1	8
51	X	8	225				
Shift 15							
52	1400	12	226-228	Sun pm	1	2	8
53	1600	10	229				
54	1800	18	230-234				
55	2000	25	235-242				

56	X	22	243-245				
Shift 16							
57	0800	18	246-249	Fri am	1	1	9
58	1200	7	250-251				
59	X	14	252-256				
Shift 17							
60	1400	10	257-259	Sat pm	1	2	9
61	1600	15	260-266				
62	1800	7	267				
63	2000	18	268-275				
64	X	3	-				
Shift 18							
65	1600	43	276-279	Mon pm	2	1	10
66	1800	20	280-282				
67	2000	29	283-287				
68	X	5	288				
Shift 19							
69	0800	17	289-292	Tues am	2	2	10
70	1200	9	293-296				
Shift 20							
71	1400	16	297-300	Tues pm	1	3	10
72	1600	7	301				
73	1800	29	302-305				
74	2000	27	306-312				
75	X	40	313-314				
Shift 21							

76	1600	16	315-319	Sat pm	2	4	10
77	1800	10	320-324				
78	2000	18	325-330				
79	X	28	-				
Shift 22							
80	2000	22	331-335	Sun pm	1	1	11
81	X	10	336-339				
Shift 23							
82	0800	31	340-347	Wed am	1	2	11
83	1200	4	348				
Shift 24							
84	0800	32	349-353	Fri am	1	1	12
85	1200	23	354-355				
Shift 25							
86	0800	40	356-362	Mon am	1	2	12
87	1200	24	363-364				
88	X	2	-				

Appendix 3

Ward A Unit Supply Individual Patient Dispensing System (Shifts 26-36)

Round	Time	Mins	Patient	Day am/pm	Observer	Obs No	Nurse
Shift 26							
89	0800	24	365-374	Fri am	1	1	1
90	X	3	375-376				
Shift 27							
91	0800	23	377-386	Mon am	1	2	1
92	X	14	387-391				
Shift 28							
93	0800	50	392-400	Wed am	1	1	2
94	1200	21	401-404				
95	1400	13	405-406				
96	X	2	407				
Shift 29							
97	0800	54	408-417	Thurs am	1	2	2
98	1200	16	418-419				
99	1400	24	420-422				
100	X	1	-				
Shift 30							
101	0800	68	423-433	Tues pm	2	1	4
102	1200	50	434-443				
Shift 31							
103	0800	36	444-447	Wed am	2	2	4

104	1200	8	448				
Shift 32							
105	0800	38	449-454	Sat am	2	1	5
106	1200	20	455-456				
107	X	7	457-459				
Shift 33							
108	1600	6	460-461	Wed pm	1	2	5
109	2000	45	462-471				
110	X	6	472-473				
Shift 34							
111	0800	41	474-483	Tues am	1	1	6
112	1200	19	484-486				
Shift 35							
113	1400	18	487-293	Thurs pm	1	2	6
114	1600	6	494				
115	2000	36	495-503				
Shift 36							
116	1600	11	504-505	Fri pm	2	3	6
117	1800	14	506-508				
118	2000	27	509-512				
119	X	3	513				

Appendix 4

Ward B Unit Supply Individual Patient Dispensing System (Shifts 37-51)

Round	Time	Mins	Patient	Day am/pm	Observer	Obs No	Nurse
Shift 37							
120	0800	22	514-520	Tues am	1	1	7
121	1200	13	521-528				
122	X	6	529-532				
Shift 38							
123	0800	12	533-536	Tues am	2	2	7
124	1200	4	537				
125	X	3	538				
Shift 39							
126	0800	24	539-545	Wed am	1	1	8
127	1200	7	546-549				
Shift 40							
128	1400	10	550-555	Fri pm	1	2	8
129	1600	9	556-668				
130	1800	7	559-560				
131	2000	19	561-566				
Shift 41							
132	0800	37	567-574	Sat am	2	1	10
133	1200	29	575-580				
Shift 42							
134	0800	38	581-587	Mon am	2	2	10

135	1200	34	588-589				
Shift 43							
136	0800	25	590-593	Fri am	1	3	10
137	1200	15	594-598				
Shift 44							
138	1600	8	599-602	Tues pm	1	1	11
139	2000	8	603-606				
Shift 45							
140	0800	13	607-610	Thurs am	1	2	11
141	1200	7	611-612				
Shift 46							
142	1400	7	613	Fri pm	2	1	12
143	1600	13	614-616				
144	2000	21	617-621				
145	X	9	622-623				
Shift 47							
146	0800	23	624-629	Sun am	2	2	12
147	1200	12	630-631				
148	X	2	-				
Shift 48							
149	1400	8	632-636	Mon pm	1	1	13
150	1600	8	637-640				
151	2000	9	641-644				
Shift 49							
152	1400	14	645-648	Wed pm	1	2	13
153	1600	7	649-652				

154	1800	12	653-657				
155	2000	20	658-662				
156	X	1	663				
Shift 50							
157	0800	13	664-668	Thurs am	1	1	14
158	1200	6	669				
159	X	7	670-672				
Shift 51							
160	0800	27	673-679	Fri am	1	2	14
161	1200	22	680-684				

Appendix 5

Presentations and Publications arising from this thesis.

1. McNally KM, Page MA, Sunderland VB. Ward stock and unit supply drug distribution: influence on nursing time, pharmacy time and medication errors. Australian Journal of Hospital Pharmacy. 1997; 27 (1): 22-7

2. McNally KM, Page MA, Sunderland VB. Failure mode and effects analysis in improving a drug distribution system. American Journal of Health-System Pharmacy. 1997; 54: 171-7

3. McNally KM, Sunderland VB. No-blame medication error reporting by nursing staff at a major teaching hospital. International Journal of Pharmacy Practice. (submitted for publication)

4. McNally KM, Page MA, Sunderland VB. Drug wastage costs in two methods of drug distribution at a teaching hospital; ward stock versus unit supply. Lancet (submitted for publication)

5. McNally KM, Page MA, Sunderland VB. Medication administration errors; a study comparing error rates in the existing ward stock system to a unit supply dispensing system in a teaching hospital (abstract). Australian Journal of Hospital Pharmacy. 1994; 24: 132-3. Poster presentation. Society of Hospital Pharmacists of Australia 21st Federal Conference 1993. Sydney, Australia

6. McNally KM, Page MA, Sunderland VB. Non-injectable medication costs in two systems of medication distribution: ward stock versus unit supply (abstract). Australian Journal of Hospital Pharmacy. 1997; 27: 185. Poster presentation. Society of Hospital Pharmacists of Australia State Branch Conference 1996. Perth, Australia

7. McNally KM, Page MA, Sunderland VB. Non-injectable medication costs in two systems of medication distribution: ward stock versus unit supply (abstract).

Australian Journal of Hospital Pharmacy (submitted for publication). Poster presentation. Society of Hospital Pharmacists of Australia 23rd Federal Conference 1997. Adelaide, Australia

8. McNally KM, Sunderland VB. No-blame medication error reporting by nursing staff at a major teaching hospital (abstract). Australian Journal of Hospital Pharmacy (submitted for publication). Poster presentation. Society of Hospital Pharmacists of Australia 23rd Federal Conference 1997. Adelaide, Australia

Appendix 6

Medication System Evaluation

System Failure Report Form

Circle where appropriate

1. Medication omitted (not given to patient at all or by the time the next dose is due)
2. Incorrect dose given to patient (higher or lower than prescribed dose)
3. Extra dose given (dose given more often than prescribed to be given)
4. Wrong formulation given (eg: SR preparation given instead of plain tablet)
5. Incorrect drug given to patient
6. Wrong route of administration used (eg: oral instead of IV)
7. Documentation error (eg: dose given but not signed for on chart or signed on chart but not given)
8. Drug given to wrong patient
9. Time dose given different to charted time (more than 30 minutes and less than 2 hours)
10. Time given different to charted time (more than 2 hours)

Extra Information (if report requires extra explanation)

_____

_____

_____

_____

Name_____Date_____ Time_____

Appendix 7

Sir Charles Gairdner Hospital Accident, Incident and Error Report Form

(See over)

Note: For copyright reasons Appendix 7 has not been reproduced.

(Co-ordinator, ADT Project (Retrospective), Curtin University of Technology, 4.12.02)