Conveying Meaning Through Design in a Safety Critical Medical System

A thesis submitted for the degree of Doctor of Philosophy

by

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Abstract

Medication errors account for a significant number of medical errors. Giving medications to patients is an activity that carries a high risk of error. In an effort to improve patient safety in this area several approaches have been employed. Many of these have taken a systems approach in that they consider how organisational factors such as medicines management, staffing levels, ward layout, shift patterns and staff training have contributed to the errors. None of these studies describe errors in detailed form at task level. This Thesis addresses the gap in knowledge by presenting a systematic analysis of the component tasks of hospital drug administration where none exists and goes on to describe novel design artefacts that assist the identification of drugs.

The thesis highlights how hierarchical task analysis, a human factors technique, can be applied to the hospital drug administration task. Task analysis techniques have been used in many high-risk domains in industry as a means of analysing human activity in complex systems but remains an underused technique in health care. Used with the Systematic Human Error Reduction and Prediction Approach (SHERPA), hierarchical task analysis provides an effective way of predicting where errors in the drug administration task are likely to occur. SHERPA uses a taxonomy of human error modes to highlight types of error and makes suggestions to reduce these errors. Medication errors take many forms however it was decided to focus on the immediate interaction between the nurse and the patient. The measures considered to potentially

have a significant influence were adding conspicuous labelling to medication packages. These were enhanced by icons intended to represent categories of drugs. Constructing a three dimensional representation of the icon design was considered to provide nurses with an additional channel of information.

Technological solutions were proposed and a patient identity bracelet that uses a programmable chip to link the patient to their prescribed medication was viewed as having a huge potential to simplify the checking aspect of administering medications in which the nurse compares a medication order which is often badly written with available drug stock. The device prevents nurses giving medications to the wrong patient. It also prevents them administering an overdose.

Table of Contents

List of Appendices

List of Tables

List of Figures

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Chapter 1

Medical and Medication Errors

1.1 INTRODUCTION

Errors in health care have increasingly become the focus of media attention during the past few years. Many of these errors involve the use of drugs both within hospitals and in the wider community. As drugs become more powerful and prolific there is a need to examine the issues surrounding their distribution and use.

A summary of this Thesis is presented in figure 1.1. This work begins with a literature review of the wider context of medical errors of which medication errors are a subset. The review highlights the prevalence of medication errors in the UK and the rest of the world and considers some of the underlying factors influencing medication errors and the effect of these errors on nurses. Consideration is also given to techniques used in high-risk industries that have been employed to address the issue of medication errors.

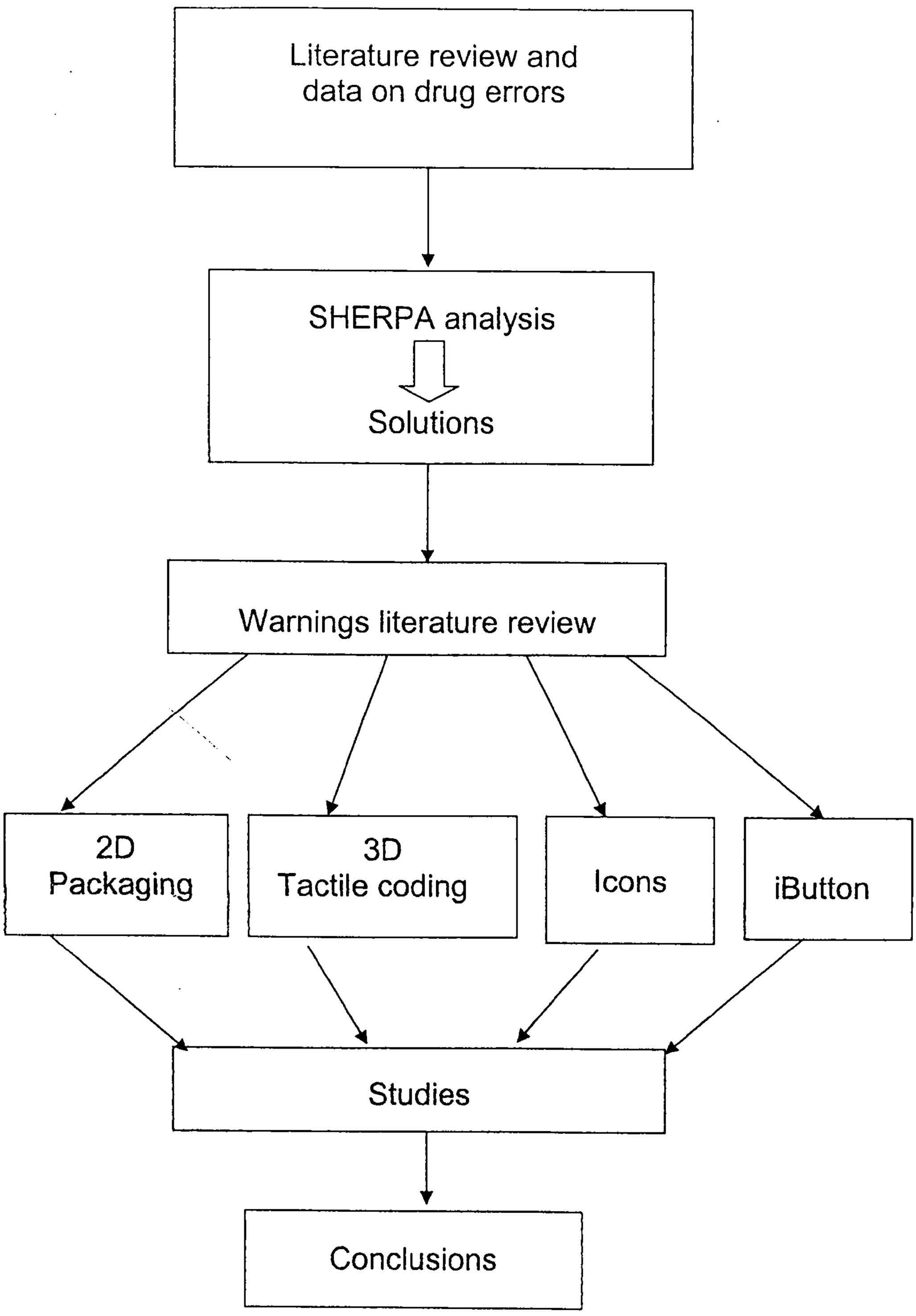


Figure 1.1: Thesis Summary

Chapter two describes how two human reliability assessment techniques, hierarchical task analysis and the Systematic Human Error Reliability and Prediction Approach (SHERPA), that have been successfully used in other safety critical domains, can be applied to the hospital drug administration task in a bid to reduce the number of errors. The SHERPA analysis highlights several drug administration errors that can be resolved by design solutions such as increasing the conspicuity of packaging, labelling and employing technology. The literature review of warnings presented in Chapter three was carried out to inform the next stage of work which involved considering how colour, the use of icons could be used to increase conspicuity in order to enhance perception of the information contained on packaging and labelling. Chapter four demonstrates the execution of these principles in that colour coding and iconography are employed to help distinguish between classes of drugs. This chapter also demonstrates how adding tactile coding features to packaging has the potential to increase recognition types of drugs. Chapter five is concerned with designing icons for use on drug packages and testing for appropriateness and recognition.

The SHERPA analysis described in chapter 2 recommends the use of technology to address several medication errors such as giving the wrong drugs to patients, failure to check patients' charts or failure to check patients' identities. Chapter six describes the design of an intelligent patient identity bracelet that uses ibutton technology that can be programmed to make a direct link between the patient and their medications, whilst chapter seven provides a summary of the thesis.

This Thesis contributes to knowledge by presenting a study of medication error at task level. Many studies have focussed on describing and categorising error types first and have considered causal factors such as the nature of nurses' tasks as a secondary issue. In presenting a task analysis of the hospital drug administration task this study is offering something that has not been done before. In systematically analysing medication errors using the SHERPA technique the study applies a well-established human error identification technique to a novel domain. The Thesis goes on to develop and test novel design products developed to address aspects of the medication error problem.

1.2 LITERATURE REVIEW

1.2.1 Medical Error

Medical errors affect up to 850,000 people in the UK each year (Department of Health, 2000). These errors cost the NHS up to £2 billion in additional treatment, extended time spent in hospital and in community care. The cost of clinical negligence settlements is about £400 million. These figures are based on a study by Vincent et al (2001) which indicated that 10.8% of 1014 patients admitted to two London hospitals suffered adverse events. Of these 66% (63) suffered minimal impairment or recovered within one month. Twenty-one patients (19%) suffered moderate impairment and 7 (6%) were permanently harmed whilst 9 (8%) died. In 48% of cases these adverse events were judged preventable.

Medical error is also a significant cause of death in the US. The Harvard Medical Practice Study (Brennan et al, 1991) using data obtained from 30,121 randomly selected patient record charts taken from 51 acute non-psychiatric hospitals for the

year 1984 identified a total of 1278 adverse events. An adverse event is an unintended injury resulting from any form of medical treatment rather than the disease process (Leape et al, 1995). From this figure it was estimated that in New York State, adverse events occurred in 3.7% of hospitalisations and 27.5% of these were due to negligence. For 70% of patients the adverse event led to slight temporary disability. Seven percent of patients suffered permanent disability and in 13.6% of cases the outcome was fatal.

Similar findings were noted in a study by Gawande et al (1999) of the states of Colorado and Utah. The charts of a random sample of 1500 discharged patients were reviewed. Adverse events occurred in 2.9% of cases, half of which were considered preventable. Of these, 6.6% lead to the death of the patient and 19.3% related to the use of medication.

More than 33.6 million people were admitted to US hospitals in during the year 1997. Extrapolating the results of these two studies imply that between 44,000 and 98,000 Americans die in hospitals each year as a result of medical errors. These figures exceed the number of deaths resulting from vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516). Total national costs in terms of lost income, disability and health care costs are estimated to be between $37.6 billion and $50 billion for adverse events and between $17 billion and $ 29billion for preventable adverse events (Kohn et al, 1999).

1.2.2 Medical errors in Australia, New Zealand and Canada

The Quality in Australian Health Care Study (Wilson, 1995), was modelled on the Harvard Study in that it was also a retrospective chart review study, this time using 14,179 medical record charts of admissions to 28 hospitals in New South Wales and South Australia. Adverse events occurred in 16.6% of admissions and half of these were considered preventable. In a review of various data sources Runciman (2003) revealed that between 2 and 4 percent of all hospital admissions involved medication related incidents and up to 75% of these were preventable. The drugs most often implicated are: anticoagulants, anti-inflammatories, opiods, antihypertensives, antibiotics, cardiac glycosides, diuretics, hypnotics, anti-convulsants, and antipsychotics.

Davis (2002) reviewed 6579 medical records drawn from patients admitted to 13 general hospitals in 1998. The sample was highly representative of admissions to all of New Zealand's generalist hospitals with 100 or more acute beds. The sample figures for age, gender, ethnic group, discharge status and mortality were comparable to national data. Adverse events occurred in 12.9% of admissions and most of these had a minor impact.

Baker et al (2004) randomly selected one teaching and three community hospitals in each of 5 provinces of Canada. A total of 4164 patient charts were sampled and 3776 were included in the initial screening. Full screening was carried out on 3745 charts. Of these, 1527 (40.8%) were assessed as positive for one or more screening criteria and were reviewed by physicians. A total of 1133 adverse events were

identified in 858 charts and of these 401 (46.7%) patients suffered harm that resulted in an extended stay in hospital, disability or death.

1.3 MEDICATION ERRORS

Ferner and Aronson (2000) define a medication error as "a failure in a drug treatment process that leads to or has the potential to lead to harm to the patient." The definition most commonly used is that given by the National Co-ordinating Council for Medication Error Reporting and Prevention (NCCMERP) in the USA:

> "*...any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems including: prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use.*"

American systems for monitoring medication errors are more advanced than those in the UK. For instance the United States Pharmacopeia (USP) in association with the Institute for Safe Medication Practices (ISMP) has monitored medication errors since 1991. It also works with the Food and Drug Administration (FDA) to provide information and implement working practices in an effort to reduce errors. Since 1998 the USP has collected information about medication error through MedMARx, an internet-based reporting system. A report of its findings is published annually and during the year 1999, 184 healthcare facilities sent a total of

41,296 error reports of which 42% were due to administration errors (Figure 1). The other errors that occurred were: prescribing (13%), transcribing (27%), dispensing (17%) and monitoring (1%). Sixty three percent of the errors were not intercepted before they reached the patient and 3% of errors caused harm or a fatality.

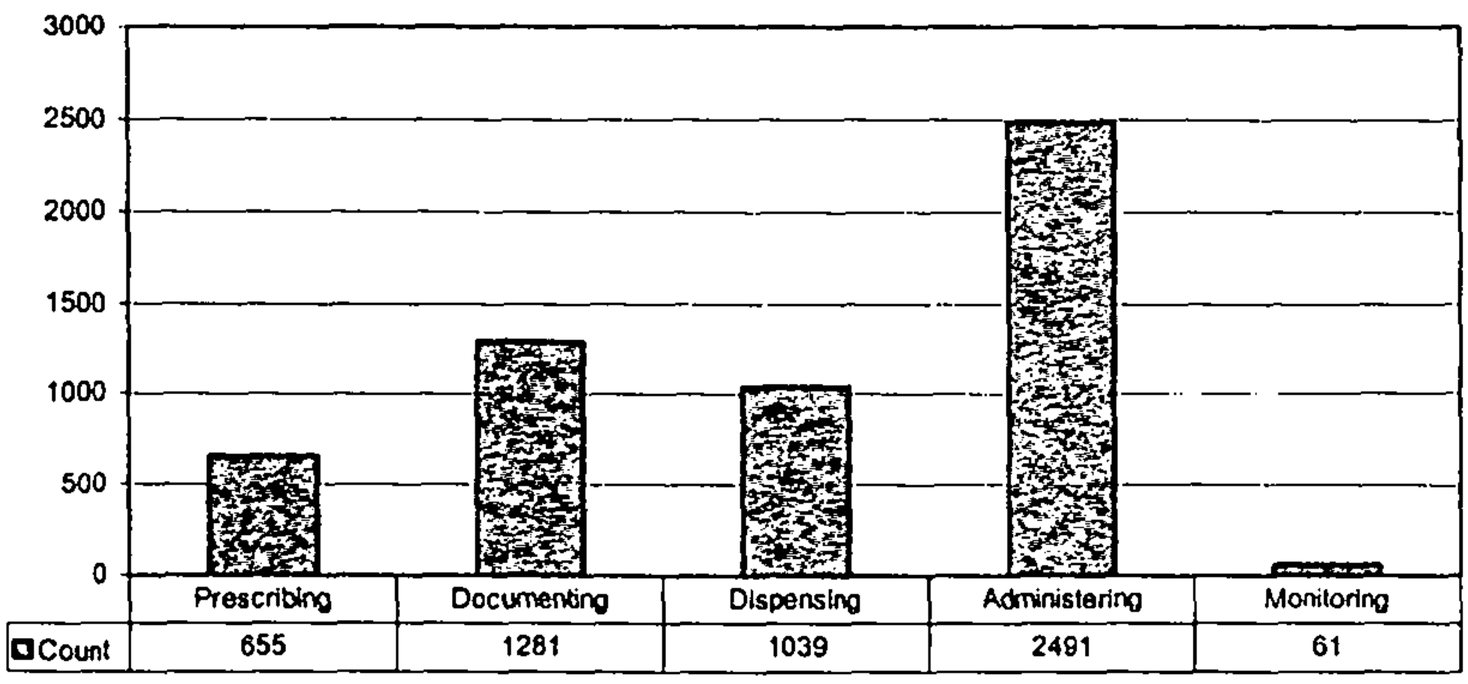


Figure 1.2: Node where most errors have been reported (USP, 2002)

It is only recently that medication error reporting systems have been set up in the UK on a similar scale to the MedMARx system. This has largely happened as the result of Government concern about the number of errors occurring in hospitals. The National Patient Safety Agency (NPSA) was set up in 2001 by the Department of Health to improve the quality of patient care at a national level. Its remit is to gather and analyse safety-related information from the existing reporting healthcare systems and to implement a learning and feedback system ensuring that lessons are learned from errors, risk areas are identified and addressed and solutions put into place to prevent harm.

1.4 MEDICATION ERRORS IN THE UK

The Audit Commission Report, A Spoonful of Sugar (2001), indicates that about 1200 deaths occur in the UK each year due to medication related problems. Of these, 200 are the result of medication errors. The figures given by the Department of Health (2004) range from eight to 24 percent; whilst approximately a quarter of all claims to the medical defence union relate to drugs. However it should be pointed out that some of these claims might also be due to adverse drug events (ADEs). An ADE is an injury caused by a medication (Leape et al, 1995). It may or may not be the result of an error.

Much of the quoted literature is of North American origin (Bates et al, 1995; Leape et al, 1995; Lesar et al, 1997; Classen et al, 1997, Cowley et al, 2001, Kaushal et al 2001) however large medication error studies have been conducted in the UK (Dean et al, 1995; Ross et al, 2000; Bruce and Wong, 2001; Taxis and Barber, 2003).

Dean et al (1995) compared medication errors in a hospital in the United States and a hospital in the United Kingdom. The study was conducted in wards with a high oral-drug-related workload in two large university hospitals. Medication errors were identified retrospectively in the US hospital by comparing the observer's notes with the original drug orders made in the patient's chart by the physician. In the UK hospital, identification of errors took place concurrently; as doses were administered, they were compared with the orders on the medication chart. In the US hospital 919 opportunities for error were observed and the medication error rate was 6.9%. Incorrect doses and unordered doses were the most common types of

error. In the UK hospital, 2756 opportunities for error were observed and the error rate was 3.0%. The most common types of errors were omitted doses and incorrect doses.

Ross et al (2000) carried out a study to determine the incidence and type of medication errors in large paediatric hospital. Their results indicated that over a five-year period from April 1994 to August 1999 the incidence of medication errors was 0.15% (one error in 662 admissions); the neonatal intensive care unit experienced the highest rate at 0.98%, nevertheless most errors occurred in the medical wards. Nurses reported most errors and at the time of reporting most errors were considered to be minor. In this study the age of the children involved in medication errors was not a strongly associated factor except in the case of younger children. Forty four percent of errors occurred in children under two years of age. Incorrect infusion rate was the commonest error followed by incorrect dose (14.8%) whilst the third most common error was giving the patient an extra dose. Fifty six percent of errors involved drugs given by the intravenous route and oral medication errors accounted for 34% of cases. The most frequent drugs involved in these errors were antibiotics. Intervention measures included instruction of junior doctors in good prescribing practice by a senior paediatric pharmacist and the provision of paediatric formularies. Training in the use of intravenous systems was provided for junior medical staff when they started work at the hospital.

Taxis et al (1999) compared the incidence of medication errors in a UK hospital that used the ward pharmacy system and two German hospitals – one using the unit

dose system and the other using the traditional German system. The ward pharmacy system entailed keeping the most frequently dispensed drugs on the ward as stock. Nurses administered medication by pushing a wheeled trolley from bed to bed during each of the four daily drug rounds and recorded the doses given. In the traditional German system each ward kept a large floor stock of formulary drugs that were ordered from the pharmacy twice each week by nursing staff. Doctors prescribed medication in a section of the of the patient's medical notes which was then transcribed by the nurse onto a drug administration chart for each patient. Each patient's drug administration card was placed under a plastic cover of their section of the drug administration tray. Nurses prepared medication using the charts in the drug preparation room for each of the four daily drug rounds. Patients' drugs were prescribed on an admission sheet. Any further changes made were written on sheets and added to the patients' notes. In the case of the unit dose system nurses and pharmacists could enter prescriptions into the computer and medication was dispensed in the pharmacy in single packages each with the patient's name, room number, drug details and time of administration. The doses were placed in individual patient drawers in a drug trolley.

Medication errors were identified by observing the preparation and administration of regularly scheduled solid oral medications. The medication error rate was 8.0% in the UK hospital, with most errors occurring during medication administration. In the German hospitals the error rates were lower. The hospital using the traditional system recorded an error rate of 5.1% mainly due to omission, wrong dose or extra dose errors, whilst in the hospital using the unit dose system the error rate was 2.4%

largely due to omissions, which originated at the transcription stage. These omissions also resulted in wrong drug and wrong dose errors. In both the German systems the errors were largely due to transcription of the original prescription. Suggestions to overcome these problems were to use the original prescription for medication administration and to use cabinets with the patients' own drugs.

1.5 MEDICATION ERRORS WORLWIDE

A study by Philips et al (2001) examined 5366 medication error reports from across the world submitted between1993 and 1998. Fifty-nine reports were excluded as duplicates or intentional overdoses. Patients suffered serious outcomes in 68.2% of cases and 469 (9.8%) people died. The most common types of error resulting in patient deaths were:

- Improper dose 40.9%
- Wrong drug 16%
- Wrong administration route 9.5%
- Wrong strength 5.7%

The most common causes of error were deficits in performance and knowledge (44%) and errors in communication (15.8%). A summary of further studies is presented in table 1.1.

1.6 CAUSES OF ERROR

Medication use is complex and is dependent on the successful interaction of health professionals functioning within different disciplines. Errors can occur at any one of

Study	Method of determining errors	Study Period	Ward	Patients	Error rates	Comments
Schneider et al (1998) Switzerland	Observation	10 weeks	Paediatric ICU	12 Paediatrics	26.9% (275) opportunities for error. Wrong administration technique 32.4%; wrong time error 32.4%; wrong dose preparation 23%	Nurses took more care over drugs with observable immediate effects.
Fontan et al (2003) France	Analysis of prescription and administration reports	8 weeks	Nephrology	49 Paediatrics	Prescription: 937 of 4532 opportunities (20.7%). Administration: 1077 of 4589 (23.5%)	Prescription and administration error rates reduced by using a computerised prescribing and unit dose dispensing system.
Midlöv et al (2005) Sweden	Review medication, admission and discharge notes. Prescription forms	15 months	Transfers from own or nursing home to hospital	Elderly adults (over 65 years) 34 admission 35 discharges	142 errors occurred in 758 transfers	Errors were mainly due to inadvertent withdrawal of drugs when patients were admitted to hospital or erroneously added when they were discharged.

Table 1.1: Medication error studies

Study	Method for determining errors	Study Period	Ward	Patients	Error rates	Comments
Khan et al (2005) Pakistan	Review of drug error reports	5 years	Operating theatre	-	165 drug errors from 768 critical incidents (21%)	Most errors related to neuromuscular blockers
Graf et al (2005) Germany	Incident report forms	64 days	ICU	216	32 errors reported (15%)	Patients had main cardiovascular and pulmonary conditions.
Lisby et al (2005) Denmark	Observation, Control visit Chart review	4 months	Medical and surgical	64 adults	1065 errors from 2467 opportunities for error (43%). Administration errors 166 from 412 (41%)	Common errors were lack of drug form, unordered drug, drug or dosage omission, and lack of identity control.

Step	Action
Prescribing	Evaluate patient Establish need for medication Select right medicine Determine interaction and allergies Prescribe medicine
Documenting	Transcribe prescription Pass to pharmacy
Dispensing	Review prescription Review warnings Confirm transcription if necessary Contact prescribe about discrepancy if necessary Prepare medicine Pass medicine to patient
Administration	Review prescription Confirm transcription Review warnings, interactions and allergies Evaluate patient Administer medicine
Monitoring	Assess patient's response to medicine Report and document results

Table 1.2: Opportunities for medication error
(adapted from Clarkson et al, 2004, p 76)

the five main stages of prescribing, documenting, dispensing or preparation, administering and monitoring (table 1.2). Wolf (1993) has pointed out that nurses make medication errors regardless of their speciality and that errors occurred on medical and surgical floors, postpartum units, emergency units and medical and surgical intensive care units.

In a US study Leape et al (1995) identified several causes of medication error. These were: lack of the knowledge of the drug; lack of information about the patient; rule violations (failure to follow accepted and well established procedures); slips and memory lapses in which the individual "knew better" and could not explain why the error occurred; faulty drug identity checking; faulty interaction with other services (problems in communicating with physicians or other services when patients are in transition between units); faulty dose checking; infusion pump and parenteral delivery problems; inadequate monitoring (failure to adjust the dose of medication in accordance with blood levels, vital signs or lab values); drug stocking and delivery problems; preparation errors in either calculating and mixing drugs and lack of standardisation in drug concentrations, dosing schedules or infusion rates.

Philips et al (2001) identified 583 causes of error each of which were classified according to the NCCMERP Taxonomy of Medication Errors (1998) into one of the five major categories.

The categories are:

- communication - oral and written
- name confusion - look- or sound-alike proprietary names
- labelling - similar or misleading container labels
- human factors – performance or knowledge deficits
- packaging and design – inappropriate package or device design.

Sixty five percent (380) of the causes were due to human factors followed by communication, which accounted for 15.8% (92) causes.

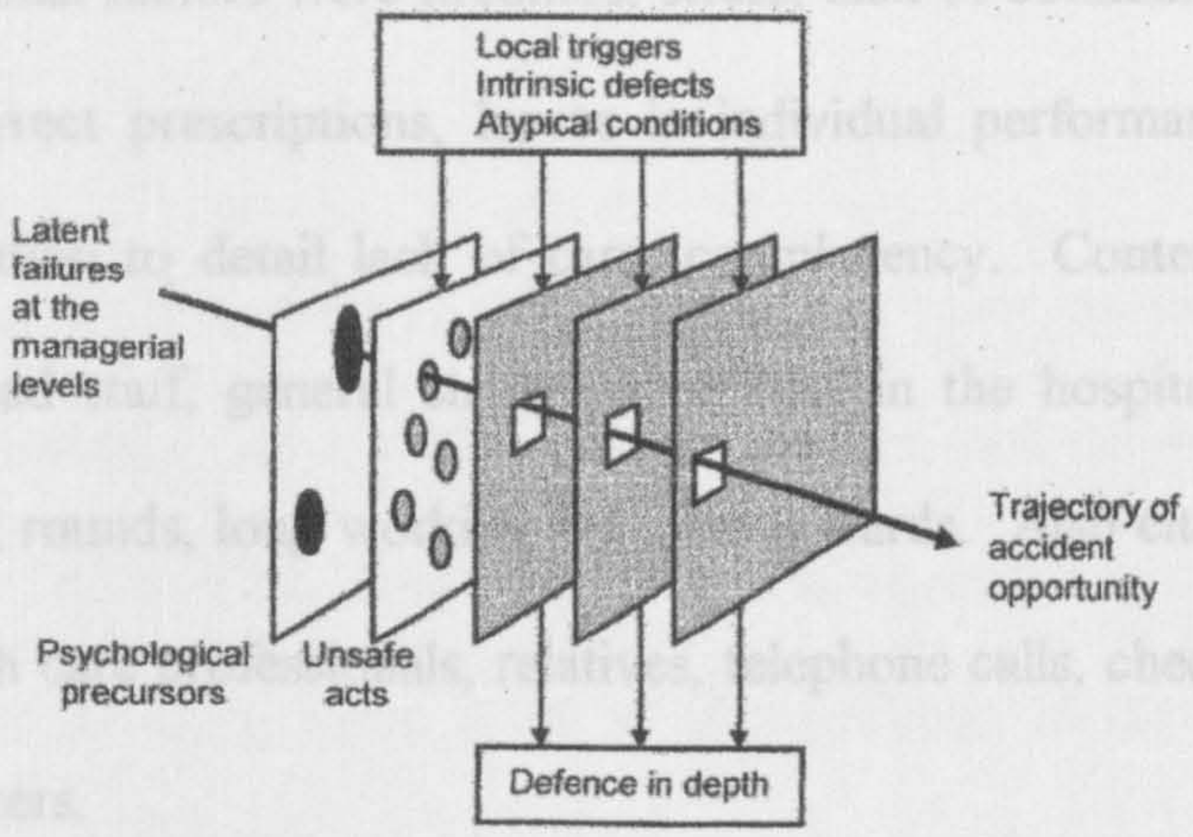


Figure 1.3: Model of how defence barriers and safeguards can be penetrated by an accident trajectory (Reason, 1990)

Responsibility for the error is often placed on the nurse as she or he is the last person in the drug administration chain. A parallel can be drawn with aviation. Pilots used to be held responsible for aviation accidents until analysis revealed other factors were highly significant. The reality is that there are many different causes of errors and they often combine to cause the incident (Vincent et al, 2000). The model in figure 1.2 illustrates how the course of an accident can by-pass a system's defences. Factors such as good design, effective safety devices, and tolerance limits and recommended operating procedures can all function as system defences against accident or failure (Reason, 1990).

1.7 THE EFFECT OF ERROR ON NURSES

In a study of nurses' attitudes and beliefs about what causes medication administration error, Hand and Barber (2000) identified three different categories:

personal factors, contextual factors and knowledge based factors. Examples of personal factors were tiredness, stress, lack of confidence to challenge doctors about incorrect prescriptions, lapses in individual performance, lack of concentration or attention to detail lack of care, complacency. Contextual factors included lack of trained staff, general shortness of staff in the hospital, heavy workloads and long drug rounds, long working days, busy wards. Also cited were interruptions by other heath care professionals, relatives, telephone calls, checking drugs for colleagues and buzzers.

Medical staff are responsible for writing new drug charts on admission, rewriting full charts and writing discharge prescriptions. However, it is often the case that doctors do not perceive transcription as prescribing and consequently did not perform these tasks with the same care as when prescribing a new drug (Dean et al, 2002). This attitude leads to instances of omitted or badly written orders which then become part of the error chain.

Meurier et al (1997) report that nurses commonly become emotionally distressed as the result of error. They may become angry and feel guilty or inadequate, responses that may be associated with taking responsibility for the error.

1.8 LABELLING AND PACKAGING

Drug packaging and labelling are often poorly designed such that it is difficult to discriminate between different categories of drugs, different strengths and routes of administration. The main criterion for manufacturers is that the packaging looks

good and that the product is recognised as an identifiable brand (Kenagy and Stein, 2001). The lettering on labels is often small and in some cases difficult to read (Ferner, 1995).

According to Kenagy and Stein (2001) many packages contain visually confusing information and are more likely to be designed for the marketplace than for practice conditions. This often means that the name of the manufacturer is more prominent than the drug name. It is often difficult to distinguish between two or more strengths of the same preparation and when the manufacturer changes the packaging or the brand name the drug is unrecognisable and practitioners become confused.

Confusing drug names are also a significant source of medication errors. Drug names often look similar when written down and sound alike when referred to verbally. Examples of this are Tolbutamine and Terfenadine (Kenagy and Stein, 2001), Flomax and Vlomax (Phillips et al, 2002) and prochlorperazine and procyclidine. The Audit Commission (2001) cites the case of a cancer patient being prescribed the sedative temazepam instead of the anti-cancer drug tamoxifen. Further examples are shown in figure 1.4.

Examples of sound-alike and look-alike nonproprietary name pairs involved in errors

Names with common chemistry roots	Names with common USAN stems	Other sound-alike/ look-alike non-proprietary names
Acetazol**amide**	Valacyclo**vir**	Anakinra
Acetahex**amide**	Valganciclo**vir**	Amikacin
Chlorpromazine	Azithro**mycin**	Prednisone
Chlorpropamide	Erythro**mycin**	Primidone
Dop**amine**	Nife**dipine**	Metoclopramide
Dobut**amine**	Nicar**dipine**	Metolazone
Hydrocodone	Doxo**rubicin**	Vecuronium
Hydrocortisone	Dauno**rubicin**	Vancomycin

Figure 1.4: An illustration of similarities between generic drug names (FDA, 2003)

Michaeli (2002) describes how a name confusion error caused a fatality in the treatment of a neonate. The child had been born suffering the effects of pethidine given to the mother during labour for pain relief. Whilst attempting to resuscitate the infant the doctor requested the drug naloxone which reverses the effects of opiod overdose. The nurse gave him lanoxine which is commonly used for heart failure. The infant died from ventricular flutter. In this case, the similarity of the drug names and the labels on the injection vials contributed significantly to the error. With the increased numbers of generic drugs, this kind of mistake is a common one that might be preventable if generic names were printed in letters that are more conspicuous than brand names.

1.9 ADDRESSING THE PROBLEM

1.9.1 Reporting systems

In the past accident investigation has been people-centred and this has often resulted in punitive measures. This approach does not remove the potential for recurrence of the incident as the underlying causes are not addressed. Anonymous incident reporting systems are likely to be more successful at reducing errors because potential problems are more likely to be reported as well as actual errors (Anderson and Webster, 2001).

Galletly and Mushet (1991) describe a data gathering and analysis system that identified the factors that aided and hindered the process of error detection, diagnosis and management. An average of 8.1 factors were reported as contributors to each reported error. The authors go on to describe a systems oriented approach to identifying and resolving problems occurring in anaesthesia by devising a schema to organise systematic data collection. Attention was also given to recovery pathways and factors that helped or hindered the effects of error.

1.9.2 Failure mode and effects analysis (FMEA)

High-risk industries (aerospace, defence, nuclear power generation) accept human error as an artefact of human functioning and have taken steps to address it systematically by a variety of means. Failure mode and effects analysis (FMEA) is one such method and was originally developed for use in the field of reliability engineering. The approach is based on the assumption that there are always circumstances in which errors will occur regardless of how knowledgeable or careful

the individual is. At its initial stage FMEA sets out to describe a system and all its functional aspects in detail. It allows the analyst to examine critical aspects of a given process in order to identify all possible or likely errors and to indicate what their effects will be. The steps to follow are:

- Describe the system in detail and its functional blocks
- Identify all possible failure modes and their associated effects
- Develop a critical items list
- Document the analysis

FMEA has been applied to drug administration as a process of continuous quality improvement and is usually carried out by an interdisciplinary group of healthcare professionals (Cohen et al, 1994). A FMEA anticipates what errors can be made and what the results will be. Thus for each medication the analyst will ask what will happen when someone mistakes a drug package for something else; uses the wrong amount of drug, gives the drug to the wrong patient, gives the drug by the wrong route, gives the wrong rate of a drug and so on. The analyst then goes on to consider how best to prevent incorrect action being completed or to minimise their ability to cause an adverse event if they are completed.

1.9.3 Root cause analysis

Root cause analysis (RCA) works backwards in time from the adverse incident to identify and record each salient event (Dhillon, 2003). In collecting the relevant information it is important that the focus of inquiry remains firmly on the facts of

what occurred and why rather than seeking out individuals and apportioning blame. In the US the Joint Commission on the Accreditation of Healthcare Organisations (JCAHO) recommends that health care facilities respond to events in an effective manner within 45 days using RCA. In the UK, the NPSA has developed a web based toolkit that can be accessed by healthcare professionals and used in their workplace.

The benefits of using RCA are that it is a well-structured approach that focuses on processes and is therefore an effective tool to address organisational and systems issues. Its strength lies in the fact that it can uncover underlying root causes of apparently separate incidents. On the downside, it can be a labour intensive, time-consuming technique and it is possible that the analyst might be influenced by the effects of hindsight. One other important factor is that it is impossible to determine if the root cause identified is the one that actually caused the accident.

1.9.4 Technological solutions

There are 100 steps from the time a prescription is written to the time a patient receives the medication. Technology has the potential to reduce medication errors by reducing complexity, avoiding over-reliance on memory, simplifying key processes, and, if designed and implemented properly, increasing efficiency. It can also be a cost-effective tool for improving quality (Hospitals and Health Networks, 2001).

In recent years technological solutions have been employed in an effort to reduce errors in prescribing. These systems alert the physician to inappropriate dosages which in turn contribute to potentially fewer administration errors. Johnson et al (2002) describe how a bar code medication administration (BCMA) system could be used to reduce drug administration errors. This is an automated system using wireless, point of care technology with an integrated bar code scanner. In the UK GPs also use prescription writing software however this technology is only used in a few hospitals.

Other interventions involving information systems that have considerably reduced medication errors particularly those occurring during the prescription stage are: computerised physician order entry, computerised physician decision support, prescription filling robots, bar coding, automated dispensing devices and computerisation of the medication administration record (Bates, 2000 and Ragan, 2005).

1.9.5 Potential for other human factors solutions

The success with which human factors solutions have been applied to this problem in the past suggests that other human factors strategies could be utilised successfully within the present context and these are discussed in the next chapter.

Chapter 2

Applying HTA and SHERPA To Drug Administration

2.1 BACKGROUND TO MEDICATION ADMINISTRATION

2.1.1 General background

Many of the above studies have systematically analysed the context of drug administration. Some of these, as pointed out in Chapter 1, have used a human factors approach, the benefits of which have been highlighted by Schneider (2002) within the context of medication errors. He makes the point that health care providers need to be more aware of the limits of human performance and that system changes need to be made to accommodate these limits. There is still an expectation of perfection among medical professionals at a time when risk is an accepted part of daily life in other fields of activity. This is in part due to training and a number of other factors such as the culture of blame and the punitive measures that still exists within the health care domain. The added pressure of increasing media coverage of errors in recent years has placed the medical

profession under intense public scrutiny which in turn has lead to a certain degree of defensiveness.

There are no studies that have applied task analysis to the hospital drug administration task. Task analysis is a method of describing and analysing how people interact with systems and with other people within that system. It describes what an operator or person is required to do in terms of actions or cognitive processes or both in order to achieve the goal of the system (Kirwan, 1994).

Giving medications to patients is a fundamental nursing role. It is also an activity that carries a high risk of error, as the involvement of different health care professionals means that errors may occur at any stage of the process (Hand and Barber, 2000). According to Anderson and Webster (2001) drug administering medication is probably the highest risk task a nurse can perform, occupying up to one third of their time in hospitals. Nurses seek to give medications correctly or perfectly. However their efforts are often confounded by poorly written prescriptions, constant interruptions, conflicting demands and high workloads.

2.1.2 The ward pharmacy system

In the UK many hospitals have used the ward pharmacy system in which about 80% of medications administered are held as ward stock. These drugs are the most frequently used and are stocked in bottles of 50 or 100 tablets or capsules. Physicians use the patient's chart to indicate to the nurse which medications the patient is to receive. This is kept with the patient and used to record drug

administration. The order includes the drug name, the dose and the drug administration round when it is to be administered. Nurses make a drug administration round with a trolley four to six times daily depending on the ward. Each dose is recorded on the medication chart, which usually allows 14 days of documentation. This allows the patient's most recent drug history to be seen. Pharmacists visit their designated wards daily to review all patient charts performing a clinical and supply function. If a drug that is ordered that is not held as ward stock, the pharmacist makes a note on the medication chart and a supply sufficient for several days is dispensed with the patient's name on the container (Dean et al, 1995).

Type of Error	**No of Errors (%of Total)**
Omission	49 (58)
Incorrect drug	6 (7)
Unordered dose	3 (4)
Incorrect dose	12 (14)
Incorrect route	0 (0)
Incorrect formulation	8 (10)
Other	6 (7)

Table 2.1: Types of medication administration errors in a UK hospital

The errors identified from the above study by Dean (ibid) are shown in the table 2.1. The causes behind these errors were reported as: incorrect selection by nurse (40%), unavailability of medication on unit (39%), unclear prescription or incorrect medication administration record (13%), drug chart unavailable (5%). The methodology used in this study was disguised observation – the investigator's

presence was explained to the nursing staff as being part of a medication administration and work-sampling study. The study did not look at the individual tasks associated with medication administration.

2.1.3 Using patients' own drugs

Patients are often required to take their medication into hospital so that a full medication record can be taken. The Audit Commission (2001) recommended that patients should use their own drugs whilst in hospital rather than have them thrown away. This recommendation has led to the current transitional state of the in-patient drug distribution system in which some hospitals use the ward pharmacy system as described above and others use the patients' own drug system. It is not unusual to find the two systems operating on different wards within the same hospital.

Dean and Barber (2000) carried out an observational study to examine the effects of using patients' own drugs on the incidence and severity of medication administration errors when compared to the more traditional ward pharmacy system. In this study a medication error was defined as any dose of medication administered or omitted that deviated from the written medication order. A total of 257 medication administration errors were noted from 6,067 opportunities for error. Error rates were 4.3 per cent for the traditional system and 4.2 percent for the patients' own drug system. The difference was not significant and contrary to expectations using patients' own drugs did not reduce administration errors. The reason for this was due partly to factors relating to the drugs such as the nurse

selecting the wrong number of tablets for administration. Similarly, unavailability of a particular brand or formulation of a drug led to it being omitted altogether. Additionally labelling on patients' medication was more varied compared to the standard format of medications dispensed from the hospital pharmacy.

2.1.4 Equipment

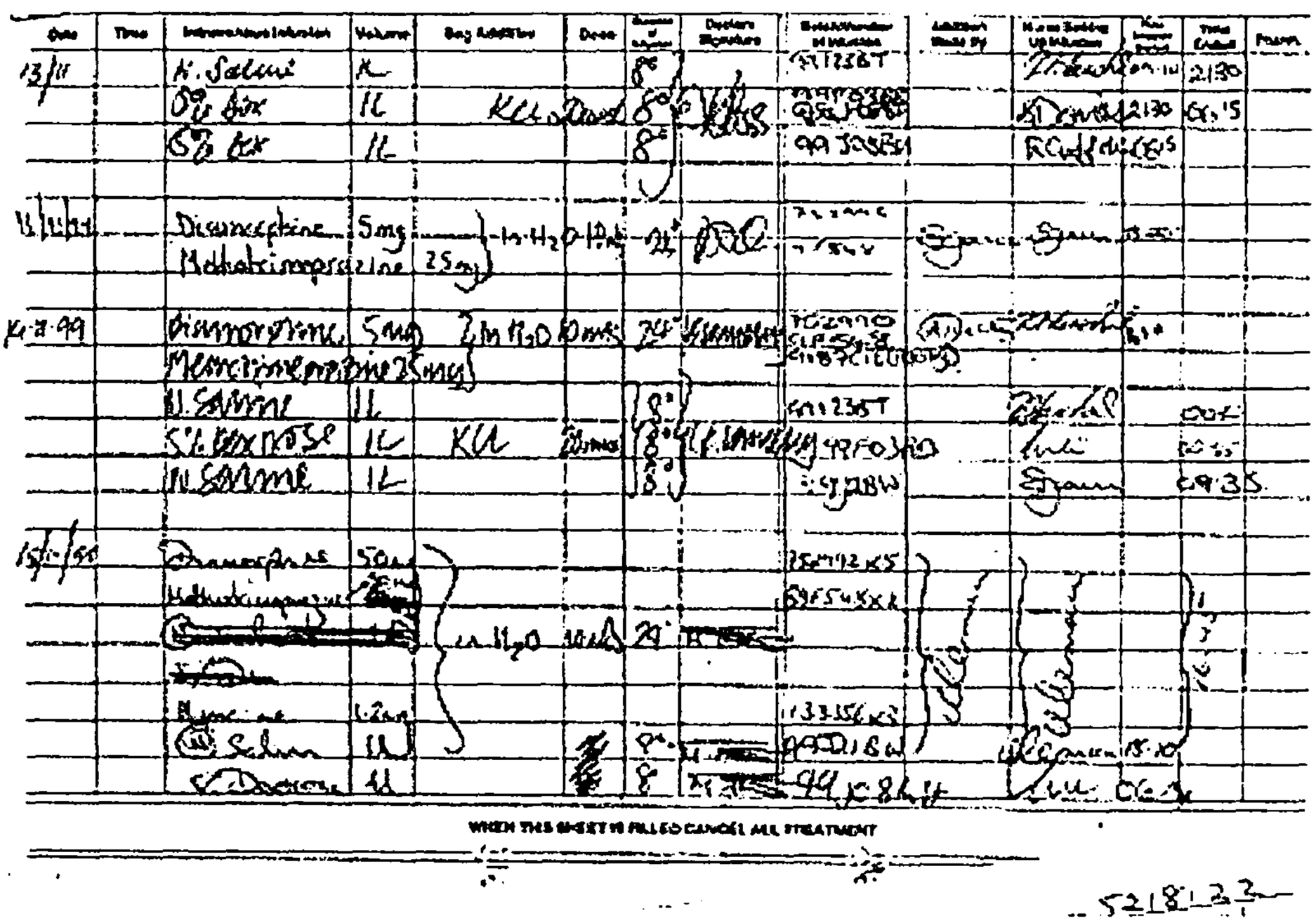


Figure 2.1 Part of a patient medication administration record
(Source: Audit Commission Report – A Spoonful of Sugar, 2001)

Figure 2.1 manifestly illustrates how confusion arises when attempting to interpret the doctors' orders. The drug names are badly written and the deletions, though noticeable create difficulty in making out the doctor's intention.

The problem of badly written drug orders has potentially been overcome by the introduction of physician order entry systems (Bates, 2000) however this will be discussed in more detail in the chapters that follow. Medications are often stored in cupboards in roughly alphabetical order or in trolleys in an arbitrary manner as illustrated by figures 2.2 and 2.3.

Figure 2.2: Drug Storage in a trolley

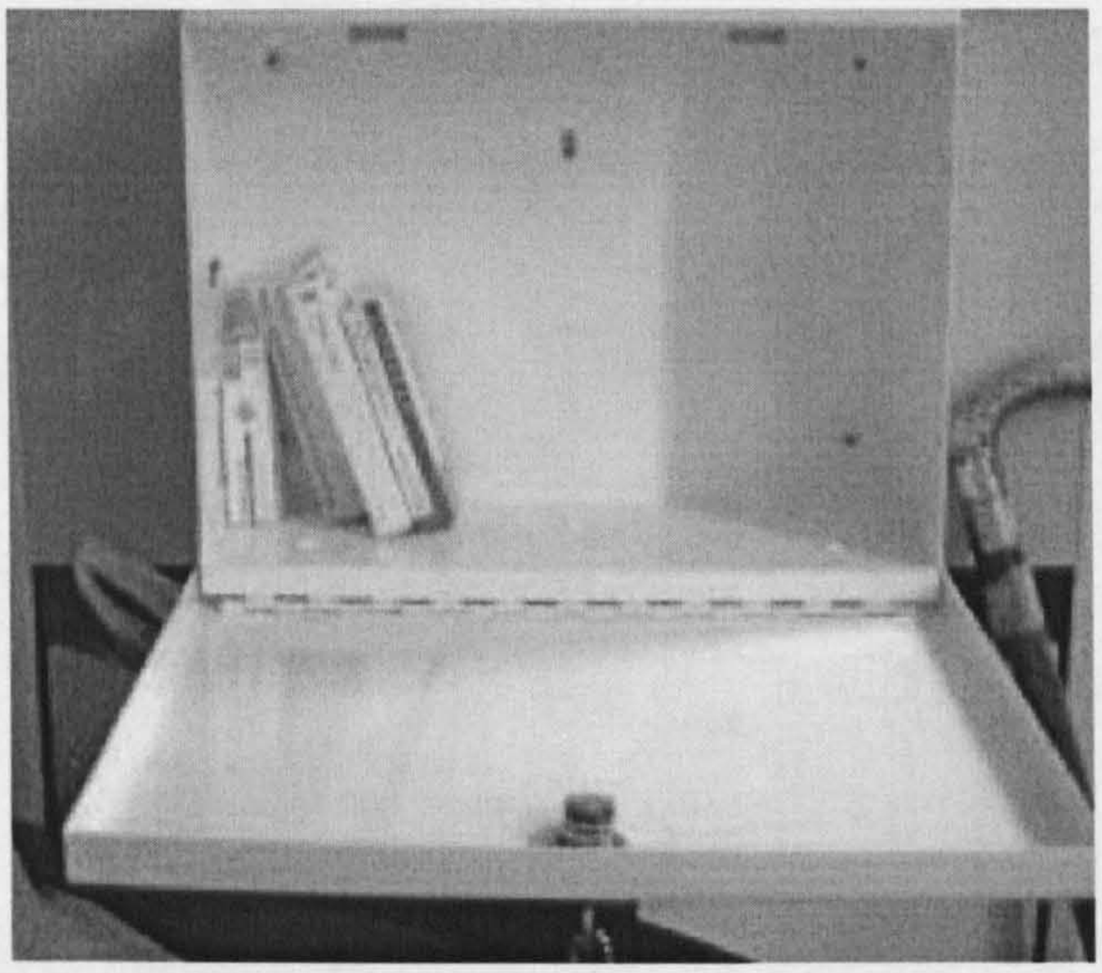


Figure 2.3: Patient's own drugs in bedside medicines locker

2.2 OVERVIEW OF TASK ANALYSIS

2.2.1 Defining task analysis

The term task analysis refers to a range of techniques used by ergonomists, designers, operators and assessors to describe or evaluate human machine and human-human interactions in systems. Task analysis can be defined as the study of what an operator (or team of operators) is required to do in terms of observable physical actions or cognitive processes to achieve the system goal. It is a methodology that can also document the information and control facilities used to carry out a task. A task analysis enables the analyst to collect information and organise it in a systematic way in order to gain a detailed understanding of human involvement within a system. It enables information to be collected and organised in a way that will usefully inform judgements and decisions (Kirwan and Ainsworth, 1992).

2.2.2 The concept of the 'task'

Although the concept of the task is the focus of task analysis there is little consensus about what constitutes a task (Stammers and Shepherd, 1995). Miller et al (1953) described the task as "a *group of discriminations, decisions and effector activities related to each other by temporal proximity, immediate purpose and a common man-machine output."* This description implies that a consistent set of behaviours are employed in achieving a system's goals. In reality, humans are adaptive in their behaviour, a prerequisite when dealing with controlled systems as these are complex and unpredictable. Behaviour is determined by higher processes and is often less influenced by the immediacy of the purpose. Use of the term 'temporal proximity' is unclear as it could refer to any period of time from one second to one day. Generally such definitions are not precise and the terms are used interchangeably.

The main commonly held assumptions are shown in Figure 2.4.

- The term 'task' generally applies to a unit of activity within work situations
- A task may be given to or imposed upon an individual or alternatively carried out on the individual's own initiative and volition
- It is a unit of activity, requiring more than one *simple* physical or mental operation for its completion
- It is often used with the connotation of an activity which is non-trivial, or even in some cases onerous in nature
- It has a defined objective.

Figure 2.4: The main elements that comprise a task (Stammers and Shepherd, 1995)

Many task analyses deal with large-scale complex activities, with the overall activity of the user defined in terms of an overall objective. This is decomposed into constituent tasks, which may themselves have subordinate tasks. The definition of the task is not simply a matter of saying 'it's what a person does'. Within this context it is more complex and encapsulates the three interacting components of task requirements (the objectives or goals carried out by the individual); task environment (the factors in the work situation that limit and determine how well the individual performs) and task behaviour (the actions that are performed to complete the task within the previous two constraints).

The first two elements - task requirements and task environment are determined by the systems context and are influenced by such factors as the organisational framework, operating requirements and procedures, capability of technology, design of interfaces and environmental conditions. These are features that can be observed recorded and predicted. The third element, task behaviour can vary as a function of individual factors and experience (Stammers and Shepherd, 1995).

2.3 HIERARCHICAL TASK ANALYSIS

2.3.1 Background to hierarchical task analysis

The task analysis most frequently used is the Hierarchical Task Analysis (HTA) technique as it is straightforward to use and can be used to address a large range of problems. Developed by Annett et al (1971), the technique allows large amounts of information to be assimilated relatively quickly unlike many of the other task analysis techniques which require extensive scrutiny. It is best to think of HTA as

a model of a system's goals "developed in sufficient detail to enable an analyst to identify each of the features pertinent to making design decisions. In this fashion, the analyst re-describes a goal in progressive detail until each aspect of the task is understood sufficiently to offer an appropriate design hypothesis. As re-description of the task develops, the analyst is able to:

- express the system's goals more explicitly
- identify appropriate features of the context with more precision
- establish methods for accomplishing the task

HTA has been applied to problems associated with issues of task design, training documentation and human reliability analysis. It has been used in many contexts such as managerial, supervisory and operating tasks in the process industries. It has also been used in office environments, warehousing and maintenance and whilst it has been employed in the para-medical professions it is still an underused technique in this area (Stammers and Shepherd, 1995).

The HTA describes a task from its top-level goals down to individual operations, although in reality the task would probably be part of a larger goal. If further description of the task is justified the HTA progresses by adding subordinate operations and a plan. Each of the tasks must completely define how to achieve the top level goal. There should not be any additional but necessary tasks missing from the analysis (Kirwan, 1994).

The three structural components of the HTA are: the plan, the stopping rule and the numbering system. The plan defines the way in which the subordinate tasks are carried out. Very often the plan is simply 'do in order', which means tasks must be carried out sequentially. Some plans however are complex and certain conditions have to be met before the next task can be carried out. The important aspect of the plan is that it determines when to move from one task or operation to the next.

The stopping rule is point at which the analyst stops re-describing the task in terms of subordinate tasks or operations. The point at which to stop is when further description would not add further useful information for analysis purposes. The level of re-description necessary depends on the purpose of the HTA and the level of detail required. However, the analyst usually makes the decision about when to stop.

All but the smallest of HTAs use a hierarchical numbering system. This is done to aid identification of the various parts of the HTA and is a very useful feature when several levels are present.

2.3.2 Lack of protocols

Prior to drawing up the drug administration HTA that follows in this chapter a search was made on the Internet using the Google search engine internet for guidelines related to medication administration by nurses. The guidelines produced by the Nursing and Midwifery Council (2002) are very generalised and do not give specific information partly because hospitals have their own formularies. Different

specialities have drugs specific to various treatment regimes. However Leape et al (1994) recommended standardisation in medication usage and this has been echoed by Cohen (1999). Dougherty and Lister (2004, p203) give useful guidance.

2.3.3 The Drug administration HTA

The HTA (shown in figure 2.5) was drawn up by the author who trained as a hospital pharmacy technician and was reviewed by two nurses, a hospital risk manager and two patient safety experts. The top-level goal of the HTA is to deliver drugs to the patient at Level 0 (Figure.2.5) and is indicated by the phrase 'administer drug to patient'. The assumption is that the order for the drug has been written on a prescription order or medication administration chart and that the drugs are available in the hospital ward. This goal can be broken down to a lower level of 4 sub-goals labelled 1 to 4 in the HTA. These are: 1) checking the patient's chart for the relevant details; 2) acquiring the medication; 3) administering the drug to the patient; 4) recording the dosage given. Plan 0 indicates the order in which the activities or sub-goals that should be carried out in order to achieve the goal.

The two actions required to achieve the sub-goal 'check patient chart' (step 1)' are 'find patient chart' (step 1.1) and 'read chart' (step 1.2). Step 1.1 encourages the analyst to think where the chart might be if not located in the most obvious place on or near the patient's bed by considering alternative locations that may need to be searched. The actions for searching these locations are entered into the HTA at a lower level as operations 1.1.1 – 1.1.5 and the sequence for carrying out these

operations is determined by Plan 1.1.1. Having found the chart it is important to read it in order to gather the relevant information. The pertinent pieces of information are 'drug name', drug dose', 'drug form', 'drug strength', 'drug route' and 'start date' (steps 1.2.1 – 1.2.6) and these are executed according to plan 1.2.

2.4 THE SHERPA ANALYSIS

2.4.1 Background of SHERPA

Having constructed a task analysis to identifying the process of drug administration at a systemic level it is possible to consider what can go wrong in terms of human errors. This is the basis of human error identification which in essence is concerned with the actions or activities people might do in a given situation rather than what they are supposed to do. Analysis of errors in this way leads not only to identification of the errors themselves but also highlights other factors such as: opportunities for error recovery, examination of the consequences of errors and identification of error reduction strategies. In order to do this a classification system of error modes (taxonomy) is devised and it is the taxonomy that underpins the framework of any human error identification technique. The advantages of using taxonomy are that it provides:

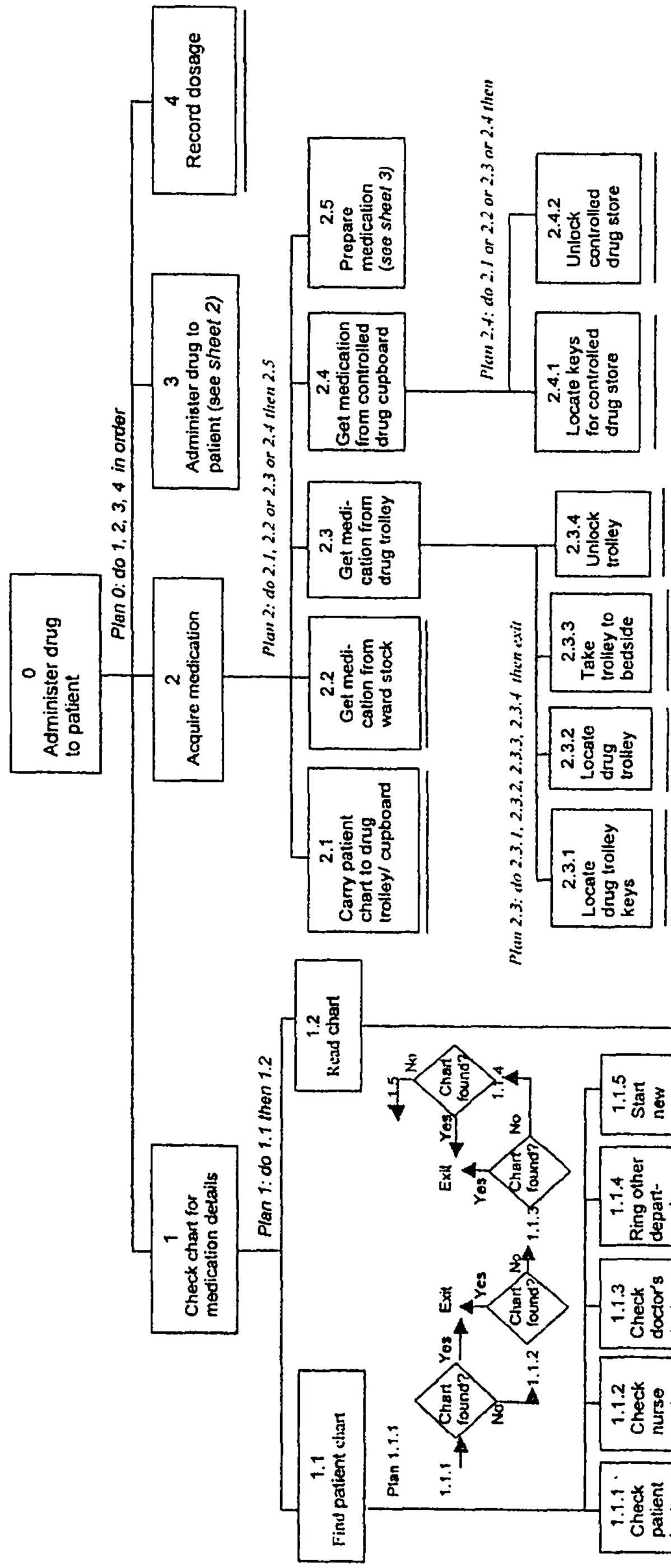
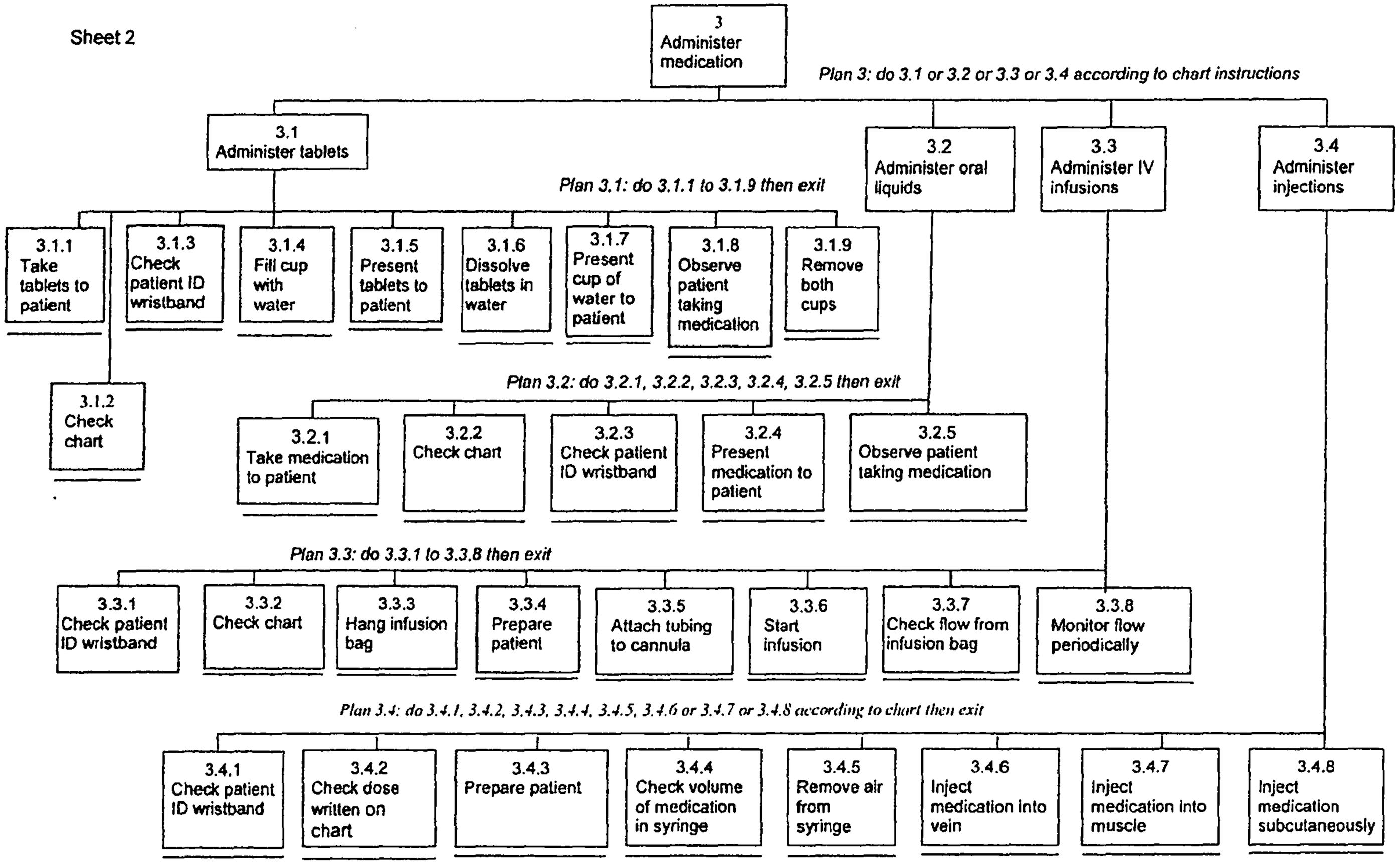
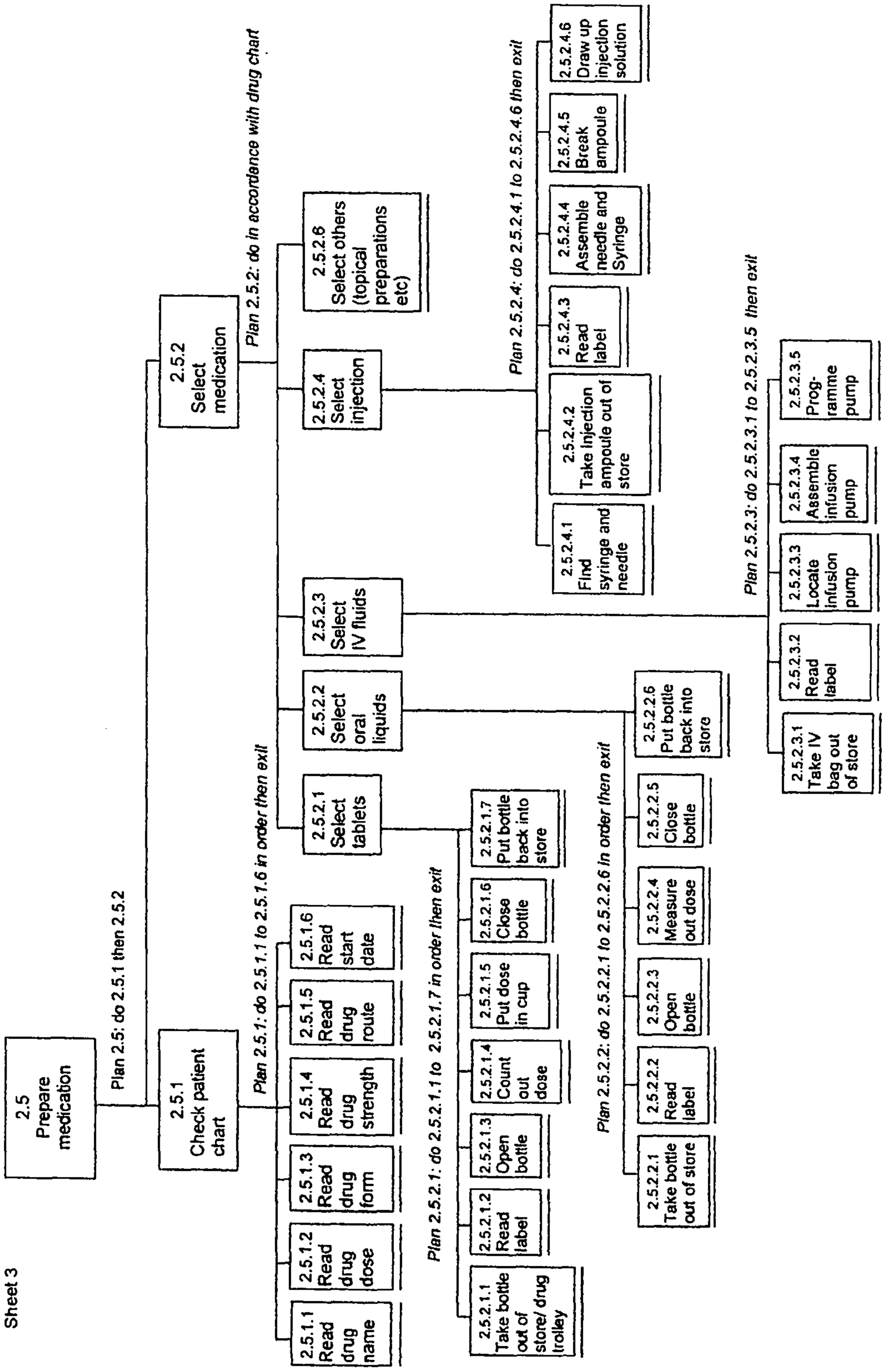


Figure 2.5: HTA for Drug Administration

Sheet 2


3
Administer medication
Plan 3: do 3.1 or 3.2 or 3.3 or 3.4 according to chart instructions
3.1
Administer tablets
3.2
Administer oral liquids
3.3
Administer IV infusions
3.4
Administer injections
Plan 3.1: do 3.1.1 to 3.1.9 then exit
3.1.1
Take tablets to patient
3.1.3
Check patient ID wristband
3.1.4
Fill cup with water
3.1.5
Present tablets to patient
3.1.6
Dissolve tablets in water
3.1.7
Present cup of water to patient
3.1.8
Observe patient taking medication
3.1.9
Remove both cups
3.1.2
Check chart
Plan 3.2: do 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5 then exit
3.2.1
Take medication to patient
3.2.2
Check chart
3.2.3
Check patient ID wristband
3.2.4
Present medication to patient
3.2.5
Observe patient taking medication
Plan 3.3: do 3.3.1 to 3.3.8 then exit
3.3.1
Check patient ID wristband
3.3.2
Check chart
3.3.3
Hang infusion bag
3.3.4
Prepare patient
3.3.5
Attach tubing to cannula
3.3.6
Start infusion
3.3.7
Check flow from infusion bag
3.3.8
Monitor flow periodically
Plan 3.4: do 3.4.1, 3.4.2, 3.4.3, 3.4.4, 3.4.5, 3.4.6 or 3.4.7 or 3.4.8 according to chart then exit
3.4.1
Check patient ID wristband
3.4.2
Check dose written on chart
3.4.3
Prepare patient
3.4.4
Check volume of medication in syringe
3.4.5
Remove air from syringe
3.4.6
Inject medication into vein
3.4.7
Inject medication into muscle
3.4.8
Inject medication subcutaneously


2.5 Prepare medication
Plan 2.5: do 2.5.1 then 2.5.2
2.5.1 Check patient chart
Plan 2.5.1: do 2.5.1.1 to 2.5.1.6 in order then exit
2.5.1.1 Read drug name
2.5.1.2 Read drug dose
2.5.1.3 Read drug form
2.5.1.4 Read drug strength
2.5.1.5 Read drug route
2.5.1.6 Read start date
2.5.2 Select medication
Plan 2.5.2: do in accordance with drug chart
2.5.2.1 Select tablets
Plan 2.5.2.1: do 2.5.2.1.1 to 2.5.2.1.7 in order then exit
2.5.2.1.1 Take bottle out of store/ drug trolley
2.5.2.1.2 Read label
2.5.2.1.3 Open bottle
2.5.2.1.4 Count out dose
2.5.2.1.5 Put dose in cup
2.5.2.1.6 Close bottle
2.5.2.1.7 Put bottle back into store
2.5.2.2 Select oral liquids
Plan 2.5.2.2: do 2.5.2.2.1 to 2.5.2.2.6 in order then exit
2.5.2.2.1 Take bottle out of store
2.5.2.2.2 Read label
2.5.2.2.3 Open bottle
2.5.2.2.4 Measure out dose
2.5.2.2.5 Close bottle
2.5.2.2.6 Put bottle back into store
2.5.2.3 Select IV fluids
Plan 2.5.2.3: do 2.5.2.3.1 to 2.5.2.3.5 then exit
2.5.2.3.1 Take IV bag out of store
2.5.2.3.2 Read label
2.5.2.3.3 Locate infusion pump
2.5.2.3.4 Assemble infusion pump
2.5.2.3.5 Prog-ramme pump
2.5.2.4 Select injection
Plan 2.5.2.4: do 2.5.2.4.1 to 2.5.2.4.6 then exit
2.5.2.4.1 Find syringe and needle
2.5.2.4.2 Take injection ampoule out of store
2.5.2.4.3 Read label
2.5.2.4.4 Assemble needle and Syringe
2.5.2.4.5 Break ampoule
2.5.2.4.6 Draw up injection solution
2.5.2.8 Select others (topical preparations etc)
Sheet 3

- a structure for the assessor
- robustness
- meaning to the assessment – defining underlying causes and reasons

Many of the tools used to model human error are descriptive. However some like the Systematic Human Error Reduction and Prediction Approach (SHERPA) are, as the name implies, predictive of error occurrence. It is a good method to use in the present study because it allows the assessor to carry out a finely detailed analysis and a thorough set of error modes (Kirwan, 1994). Within the present context using a predictive approach like SHERPA has the obvious advantage that medication errors can be analysed without actually observing them, to the benefit of both nurses and patients.

SHERPA was developed by Embrey (1986) for use in the process industries (conventional and nuclear power generation, petrochemical processing and oil and gas extraction). It is a human error prediction technique that analyses a task and identifies potential solutions to errors in a structured manner. The technique is based on a taxonomy of human error (table 2.2) that in its original form specified the psychological mechanisms underlying the error. On-going development of the technique has removed this reference to the underlying psychological mechanism. This human identification error technique allows the analyst to define the information that is useful for error reduction strategies. Kirwan (1994) demonstrates how SHERPA can be applied to the procedure for filling a road tanker with liquid chlorine. The technique has been applied to consumer products such as ticket machines (Baber and Stanton, 1996), vending machines (Stanton

Error type	Code	Error Mode
Action Errors	A1	Operation too long/short
	A2	Operation mistimed
	A3	Operation in wrong direction
	A4	Operation too little/much
	A5	Misalign
	A6	Right operation on wrong object
	A7	Wrong operation on right object
	A8	Operation omitted
	A9	Operation incomplete
	A10	Wrong operation on wrong object
Checking Errors	C1	Check omitted
	C2	Check incomplete
	C3	Right check on wrong object
	C4	Wrong check on right object
	C5	Check mistimed
	C6	Wrong check on wrong object
Retrieval Errors	R1	Information not obtained
	R2	Wrong information obtained
	R3	Information retrieval incomplete
Communication Errors	I1	Information not communicated
	I2	Wrong information communicated
	I3	Information communication incomplete
Selection Errors	S1	Selection omitted
	S2	Wrong selection made

Table 2.2: SHERPA Error Modes (Stanton and Stevenage, 1998)

and Stevenage, 1998), in-car audio systems (Stanton and Young, 1999) and aviation (Stanton et al, 2003). In the medical domain, Joice et al (1998) used SHERPA to analyse the nature and incidence of errors enacted during laparoscopic (keyhole) surgery as a means of identifying training needs and informing prospective research areas.

2.4.2 Validity of SHERPA

In a study to determine if the incidents predicted by several human error identification techniques matched those that had actually occurred, Kirwan (1992) compared SHERPA with 5 other identification techniques on the criteria of comprehensiveness, accuracy, consistency, theoretical validity, usefulness, resource usage and auditability/acceptability with the result that SHERPA was the most highly rated by expert users. Stanton and Stevenage (1998) report concurrent validity and reliability statistics of 0.74 and 0.65 respectively for the application of SHERPA by 25 novice users to the prediction of errors on a confectionery vending machine. Stanton and Young (1999) observed eight novice users predict errors on a radio-cassette machine report a concurrent validity statistic of 0.2. and a reliability statistic of 0.4.

2.4.3 Applying SHERPA to drug administration errors

The task steps from the lower levels of the HTA form the inputs for the SHERPA analysis. These are examined in turn and classified into one of the error types using the human error taxonomy shown in table 2.2 and recorded in tabular form. The most likely error modes associated with a task step or operation are considered. For example, the task step 1.1.1 in the HTA "check patient bed" is

classified as a checking activity. Looking at the associated checking error modes (table 2.2), only the most credible errors for the task step are taken into account. It is possible that whilst searching for a patient chart a nurse may fail to check the area around a patient's bed or may be called away to attend to another patient and so not complete the search. In nursing terms these are not strictly errors but within the SHERPA system these actions would prevent the goal of finding patient chart being achieved and thus fall short of the top level goal of ensuring that the correct patient receives the drug prescribed by the doctor in the correct dosage and form, at the correct time.

A table is drawn up (table 2.3) and in the first column the number of the task step is listed (1.1.1). In the second column the error mode C1 is entered. This denotes that a check has been missed. In the third column of the SHERPA table a description of the error is entered. In this case the description would be "Fail to check patient bed area". At this stage of the analysis it is possible to make a prediction of what the consequence of that error might be. The chart would remain mislaid and because the nurse had no record of what drugs were due to be taken or when, drug doses would be missed. Thus, in the fourth column under the heading "consequences" a description of the potential consequence of the activity is entered. The fifth column of the table (recovery) indicates whether or not the error can be recovered. It may be that by completing further task steps, the nurse will be able to go back and correct the original error or omission. If this is the case then the task step at which the original error may be recovered is entered in column 5 under the heading "Recovery". If it is not possible to recover the error

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
1.1.1	C1	Fail to check patient bed area	Chart not found - drug doses missed	1.1.2	L	Tagging system for location of charts.
	C2	Carry out an incomplete check at patient bed	Chart not found - drug doses missed	1.1.2	L	Tagging system for location of charts.
1.1.2	C1	Fail to check nurse station	Chart not found - drug doses missed	1.1.3	M	A tagging system for location of charts.
	C2	Carry out an incomplete check of nurse station	Chart not found - drug doses missed	1.1.3	M	Tagging system for location of charts.
1.1.3	C1	Fail to check doctor's desk	Chart not found - drug doses missed	1.1.4	M	A tagging system for location of charts.
	C2	Carry out incomplete check of doctor's desk	Chart not found - drug doses missed	1.1.4	M	A tagging system for location of charts.
1.1.4	R2	Given false information about the chart location due to mix up in patient names	Drug doses missed	1.1.5	L	System should track patient information through departments
1.1.5	A6	Start new chart for wrong patient	Drug doses missed or wrong treatment regime initiated		L	Formal chart reviews
	A8	Fail to start new chart	Doses missed leading to deterioration of patient condition		L	Local alert system for mislaid/lost charts or tagging system
1.2.1	R2	Read drug name incorrectly	Selection of wrong drug for administration	Check before administering 2.5.1.1	H	Indicate the patient condition the drug is prescribed for
1.2.2	R2	Read drug dose incorrectly	Administration of overdose or dose of no therapeutic value	2.5.1.2	H	Only use standard abbreviations or write words in full. Computerised order entry.

Table 2.3:SHERPA Output – Human Error Analysis Table

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
1.2.3	R1	Fail to read pharmaceutical drug form	Administration of ineffective dose that could lead to an overdose	2.5.1.3	M	Computerised order entry
1.2.4	R1	Fail to read drug strength	Administer an overdose or dose of no therapeutic value	2.5.1.4	M	Computerised order entry coupled with barcodes and scanning
1.2.5	R1	Fail to read drug route	Administer drug through the wrong route	2.5.1.5	L	Write in full rather than use abbreviations
1.2.6	R1	Fail to read start date	Give drug too early/late in treatment	2.5.1.6	L	Highlight or write conspicuously
2.1	A8	Fail to carry chart to drug trolley or drug storage area	May forget drug name, dose, form, route	None	M	Take chart to drug store/trolley.
2.2	A6	Get wrong medication from ward stock	Give wrong drug	2.5.1.1	H	Better labelling in storage area. Greater conspicuity of labels.
2.3.1	A9	Unable to find drug trolley keys	Unable to open drug trolley doses omitted		M	Keep keys in a designated area or have several sets of keys to given to designated staff.
2.3.2	A9	Fail to locate drug trolley	Doses omitted		L	Keep trolley in designated place. Tagging.
2.4.1	A9	Unable to find controlled drug cupboard keys	Doses omitted		L	Keep trolley in designated place. Tagging.
2.5.1.1	R2	Read drug name incorrectly	Selection of wrong drug for administration	2.5.2.1.2	H	Indicate the patient condition for which the drug is prescribed.

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
2.5.1.2	R2	Read drug dose incorrectly	Administration of overdose or dose of no therapeutic value	2.5.2.1.4	H	Only use standard abbreviations or write words in full. Computerised order entry.
2.5.1.3	R1	Fail to read drug form	Administration of ineffective dose that could lead to an overdose	2.5.2.1.2	M	Computerised order entry.
2.5.1.4	R1	Fail to read drug strength	Administer an overdose or dose of no therapeutic value	2.5.2.1.2 also 3.1.2	M	Computerised order entry coupled with barcodes and scanning.
2.5.1.5	R1	Fail to read drug route	Administer drug through the wrong route	3.1.2	L	Write in full rather than use abbreviations
2.5.1.6	R1	Fail to read start date	Give drug too early/late in treatment	3.1.2	L	Highlight or write conspicuously.
2.5.2.1.1	A6	Take wrong bottle out of store/drug trolley	Give wrong drug	2.5.2.1.2	H	Smart labelling.
2.5.2.1.2	R1	Fail to read label	Give wrong drug	Immediate	M	Make labels on packages more conspicuous
	R2	Read label incorrectly	Administer an overdose or dose of no therapeutic value		M	More training about drugs. Colleague checks.
2.5.2.1.4	A7	Miscount dose	Administer an overdose or dose of no therapeutic value	Check controlled drug book in the case of controlled drugs	M	Colleague checks the dose.
2.5.2.1.6	A7	Put wrong dose in cup	Administer an overdose or dose of no therapeutic value		M	Have colleague check dose.

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
2.5.2.1.7	A7	Put bottle back in wrong place	Wrong medication may be selected by the next person		M	Develop clear labelling system in storage area.
2.5.2.2.1	S2	Take wrong bottle out of store	Administer an overdose or dose of no therapeutic value		L	Use colour coding.
2.5.2.2.2	R1	Fail to read label	Wrong drug administered	Immediate	M	Make labels on packages more conspicuous.
	R2	Read label incorrectly	Give wrong drug or dose		M	More training about drugs. Colleague checks.
2.5.2.2.4	A6	Use incorrect measure	Give too much/little to patient resulting in over/under dose		L	Colleague checks what has been measured.
2.5.2.2.6	A7	Put bottle back in wrong place	Wrong medication may be selected by the next person		M	Clearer labelling in storage area.
2.5.2.3.1	S2	Take wrong IV bag from store	Give wrong drug		H	Clearer labelling in storage area.
2.5.2.3.2	R1	Fail to read label	Give the wrong drug or wrong dose	Immediate	H	Make labels on packages more conspicuous.
	R2	Read label incorrectly	Give the wrong drug or wrong dose		H	Make labels on packages more conspicuous.
2.5.2.3.3	A9	Unable to locate infusion pump	Might select wrong equipment eg syringe driver		H	Keep pumps in a central storage area or equipment library.
	S1	Select wrong pump	Give wrong dose		H	Have a guidance chart available. Reduce number of pumps to simplify selection.
2.5.2.3.4	A7	Assemble pump incorrectly	Free flow of medication resulting in overdose		H	Training in infusion pump usage. Reduce the number of different pumps used.

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
2.5.2.3.5	A7	Enter wrong programme	Wrong or no dose delivered	Immediate	H	Redesign interface to simplify programming task.
	A9	Programming incomplete	Wrong or no dose delivered		H	Redesign interface to reduce the number of programming steps.
2.5.2.4.1	S2	Locate wrong sized syringe	Give wrong dose		H	Pre-filled syringes
2.5.2.4.2	S2	Take wrong ampoule from store	Give wrong drug or dose		H	Clearer labelling of storage area or smart labelling system.
2.5.2.4.3	R2	Read label incorrectly	Give wrong drug or dose		H	Clearer labelling on ampoules or Smart label
	R1	Fail to read label	Give wrong drug or dose	Immediate	H	Clearer labelling on ampoules or smart label
2.5.2.4.4	A7	Attach wrong needle to syringe	Injure patient		L	Limit the selection of needles.
3.1.1	A7	Take wrong tablets to patient	Wrong drug given		H	Bar coding
	A6	Take tablets to wrong patient	Wrong drug given	3.1.2	L	Bar coding
3.1.2	C1	Fail to check chart	Wrong drug given	Immediate	L	Barcoding
3.1.3	C1	Fail to check patient ID	Wrong drug given	Immediate	H	Bar coding
3.1.4	A6	Present tablets to wrong patient	Wrong drug given		M	Bar coding
3.1.7	A8	Fail to observe patient taking medication	Patient does not take medication	Immediate	H	Checklist

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
3.2.1	A6	Take medication to the wrong patient	Give patient receives the wrong drug	3.2.3	L	Bar coding
3.2.2	R1	Fail to check chart	Wrong drug given	Immediate	L	Barcoding
3.2.3	C1/R1	Fail to check patient ID	Wrong drug given	Immediate	H	Bar coding
	A7	Present wrong medication to patient	Wrong drug given		M	Bar coding
3.2.4	A6	Present medication to wrong patient	Wrong drug given		L	Bar coding
3.2.5	A8	Fail to observe patient taking medication	Patient does not take medication.	Immediate	H	Checklist
3.3.1	R1	Fail to check patient ID	Wrong drug given	Immediate	H	Bar coding
3.3.2	R1	Fail to check chart	Wrong drug given	Immediate	L	Barcoding
3.3.3	A8	Fail to prepare patient	Might introduce infection		L	Adopt infection prevention procedures.
3.3.4	A7	Attach incorrect tubing to cannula	Infusion flow may be obstructed		L	Tubing manufactured such that it can only be connected to specific items. Limit choice of equipment.
3.3.5	A8	Fail to start infusion	No drug given	Check flow	M	Training.
3.3.6	A8	Fail to check flow from infusion bag	Over dose or no drug delivered		H	Formal checking system.
3.3.7	A9	Monitor flow infrequently	Infusion tube becomes blocked		H	Formal checking system.
3.3.7	A8	Fail to monitor flow	Patient receives the drug as a bolus resulting in an over dose		H	Formal checking system.

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
3.4.1	C1	Fail to check patient ID	Wrong drug given	Immediate	H	System that requires verification of patient ID or Bar coding.
	C3/R1	Check ID of wrong patient	Wrong drug given	Immediate	H	Bar coding or wearable PDA.
3.4.2	C1	Fail to check dose written on chart	Wrong dose given		M	Computerised order entry coupled with barcodes and scanning.
3.4.3	A8	Fail to prepare patient (swab skin)	Infection introduced		L	Adopt infection prevention procedures
3.4.4	C1	Fail to check volume of medication in syringe	Overdose given		L	Training in administering injections
3.4.5	A8	Fail to remove air from syringe	Air bubbles introduced into patient's bloodstream causing death		L	Training in administering injections.
3.4.6	A3	Add to IV bag	Administer by wrong route		M	Read instructions. Training to increase knowledge of medication.
	A3	Inject into muscle	Administer by wrong route – could cause muscle damage		M	Read instructions. Training to increase knowledge of medication.
3.4.7	A3	Add to IV bag	Administer by wrong route		M	Drugs added by pharmacy only.
	A3	Inject into vein	Intravenous administration could be fatal		M	Read instructions. Training to increase knowledge of medication.
3.4.8	A3	Inject into vein	Administer by wrong route		M	Read instructions. Training to increase knowledge of medication.

then the "Recovery" column is left blank. The probability of the error occurring is denoted in the table by P and is categorised as low (hardly ever occurs), medium (has occurred once or twice) or high (occurs frequently). The final column shows the remedial measures that could be taken to reduce that particular error. These are mainly in the form of design solutions however it is recognised that in order to be effectively implemented any design solution would need to regulated by the appropriate organisational controls.

2.4.4 Remedial design solutions

2.4.4.1 Technology

In the SERPA analysis tagging was suggested as a solution to the problem of missing medication administration records. It is also a useful system for the location of equipment. Medication errors are made in prescribing because of slips in attention or because prescribers do not apply the relevant rules (Dean et al, 2002). Computerised order entry might be a better solution to resolve the problem of missing charts since the drug information is held in a data bank. This system solves the problems related to prescribing (bad handwriting, non-standard abbreviations, incomplete drug orders) and in particular errors related to compatibility of combined drugs or patient allergies. Computerised order entry coupled with bar coding would solve the problem of reading the wrong drug name or not reading it at all.

Although technology has great potential to reduce a high number of errors care needs to be exercised when employing such a costly solution. Potts et al (2004) reporting a prospective trial of computerised physician order entry in a paediatric

unit noted that whilst medication prescribing errors were reduced by 99.4% and rule violation errors by 97.9%, potential adverse drug events were only reduced by 40.9%. Whilst the total error reduction was significant but the overall level of error reduction suggests other factors associated with drug administration and patient monitoring needed to be addressed.

Nurses have said they feel they don't have time to read the labels. So using a scanner to read a barcode on a package goes a long way to overcoming this problem. Barcoding solution can be extended to patient identification information. Bar coded labels would overcome the problem of reading wrong drug names from packaging. Patient identity problems could be resolved by this methodology. It is still important, however, to maintain standard patient identification systems and to attach standard labels on packaging to act as a double check or as a back-up in the event of equipment failure.

2.4.4.2 Labelling

Medical personnel often complain about the similarity of drug labels which makes it difficult to discriminate between products. Pharmacy products dispensed for named patients have a small white label printed with the patient's name, the drug name, administrations instructions and any warnings in a small black or grey font. The result is that very often the bottles and labels all look similar. Adding colourful or eye-catching features to the packaging or labelling would increase the nurse's capability to distinguish products. For instance, highlighting salient information such as drug name and strength would enable these features to be readily picked out and might be a useful solution. Increasing the conspicuity of

product labels should help to improve search strategies. This concept could also be extended to storage areas so that one class of drugs is not mistaken for another. Using colour labels to distinguish categories of drugs is a common practice is anaesthesia.

2.4.4.3 Equipment

Selecting the wrong needle for a syringe assembly or the wrong tube for an IV set might be due to genuine lack of knowledge or because of the large availability of items from which to select. Limiting the variety of equipment from which selections are made is a good way to force individuals to make the right choice. This could be achieved by purchasing from a small number suppliers and then making accessible only the minimum variety of equipment. This would help agency nurses and those who work on several units. Writing formal protocols for setting up and checking IV systems as well as attaching simplified instructions to the device itself which could be seen when programming is in progress would be useful.

Errors frequently occur because both doctors and nurses do not have sufficient training in the use of medication. Dean et al (2002) recommend training junior doctors in the principles of drug dosing before they start prescribing and more training about the effects of drugs is advocated by Kohn et al (1999).

2.4.5 Discussion

The SHERPA table (table 2.3) highlighted the errors of: drug omission, incorrect drug, incorrect dose, incorrect formulation, giving extra doses and giving drugs by the incorrect route. These matched the errors cited in the studies of Philips et al

(2001) and Ross et al (200) in chapter 1 and Dean et al (1995) at the beginning of this chapter. Table 2.4 gives a summary of the recommended design solutions. From the summary it can be seen that barcoding, tagging and computerised prescription order entry have the greatest potential to resolve errors with the most critical consequences.

	Criticality			
Solution	L	M	H	**Total**
Barcoding	3	5	5	13
Computer order entry	-	5	2	7
Increase label/package conspicuity	-	4	5	9
Smart labelling	-	-	2	2
Tagging	5	4	1	10

Table 2.4: Summary of SHERPA findings

The main purpose for carrying out this analysis was to highlight areas where design solutions would have the greatest impact. The overall aim is to protect patients from error or in the event an error does occur to allow the nurse the opportunity to recover. The analysis predicts what steps can be taken to achieve resolution and highlights those aspects of the drug administration process where design solutions would have the greatest impact. These were identified as drug information systems, labelling, drug storage and patient information systems. Technological solutions including electronic tagging, bar coding and computerised order entry have been suggested as error reducing strategies for a number of errors.

Many of the tasks presented in the HTA could be subdivided into further levels of component tasks and operations thus revealing a highly detailed description of the drug administration task. The SHERPA error mode taxonomy prompts the analyst to consider potentially unforeseen errors and the error reduction strategies are readily identified. The strength of the SHERPA technique is that it can be used to analyse tasks or processes at many different levels. The technique could be adapted to different ward settings and could also be applied to a range of different health care procedures. For instance, the method could be used to analyse equipment usage in order to highlight training requirements or to re-draft protocols as part of the quality review process.

One disadvantage of using SHERPA as an error prediction tool is that a task analysis has to be drawn up before error predictions can be made. In order to gain a full description of every step of the drug administration task, several long HTAs would be required. Thus it could prove time-consuming to obtain a high level of detail particularly in cases where no formal protocols exist. Another weakness of SHERPA is that actions considered highly unlikely are excluded from the analysis. An example of such exclusion occurs at step 3.3.2 of the HTA ("hang an infusion bag") as part of setting up an IV infusion. Failing to hang an IV bag would be considered by most nurses as an impossible error to make. But if the situation arose where there was a shortage of infusion stands or the infusion bag had been removed from the stand whilst the patient was being moved, then this situation would not be so improbable. However, failing to hang the IV bag due to a shortage of stands would constitute a systems error and thus this error mode should be included in the SHERPA analysis.

Medication administration errors occur due to a number of varying and often interacting factors that may originate from organisational practices, the working environment or personal and professional practices. There is an underlying assumption that the SHERPA taxonomy is able to capture the full range of error producing activity whereas this is not the case. Communication with patients and their relatives, colleagues and various departments all impinge on the process of drug administration. These factors cannot be analysed effectively using the taxonomy and would require other techniques.

The task analysis could be extended to take account of the activities occurring during the administration of controlled drugs, injections that have to be reconstituted or diluted and those that are calculated according to the patient's weight. The overall technique could be used to compare different systems of administering medication. The errors highlighted refer to the ward based pharmacy system. Further work could be carried out to predict errors that might occur within the patient's own drug system. Validation of the errors predicted in the model need to be compared with data gathered by observation of actual drug administration in ward settings in order to analyse both opportunity for error and the types of error that actually occur. This simplified model excludes the condition of the patient and the routine checks (blood pressure, temperature, kidney function) that are carried out on a regular basis. The model would benefit from inclusion of patient states, as these have direct bearing on how nurses respond.

This chapter illustrates how two human error identification techniques can be applied to the process of administering drugs to hospitalised patients as a means of preventing error or reducing the effects of error. Whilst this chapter considers the actions of an individual nurse in the process of administering drugs, it is recognised that, as noted above drug administration errors are rarely entirely due to the actions of a single individual. There is still an expectation of perfection among medical professionals at a time when risk is an accepted part of daily life in other fields of activity. This is due to training and a number of other factors such as the culture of blame and the punitive measures that still exists within the NHS. The blame culture is slowly changing largely due to several patient safety initiatives set up by the Department of Health and through the activities of the National Patient Safety Agency.

Having considered what can go wrong during drug administration the next phase of the research was to design products that would reduce these errors or at the very least highlight the errors before they reached the patient. Technological products were suggested in the SHERPA analysis as solutions to the largest number of errors and this issue is the focus of chapter six. Increasing conspicuity on packaging addressed 9 errors (table 2.4) and this is the subject of chapter 4. However, prior to that, consideration was given to the design and development of warning signs and labels as it was felt that the research previously carried out in this field would inform the development of products with eye-catching features.

Chapter 3

A Literature Review on Warnings

3.1 INTRODUCTION

One of the design solutions suggested in the SHERPA analysis in chapter 2 to address the problem of failing to read product labels was to increase their conspicuity in an effort make them more eye-catching. Catching people's attention in order to influence their behaviour has been achieved with a high degree of success in the design and production of warning signs and labels primarily through the use of colour and pictures. Extensive research in this area has lead to a wealth of literature, therefore reviewing this should provide useful principles that could be applied to the design of medication labels.

Warnings operate in several ways but most ostensibly their purpose is to decrease the risk of accidents or serious injury and thereby promote safety. Warnings are intended to influence or modify people's behaviour such that they act in a safe manner. Another aspect of a warning is to provide information that enables people

to understand the hazard, thus enabling them to make informed decisions (Laughrey and Wogalter, 1997).

An effective visual warning has four message components according to Adams et al (1998) and Wogalter et al (2002). The first, the signal word, attracts attention; the second component identifies the hazard; the third describes the consequences of exposure if the individual is exposed to the hazard; whilst the fourth provides directives for avoiding the hazard. Signal words such as DANGER, POISON AND DEATH are often used on warnings as they have been found to connote high levels of hazard (Wogalter et al, 1989: Young, 1998), whereas warnings containing the words WARNING and CAUTION tend to convey lower levels of hazard.

Despite the importance of the words used to convey the presence of a hazard the effectiveness of a warning is influenced by other factors. For instance Trommelen (1997) has pointed out that when people are presented with new information they are more likely to read and remember it. Conversely, the more often a warning is encountered the less likely the person will be to notice it on subsequent encounters (Wogalter et al, 2002). Edworthy and Adams (1996) suggest the ultimate effectiveness criterion of a good warning sign is the extent to which the warning leads users to comply. This is in comparison to the level of compliance in the absence of the sign. They contend that because well-designed signs do not produce 100% compliance, other determinants such as social and individual factors may influence users (figure 3.1).

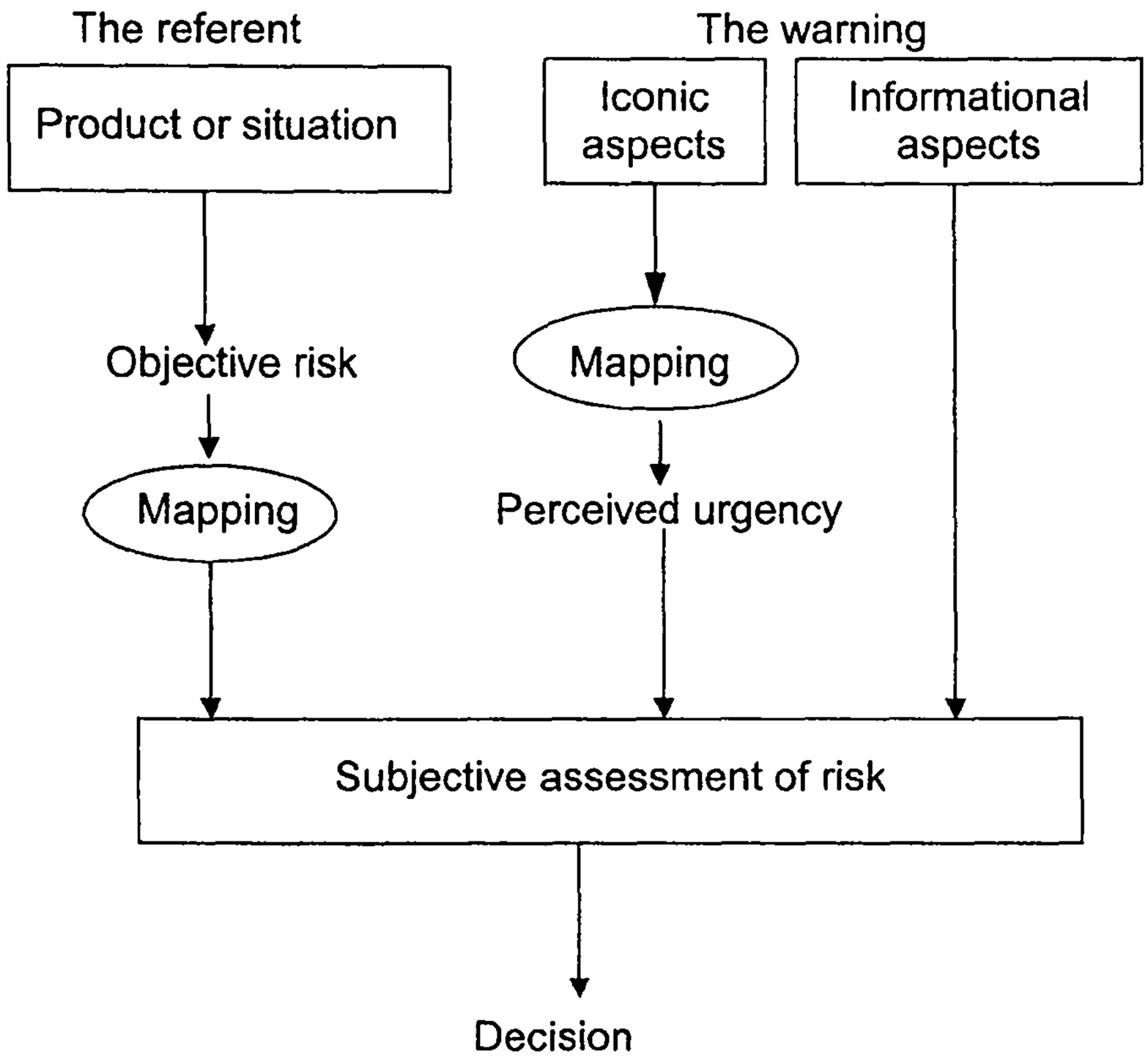


Figure 3.1:Components of warning compliance (Edworthy and Adams, 1996)

Warnings are often presented on labels attached to products and whilst it has been demonstrated by Adams and Edworthy (1995) that using larger print increases the hazardousness ratings of warning by users, the limited size of labels, particularly those attached to small packages restricts the size and the amount of information that can be presented. This has the effect of reducing conspicuity, legibility and sometimes comprehensibility (Wogalter and Young, 1994). A warning sign must first be legible before it can be comprehended and is of significance to those whose vision might be compromised, a concern not only of elderly or partially sighted people but also in environments of poor visibility (smoke, fog, poor illumination, darkness). Legibility can be augmented by incorporating redundant features into the

warning message such as shape, borders, colours, pictorials (Riley et al, 1982; Young, 1998) or combinations of these as demonstrated by Riley et al (1982), Chapanis (1984), Rodriguez (1991), Cochran et al (1981) and Serig (2003).

This literature review looks at some of the various methods that have been devised to test the effectiveness of warnings, or the degree to which the warning accomplishes its intended effect. Many of the studies outlined in the following sections examine non-verbal aspects of the warning such as the use of colour, shape or pictorials. Consideration will also be given to aspects of users' attitudes, beliefs and expectations when they encounter warnings.

3.2 CONSPICUITY

In order to be effective, a written warning must be noticed, read, understood and heeded. Although the ability of a warning to influence behaviour is subject to several factors, noticing it in the first place is of prime importance. Conspicuity relates to how prominent or eye-catching warnings are and several elements have been added to warning notices and labels to increase their ability to capture the attention. These include the use of large size text (Adams and Edworthy, 1995), colour (Kline et al, 1993), graphics (Kalsher et al, 1996) and shape (Riley et al, 1982; Wogalter and Young, 1994). Barlow and Wogalter, (1991), and Wogalter and Young (1994) increased the overall size of the product label was to enable more information be printed. Laughrey and Brelsford (1991) made signs larger to enable them to be seen by the elderly.

Young (1991) orthogonally manipulated colour, pictorial signal icon and border features to determine their effect on the noticeability of warning information. Seventy-two participants were asked to view 96 simulated alcohol labels presented singly on a computer screen. For each label subjects pressed buttons labelled 'yes' or 'no' to indicate respectively the presence or absence of warnings. The computer measured the time taken to respond. Where pictorials were present on warnings, faster response times were noted than when they were absent. Warnings printed in red were located more quickly than those printed in black and warnings paired with an icon were located more quickly than those without. Using a border did not produce a significant reduction in response latencies compared to warnings without a border. The results demonstrated that using pictorials, colour and icons increased noticeability of warning information.

Safety messages or warnings occurring in familiar situations or on familiar products are less likely to be noticed (Otsubo, 1988). In a study designed to assess the effectiveness of different types of label on two consumer products incorporating two levels of perceived hazard Otsubo presented 131 participants with four label types. These were: words only, pictograph only, words and pictographs and no warning. The consumer products representing low and high hazard respectively were a jigsaw and a circular saw. Effectiveness was assessed by which of the participants noticed, read, complied with and recalled the warning message. The notices were more effective on the product perceived to be more dangerous than the one perceived as less hazardous. The data gathered suggested that people more familiar with the use of the product would tend to read, comply with and recall the warning less than those less familiar. Furthermore, (Wogalter et al, 2002) contend that people who have had

an accident or know someone who has been injured using a product are more likely to exercise caution when using that product. This behaviour is related to perception of risk which will be discussed in greater detail below.

3.3 TEXT

3.3.1 Signal Words

Warnings often contain words intended to attract the attention of the user or to alert them to the hazardousness of the situation or action in which they are engaged. The most commonly used signal words are DANGER, WARNING, and CAUTION (Wogalter et al, 1989; Chapanis, 1994 and Laughrey and Wogalter, 1997). The signal words DEADLY, LETHAL and DANGER were found by Young (1998) to significantly differ from CAUTION and NOTICE. In this study the word WARNING did not differ from DANGER or CAUTION. Wogalter and Silver (1995) identified the additional words of ATTENTION, NOTICE, CAREFUL, DEADLY, NOTE as having high carefulness ratings. Rated from the greatest to the least. Their results indicated a significant main effect of signal words in the following order: DEADLY, DANGER, WARNING, CAUTION, CAREFUL, NOTICE, ATTENTION, NOTE.

Wogalter et al (1994) report higher hazardousness ratings for LETHAL than DANGER when the two words were combined with a signal icon. Whilst in a study by Young (1998) subjects compiled signs for 30 different scenarios. DEADLY was considered the most hazardous, followed by LETHAL, DANGER, WARNING, CAUTION and NOTICE. DEADLY and LETHAL were considered as conveying significantly more hazard than CAUTION and NOTICE but less than WARNING.

WARNING was considered to convey more hazard than NOTICE but less than CAUTION.

Presenting the text in different colours or with colour backgrounds also has an effect on hazardous ratings as demonstrated by Chapanis (1994), Braun and Silver (1995) and Young (1998). The effects of colour will be discussed further in section 3.4.

3.3.2 Size

The physical size of the signal word characters are likely to be more easily read (Laughrey and Wogalter, 1997). Work by Silver and Braun (1993) has indicated that varying the font used affects perceived readability with 10-point print considered more readable than 8-point print and that a 2 point contrast between the signal word and text size is more effective than a difference of 4 points.

Adams and Edworthy (1995) studied the effects of text point size by examining the relative changes in perceived urgency produced by manipulating font size (8-32 points), border width (1 to 8 points), white space around the signal word (2 to 32 points) and colour. The signal word warning was emphasised by presenting it in red, surrounded by a border. Increasing the text size by 4 points produced the same degree of perceived urgency as increasing border width by 2.3 points. Adams and Edworthy (ibid) indicated that when the signal word was printed in black it needed to be twice as large as when printed in red to produce the same urgency rating. The effect of white space on perceived urgency was found to be very small compared to the other variables. It was considered not worthwhile for label designers to emphasise the signal word by providing additional space around it.

Using bold type text is preferable as it has good contrast with most backgrounds, however the stroke width should not be so wide that the features of individual letters are obscured (Sanders and McCormick, 1993).

3.4 COLOUR

According to Ryan (1991) using colour in warnings serves as a redundant coding dimension and the effects of using colour in coding for visual displays has been examined by Christ (1984). It is particularly useful to draw attention to a signal in crowded displays such as control panels and enhances the communication of hazard.

Kline et al (1993) demonstrated that coloured warning labels were perceived as more readable and connoting more hazard than achromatic labels. Red conveyed significantly more hazard than the other colours. This finding has been replicated in the studies of Braun et al (1994), Braun and Silver (1995) and Wogalter et al (1995). The other colours in descending order of hazardousness are orange, black, green and blue. Higher rates of compliance were recorded when the warning label was printed in red rather than in green or black.

Whilst red is often perceived as connoting the highest level of hazardousness, Wogalter et al (1995) point out that with the exception of this colour, people do not make fine hazard level distinctions between colours. This view accords with Young (1998) who found that the surround colour of signal words did not cause subjects to perceive colours in the hierarchy suggested by the American National Standards Institute, ANSI Z535 (1998). There were three tiers of hazard with red as the highest,

orange and yellow representing the mid level and blue signifying the lowest level of hazard. Young's findings indicated that people tend to connote hazard as high (signified by red) or low (denoted by blue).

Chapanis (1994) evaluated the level of hazard conveyed by safety signs displaying the signal words DANGER, CAUTION and WARNING printed in red, orange, yellow and white. These were assessed by combining them with the background colours of red, orange, yellow and white. The colours rated in descending order of perceived hazard were given as red, orange, yellow and white however trade-offs between signal words and colours were noted. Combining the elements produced various hazardousness ratings with DANGER printed in black on a red background considered to convey the greatest level of hazardousness. There was little consistency among participants of the best colours associated with CAUTION and WARNING. Trade-offs have also been demonstrated by Braun et al (1994) and Braun and Silver (1995). Using 21 signal words presented in red, orange, green and black, rated on a 9 point Lickert scale ranging from 'not at all hazardous' to 'extremely hazardous'. Braun and Silver (ibid) demonstrated that the word DEADLY presented in black was rated as conveying the same level of hazard as CAREFUL presented in red. Thus communication of hazards is a function of both the signal word and the colour in which it is printed.

The use of colour panels can be a useful way to build redundancy into warnings, however Young (1998) has pointed out that standard recommendations tend not to specify panel formats in a way that enables panel components to be used optimally.

Moreover, using panels can make the signal word more difficult to read (Wogalter et al, 1999).

3.5 WARNING SHAPE

As pointed out in the previous section warning signs have often incorporated colour and shape as redundant features to improve detection, legibility and comprehension. Riley et al (1982) examined 19 different geometric shapes of warning labels by pair comparisons. When shape alone was the determining factor for describing a warning, an equilateral triangle pointing downwards was the most preferred warning shape of the 19 shapes compared. The results suggest shapes that appear unstable are preferred as warning shape indicators. Other preferred shapes are shown in figure 3.2.

Research by Serig et al (2000) examined the extent to which container shape and colour of consumer packaging influenced hazard perception of the product. Pre-existing schemas and scripts about the products derived from past experience appeared to determine how to safely transport, store and use them. The study findings indicated that colour type selection appeared to be influenced by the described levels of hazard, red being associated with high hazard and white with low hazard. As the perceived hazard increased so did the participants' intention to engage in precautionary measures.

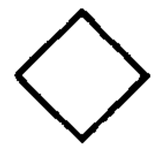
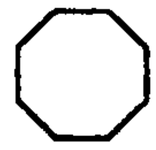
Rank	Shape	Shape number
1		4
2.5		10
2.5		15
4.5		5
4.5		3
6		17
7		18
8.5		2
8.5		13
10		12

Figure 3.2: Ranking of preferred shape (Source – Riley, 1991)
Identical rank values indicate that shapes had the same preference scores and the appropriate consecutive ranks were averaged.

The experiment demonstrated that participants were able to design product packages that signalled the identity and potential hazard of the contents, implying that they were able to use package shapes to identify levels of hazard that might be present in consumer products. People were familiar with types of product being presented in certain types of packaging, for example milk, in a cardboard carton. They were able

to consistently identify from line drawings the package shapes that were more likely to contain hazardous products such as pesticides compared with more non-hazardous packaging likely to contain food products. These results indicated that people use shape as cues to inform them about the hazardousness of materials in combinations of colours and shapes that are relatively independent of each other as coding variables.

Wogalter and Young (1994) compared tag and wing designs with a conventional design, to see what effect there would be on behavioural compliance with a warning on a small container of glue. Forty-four student participants were asked to construct a model using the glue without being informed of the real purpose of the study. After completing the task participants were asked: whether or not they noticed the instructions on the glue bottle, whether they read the instructions, to recall (or guess) what the instructions said; whether they noticed the warning, whether they had read the warning, to recall (or guess what the warning said); if they had any experience of constructing models and approximately how many models they had previously constructed.

In this study the participants complied more often with the tag warning than with the wings or the control warnings (Figure 3.3). This was attributed to the noticeable way in which the warning was presented on the tag. Participants were readily able to see the warning as it faced upwards and was continuously visible throughout the duration of the task. With the control and the wing design the bottle had to be picked up from the table in order to see the warning which could be covered by the

participant's hand whilst holding the container. Thus increasing the size of the label can have the effect of increasing its conspicuity and inducing greater compliance.

3.6 GRAPHICS

3.6.1 General Points

There are differences in graphics, icons, pictogram, pictorials and symbols. However the terms will be used interchangeably. Pictorials have been increasingly used across a wide range of consumer products and information during the past few years (BS 8501:2002). Pictorial symbols increase the salience of warnings and the likelihood of them being noticed (Wogalter et al, 2002), memorised (Young and Wogalter, 1990) and comprehended (Young and Wogalter, 1990; Dewar, 1999). They are generally 'readable' at a greater distance than words (Dewar et al (1976) and appear in health contexts (Kalsher et al, 1996; Morrow et al, 1996) and industrial settings (Lehto, 1998). Well designed pictorials can communicate large amounts of information quickly and can be useful for those who cannot read printed verbal messages.

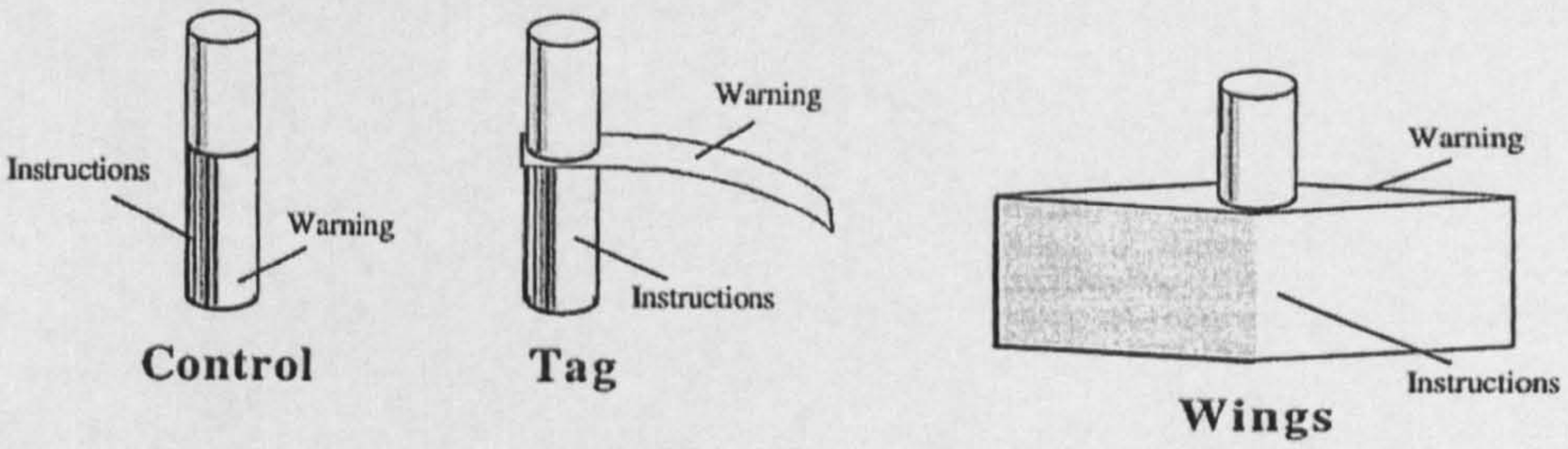


Figure 3.3: Alternative designs for warning information

Poorly designed pictorials may communicate nothing other than that a warning is present (Kalsher et al, 1996). They are most effective when communicating simple

concrete concepts (Wogalter et al, 2002) and are less effective at representing complex or abstract ideas (Bruyas et al, 1997). Kalsher et al (1996) suggest that labels with pictorials were preferred by college students to those without. When designing pictorials there needs to be enough detail to convey meaning without providing so much that legibility and comprehensibility are reduced.

Arthur et al (1997) tested a system of signs to warn visitors to Canada's national parks of natural hazards by presenting participants with black and white pictographic representations of 36 warning messages in a questionnaire booklet. Each message comprised either one or two pictographs but no words. The first picture indicated the hazard and the second picture, when present informed the user how to avoid the hazard. Context was given by indicating above each pictorial the location where it would be seen, for instance, on a beach or at the beginning of a trail. Participants were required to comment on several aspects of the signs: how well the pictographs conveyed the message, what was confusing about it, how it might be improved and if the second pictograph aided understanding. Most messages were well understood and of the 27 signs tested only 7 received wrong responses of greater than 20%.

In a study by Mayer and Laux (1989) 139 participants identified 16 pictograms from the Westinghaus Product Safety Label Handbook. The results ranged from 100% identification of pictograms to completely unrecognisable. Generally pictograms representing simple clearly identifiable hazards of protective equipment were more identifiable than symbols.

Use of symbols or pictorial representations to convey warnings is not without problems as demonstrated by Bruyas et al (1997) and some pictorials currently in use are not always well understood (Wolf and Wogalter, 1998 and Davies et al, 1998). In the Mayer and Laux (1989) study pictograms depicting injury occurring to a hand were more recognisable compared to those showing the entire body. Pictograms developed for concrete concepts are often well understood but conveying ideas or abstract principles using pictorials has proved notoriously difficult. Processing pictures and images is a complex perceptive and cognitive activity as viewers have to call upon their diversified knowledge of the items being represented. Being able to recognize an object does not necessarily mean the message associated with it will be understood. In order to convey complex information it is sometimes necessary to combine several codes or elements which requires the user to make inferences to link them. Warning messages associated with water hazards caused problems with understanding in the studies of Arthur et al (1997) and Dewar and Arthur (1999). Similarly conveying abstract notions such as the passage of time, the presence of radiation, or the pharmaceutical concept 'take until gone' pose great challenges for designers. Dewar and Arthur (ibid) used sequential pictograms to convey the complex warning: 'Fishing here is dangerous. Waters can rise rapidly anytime. You may lose your balance and be swept away in the current' (Figure 3.4.).

Young and Wogalter (1990) demonstrated that conspicuous print warning messages presented with icons in an instrument manual facilitated comprehension and memory for warning messages and enabled users to better identify the semantic meaning of the icons.

Figure 3.4: Sequential pictographs Original and redesigned versions of 'No fishing, rising water'

Bruyas et al (1997) devised a study to examine how users attribute meaning to complex messages by analysing how meaningful links were built between complex pictogram components. Two groups of participants (young and old) were shown road safety signs on a computer screen in one of 6 display times ranging from 100 milliseconds to 5 seconds. The findings indicated that whilst participants recognised familiar symbols they did not always understand their meaning if the representation was unexpected such as in the instance of a damaged or crashed car. Furthermore, using the same symbol in various contexts also impaired recognition. An example of this is the use of the arrow symbol, which is used in the Highway Code in various differing contexts. This research demonstrated the pitfalls of using rules unknown to users in warning of potential hazards.

3.6.2 Training

Brelsford et al (1994) conducted a study to determine whether or not the level of comprehension and retention of heterogeneous pharmaceutical pictorials could be enhanced. A training paradigm was used in which sixty participants were asked to identify and explain the significance of concepts represented by 40 pictorials. Half the participants viewed the pictorials with a defining label printed below each pictorial. The other half viewed the pictorials with a verbal label and an accompanying short explanation of the concept or hazard. Participants were given a brief training session after which they performed a filler task before half were tested again. All participants completed a final comprehension test 7 to 10 days later. The results indicated that training increased comprehension scores. Increased comprehension was maintained one week after the final test. Very brief instruction with only the associated verbal labels substantially increased comprehension of difficult pictorials. This was a significant finding bearing in mind that pictorials are used in a variety of contexts in which their meanings are not readily apparent and suggests that very brief training of poorly understood pictorials can improve comprehensibility.

3.6.3 Consumer Products

Davies et al (1998) investigated the role of pictograms in conveying consumer safety information, since a large amount of information is provided to consumers in pictorial form. Data collected from 325 subjects in 4 UK cities indicated that comprehension of the pictograms used on consumer products was poor. Only 3 of the 13 pictograms investigated were correctly understood by more than 66% of the

sample. Three of the 5 pictograms with the lowest comprehension scores were represented by an abstract graphic. However Davies et al (ibid) point out that as many symbol comprehension studies lack contextual information comprehension levels may be lower than might be expected in real-world situations. This issue was addressed by Wolf and Wogalter (1998) who suggested that adding contextual features to pictorial symbols helps viewers to recognise them.

3.6.4 Controls

In the case of controls which tend to be universally labelled, Woodson et al (1992) suggest that it is not always possible to represent all information pictorially as the resulting image would be unrecognisable to those unfamiliar with an object or situation. They elaborate this point by taking an example from the field of engineering. The symbol used for the choke system used on some vehicles is highly significant to engineers who are familiar with the system. However the symbol may have little meaning to many drivers who believe the symbol represents something else. Their recommendation for producing pictorials is to give just enough detail to make the symbol recognizable and no more. This is because fine detail cannot be seen in certain lighting conditions or from far away and can lead to confusion. Over-stylisation should be avoided as this may render the symbol indescriminable from the others. Using a border is useful to prevent blending in with background images.

3.6.5 Prohibitive Pictorials

A pictorial inside a red circle overlaid with left to right slash at a 40° angle is often used to denote a prohibited activity. Murray et al (1998) devised a study to test perception of 4 different variations of prohibitive notice: a slash over the symbol, a

slash under the symbol, a partial slash and a translucent slash (figure 3.5). Sixteen pictorials with different semantic message content were used. The results were that over- and under- slashes were preferred to the translucent or partial slashes. In the case of the asymmetrical symbols, orientation and slash type influenced preference. Some pictorials with the over-slash received lower evaluations when critical features were occluded. Murray et al (ibid) suggest that participants' preference for the over- and under-slash may be due to familiarity to concordance with gestalt principles of good figures. That is, the tendency to organise perceptual information into coherent patterns.

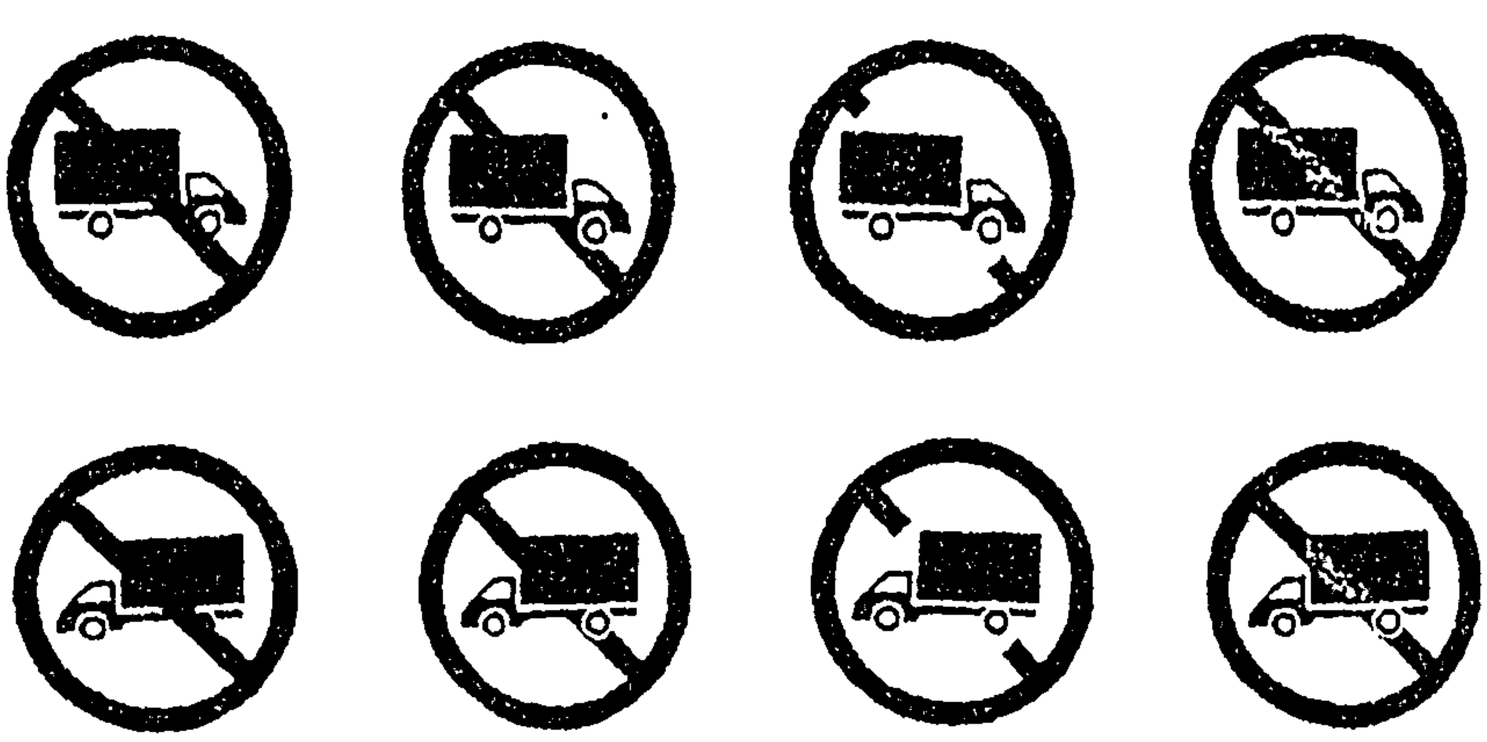


Figure 3.5: Example 'No trucks' pictorial in the 8 slash type variations and illustrating both the left and right orientation (source Murrary et al,1998)

Whilst investigating the effects of pictorial size and thickness of the red circle on glance legibility Sheih and Huang (2004) discovered that when luminance contrast is high and exposure time is long (50ms) participants were sufficiently able to process the symbols and the effects of pictorial size and slash thickness were not significant. However in conditions when luminance contrast is degraded and glance time short, a

large pictorial size benefits glance legibility. Additionally in conditions of low luminance contrast, a small slash thickness benefits glance legibility.

3.7 COMPREHENSION

Wogalter and Sojourner (1999) point out that experts sometimes have misconceptions about how warning information will be interpreted. They assume receivers of the message will understand it as it was intended. The knowledge held by experts is often ingrained and they may not appreciate the difficulty others have in understanding their position. It is important to understand that people bring their own knowledge and experience to situations. Designers of warnings need to understand that members of the target audience may not understand hazards, consequences and instructions as well as they do and may not possess what is considered common knowledge (McCarthy et al 1995, Laughrey and Wogalter, 1997).

When conveying a message to readers who may have lower reading skills or limited understanding, the label or warning should be targeted to the lowest practical level of readers. Wogalter and Sojourner (1999) give the example of the warning carried by cigarette packets of 'low birth weight' intended to warn prospective mothers that smoking is harmful to the baby. However this has been interpreted as a beneficial effect of smoking leading some women to believe that smoking during pregnancy would make labour easier due to the smaller size of the baby. Other women interpreted the phrase as a way to keep their weight down. Wogalter and Sojourner (ibid) argue that the wording should have been tested to rule out unintentional ambiguities.

Explicitness of the warning is also an important factor in comprehension. Explicit messages contain specific information about the nature of the hazard. They give definitive instructions on how to avoid the hazard as well as give information about the consequences of non-compliance. For example, 'may be hazardous to health' is vague and gives little information. An explicit warning would be, 'can cause lung cancer which almost always leads to death'. The latter explains what the problem is and the likely outcome (Wogalter 1999).

3.8 COMPLIANCE

3.8.1 General Points

Recommendations have been made that effective warning signs should have a number of components such as alerting word, statement of the hazard, of it's seriousness and probable consequences and how to avoid the hazard (Adams et al, 1994). It might be tempting to think that displaying a conspicuous warning adhering to some of the findings highlighted in previous research would guarantee compliance. Wogalter et al (1994b) demonstrated improved rates of compliance in response to lift signs that had been enhanced by the use of colour, a signal word panel, pictograms and explicit wording of the required behaviour. Many warnings are designed to be seen though other modes of presentation are often more effective. Verbal warnings have been investigated by Edworthy (1994), Barzegar and Wogalter, (1998), Hellier et al (2000) and Edworthy et al (2000). Selcon et al (1995) demonstrated that using four sources of warning information produced significantly better compliance among participants than either three or two sources.

Braun and Silver (1995) examined the effect of colour on compliance assessed by subjects putting on protective gloves as directed by the warnings printed in red. A higher level of compliance was noted than for the green and black notices.

If people noticed the warning, they were very likely to read, recall and comply with it (Wogalter and Young, 1994). In their study where 100% of participants noticed a warning 80% of them complied with it. However in a previous study Friedman (1988) demonstrated a lower rate of compliance. In a 3x2x2 between subjects design the effects of three independent variables were examined: the conspicuity of the warning, compliance with the warning and recall of the warning information on either a bottle of liquid drain opener or wood cleaner. The dependent variables were the manner of presenting the warning information, product familiarity and compliance requirements. Measures were taken of subjects noticing, reading, remembering and complying with the warning

Across all conditions subjects did notice the warning in 88% of cases. Despite this, they did not always read the warning. In fact, 46% read the entire warning but only 27% followed it. Forty nine percent correctly recalled the danger associated with the product and 42% recalled the precautionary action correctly. In those experimental conditions where a symbol was presented on the back panel, 30% of subjects noticed it. However it was correctly identified by only 23% of them. People were more concerned to learn about what the product did rather than the dangers associated with its use. Once people had read the warning, several factors influenced their compliance. The more hazardous the product was perceived to be, the more likely users were to comply with the warning.

This accords with the findings of Davies et al, (1998) and Ursic (1984). Moreover, in the Friedmann (1988) study some users felt that if they used the product in what they considered to be a safe manner they would not be hurt. This belief may have been a consequence of the type of warning presented on the product or due to the personal attributes of the person using the product. Placing a symbol on the label of the product increased the perceived hazardousness but had no effect on levels of compliance.

3.8.2 Cost of compliance

The strong association between noticing a warning and compliance accords with the findings of other studies: Wogalter et al (1987), Dingus et al (1991) and Rodriguez (1991). However noticeability is not the only factor promoting compliance. Wogalter et al (1989) discuss the effects of effort involved in complying with the warning. In the cases where users were required to put on protective gloves that had been conveniently placed, compliance with the warning was high.

In instances where personal protective equipment (PPE) is not convenient to locate and use, compliance is likely to be fairly low (Otsubo, 1988). Otsubo also demonstrated that less confident users to tended to read and comply with warnings and the type of warning label had no effect. However in all conditions with a warning label there was an average compliance of 25.5%. Where no warning label was present no precautions were taken by the participants The findings support the view that conspicuous placement of warning labels on products will influence people

to behave cautiously, but it is questionable whether this alters their perception of risk, a point that will be taken up later in this chapter.

3.8.3 Stress

Complex behaviour has been observed between reading labels and compliance. Wogalter et al (1998) demonstrated that external factors such as stress influences rate of compliance. Participants complied more frequently with the warning by wearing protective equipment when they were under low stress conditions (no time pressure) than those who were not. Participants in the high time stress conditions reported not reading the warning, not noticing the PPE and being less careful in performing the task.

3.8.4 Task Performance

Lehto and Salvendy (1995) argue that people often fail to read warning labels because they are focused on the task related goals and objectives and only look for information needed to successfully complete the task element they are currently performing. In other words, their attention is highly focused on a specific subtask. If the person is interrupted they may notice, read and comply with warning signs or labels. This was demonstrated by Frantz and Rhoades (1993) and Franz et al (1999) who observed that warnings which temporarily interfered with task performance were significantly more effective than those that did not.

3.8.5 Product Familiarity

Product familiarity and perception of hazardousness can also influence the level of compliance. In cases where opinions have been formed of product hazard and

appropriate use by experiences instructions or warnings are often discarded (Pollack-Nelson, 1995). This is especially true if the warning contradicts the individual's own experience. For instance, prior injury can mitigate poor effects of compliance particularly in the case of people who have been injured or those who know of someone who has been injured whilst using a product. They are more likely to be cautious and to take the precautions they judge necessary regardless of the manufacturer's warning.

Prior knowledge of a product and its associated hazards dictates behaviour with that product (Davies et al, 1998). The familiarity a person has with products or in certain situations makes them more confident of their probabilistic assessment of the situation (Papastavrou and Lehto, 1996). Their assessments are unlikely to change as familiarity increases. The warning becomes less likely to change the expected cost of intervening or the expected cost of a miss. Therefore, on familiar products warnings are less likely to change decisions and people learn to disregard them. Presenting warnings on a rotating basis could ensure that individuals are exposed to a specific warning less frequently, thus reducing the negative effects of habituation (Wogalter and Brelsford, 1994).

Pollack Nelson (1995) examined the effect of labels on the behaviour of people using paint stripper, non-automotive spray paint and adhesive remover, products all containing the hazardous chemical methylene chloride. Participants were asked if they changed their behaviour as a result of what they had read on the label. About one tenth of respondents indicated they changed the way they intended to use or dispose of the product in consequence of what they had read. Users were aware of

potential hazards – health concerns were expressed by 25% of the participants working with paint strippers and adhesive removers. Seventeen percent of participants working with spray paint expressed health concerns. There was no direct relationship between label reading and precautionary behaviour such as taking fresh air breaks.

3.8.6 Perception of Risk

Adams et al (1994) suggest that without attention being drawn to them in normal use, warnings are frequently not seen or complied with. Part of the reason for this may be that most people are able to assess levels of risk associated with consumer products quickly and accurately (Wogalter et al , 1993; Davies et al, 1998). If they perceive use of the product to present a high level of hazard they are more likely to look for the warning (Friedmann, 1988; Wogalter et al, 1991). Another reason may be that on many consumer products warnings are presented in a long list of safety and use information. Product-specific hazard information is embedded in other product information appearing on packages amid manufacturers' fears that customers will not buy the item if the warning is placed more prominently (Pollack Nelson, 1995). Trommelen (1997) maintains that consumer product warnings should inform the user of what to avoid, what the product-related hazards might be and the consequences of unsafe behaviour in terms of injuries. But this approach may have the opposite effect.

If the attention of the user is captured warnings can positively affect a person's perception of the safety effectiveness of product. (Ursic, 1984). In a study that attempted to examine the impact of safety warnings on perceptions of safety

effectiveness of brands and memory of product information, Ursic (ibid) found that products with warnings were perceived as being more powerful than similar products. Warnings positively influenced the user's perception of risk perhaps because the manufacturer was deemed to have taken more care in producing and marketing the product. The type of safety warnings had little impact on the perception of the brand or on the memory of the warning. Similarly, Trommelen (1997) demonstrated that people thought products with explicit warnings were more dangerous and injuries incurred whilst using these products would be more serious than products with no warning. They also thought injuries arising from products provided with explicit warnings would be more severe than products provided with a non-explicit warning.

Papastavrou and Lehto (1996) make the point that warnings have little or no effect because they provide limited information due to their 'all or nothing' nature. Papastavrou and Lehto suggest that either the warning is present or it is not. Experiencing repeated warnings in the absence of the associated hazard often results in "cry wolf" effects such as when medical staff ignore auditory warnings on equipment. People tend to weight frequent but minor inconvenience disproportionately compared to inconvenience that is infrequent but has devastating consequences. However, if the warnings are not given frequently, they could result in costly misses. Using the examples of seat-belt wearing and smoking, the authors point out that compliance is likely if drivers are told to buckle their seatbelts when they are undone or if smokers are informed of the risk factors of lung cancer or heart attack associated with smoking were provided on the cigarette packet. Giving intelligent warnings would convey the desired sensitivity of the warning message

and shape people's attitude towards the message. It is suggested that conservative warnings should be given if the cost for a miss is high and the cost for a false alarm is small as frequent false alarms will result in people ignoring the warning.

A second approach is to use confirming information such as that provided by Dingus et al (1993) who increased the use of protective eyewear when they posted a sign on the door of a racket ball court. Stating that eye injuries related to the sport were very common (for example possessed odds of 1 in 4). Protective eyeglasses were provided in a box by the door. The low cost of compliance coupled with information about the probability of injury induced players to put on the glasses when the notice was present as compared to its absence.

3.8.7 Training

Power plant operators are trained to respond to the warnings that indicate abnormal operation. Training is important when a complex response is called for as based on the limited information given by warnings, it might be impossible for the individual to understand what actions are necessary (Wogalter et al, 2002).

3.9 DEMOGRAPHY

3.9.1 Age

Dewar and Arthur (1999) have shown that using sequential pictographs is useful to convey hazard to young people or those with low reading ability. However, older adults tend to be better at processing text than symbolic instructions compared to younger adults. This may be due to age-related differences in exposure to the two kinds of media (Dejoy, 1999; Leonard et al, 1999). Silver and Wogalter (1991)

compared the ratings of 43 signal words on a carefulness scale between college students, elementary school students and middle school students. A follow-up study with elderly subjects indicated that rank ordering did not differ significantly between the groups, although it was noted that younger students assigned higher carefulness ratings to the signal words than the college students. When given various hazard scenarios older subjects assigned words connoting higher levels of hazard (Leonard et al, 1989). This may have been related to their actual or perceived experience of injury.

Edworthy and Warren (1997) investigated the effect of colour and signal word in eight year old children. The results indicated that from an early age (about 8 years) children have already learned that the word DANGER signifies a greater hazard than either WARNING or CAREFUL. They are also aware that red is intended to convey the highest level of hazard followed by orange, green, yellow, blue then white. These findings are similar to those for adults in the cases of red, orange, yellow and white. The effects of blue and green were generally less pronounced for adults.

In the assessment of road safety signs older subjects needed a longer time to identify the drawings in order to understand them and were less confident in their responses. However they gave more descriptive responses than the younger participants. This was mainly due to the fact that they focused on different elements of the symbols than their younger counterparts, ignoring those that were unexpected and focusing more on more easily recognised features. The younger participants, on the other hand, gave less detailed descriptions these were more spontaneously integrated in the whole meaning of the message (Bruyas et al, 1997).

Lesch (2003) demonstrated that many warning symbols are poorly understood particularly by the elderly. Whilst both young and older participants had difficulty understanding symbols, older adults (50-67 years) recorded lower correct scores than did younger adults (18-35 years). With training, the scores for correctly identifying the symbols improved from 37% for older adults and 52% for younger participants to 68% and 88% respectively. Older participants also experienced difficulty in rejecting incorrect meanings.

3.9.2 Gender

Very few studies report gender differences in relation to warnings. However Larue and Cohen (1987) have demonstrated that women are more likely to read and comply with warning information than men. Gender differences have been noted on measures of the perceived hazardousness of products (Young et al, 1989; Friedmann, 1989). Products considered relatively hazardous by both males and females were assigned lower hazard ratings by males. Males were also more confident about 'knowing all the hazards' than females. Females believed that accidents were more likely if protective equipment was not worn when using the products (Friedmann, 1989).

3.9.3 Cultural differences

Wogalter and Silver (1995) carried out a study to determine whether signal words are interpreted by school children, the elderly and non-native English speakers in the same way as college students with the intention to construct a list of words that might be used for special populations. They used comprehensibility ratings for the

signal words that would provide suitable assessment criteria for a broad range of populations. These included filling in blanks and ranking the words. The rank ordering of the words was consistent across all groups. The younger students gave higher carefulness ratings than the undergraduates. The words that the younger children and the non-native English speakers frequently left blank were given lower understandability ratings. The rank ordering of the words was found to be consistent between the non-native English speakers and elderly participant groups. A shortlist of terms was drawn up that was understood by at least 95% of the youngest students and by 80% of the non-native English speakers.

In assessing the level of perception among non-native English speakers of hazard, Leung and Hellier (1998) carried out a questionnaire study designed to test perceived hazard and understandability of signal words and warning pictorials by the Chinese community in Britain as compared to English subjects. They used a point rating scale with the anchors: (0) not at all understandable, (2) somewhat understandable, (4) understandable (6) very understandable, (8) extremely understandable. Forty-three signal words used by Wogalter and Silver (1995) including: NOTE, ATTENTION, NOTICE, CAREFUL, DANGER, CAUTION, WARNING, DEADLY were assessed. There were no significant differences in the understandability ratings between Chinese and English subjects. Wogalter and Silver (1995) suggest the reason for this is the possibility that the Chinese received training on the intended meanings of these commonly used words. Further testing revealed that understandability ratings of the Chinese subjects were significantly lower than those of the English subjects.

Smith-Jackson and Wogalter (2000) compared ratings of perceived hazard of 10 ANSI colours and six symbols among English and Spanish language users. Red followed by yellow, black and orange were awarded the highest hazard ratings. The symbols rated highest were the skull, prohibition (circle with slash), and the electric shock symbols. These findings were similar to those of Wogalter et al (1994) and Wogalter et al (1998). In descending order Spanish language users specified red, orange, black and yellow as representing the highest level of hazardousness in accordance with the findings of Chapanis (1994). This research provides some support for the significance of culture in the perception of colours and symbols as well as suggesting that this factor is an important consideration when designing labels or use by other cultures.

Several trait and environmental factors that vary by culture have been shown to influence risk-perception, risk taking behaviour and compliance as well as other processes (Wogalter et al, 1997, Wogalter et al, 1998). Cultural differences may influence variables such as risk perception, risk tolerance, stress vulnerability and decisions to report injuries/accidents. Signal words used in warnings and other safety related communication have attempted to incorporate a cultural components (Smith–Jackson and Wogalter, 2000). However Wogalter et al (1997) demonstrated that Spanish language users do not communicate levels of hazard using the same words. PELIGRO the word used in the United States to communicate the highest level of hazard was rated 5th among Spanish language users. Four other words: EXPLOSIVO, MORTA, VENENO and PELIGROSO conveyed higher levels of hazardousness to them.

Smith-Jackson et al (2003) demonstrated cultural differences in the interpretation of symbols among Ghanaian students compared to US students at college level. The Ghanaian students recorded more incorrect responses than American students. The differences are likely to be due to culture-based trait variables which influence risk taking behaviour or compliance (Ajzen and Fishbein, 1980). Trait variables such as fatalism and religious belief vary among cultures and have a significant effect on attitude to and perceptions of risk (Neff and Hoppe, 1993). The culture based processing of related risk is known as the culture based risk mental model (CRMM). The CRMM is the culture-dependent knowledge, representations and decision-making patterns associated with personal risk assessment and behavioural intent Smith-Jackson et al (2003).

3.10 EVALUATION

In many of the studies outlined in this review subjective methods have been used to assess the effectiveness of warnings with participants rating warnings along several dimensions using Likert-type scales. Measures of noticeability (Friedmann, 1988), reaction time (Young, 1991 and Bruyas, 1997), comprehension, recall and knowledge (Lehto, 1998; Dewar and Arthur, 1999; Leonard, et al, 1999; Lesch, 2003) and ratings of hazardousness (Chapanis, 1994) have been assessed.

The selection criteria used to evaluate warnings must be carefully selected (Wogalter et al, 2002). Ideally all warnings should be developed and tested by measuring the criterion of behavioural compliance. However it not always possible to measure this due to the costs and risks that may be incurred. Some researchers have used behavioural intent as a substitute for behavioural compliance based on the findings

of Doll and Orth (1993). This has been measured by asking participants to rate their likelihood of acting or behaving in a particular manner.

In situations where it is not possible or desirable to measure compliance then various measures may be used in a process of triangulation. It is also best to consider the context of evaluation which is of particular importance when assessing pictorials on a computer or in a laboratory setting for which there are no environmental cues.

3.11 PHARMACEUTICAL LABELLING

One problem identified by Kalsher et al (1996) with prescription drug labels is that they lack formal specification in the order the information is displayed and the amount and type of information presented is not standard. European Directive 92/27/EEC has laid down guidelines of what should be included but not how it should be laid out. Various label characteristics affect readability of prescription drug labels. These include line space, letter contrast, print and label background colour, type and style. Prescription product inserts (PPI) are increasingly used to provide information about drugs. These contain information that patients might need to know such as any relevant warning and any necessary instructions to ensure correct drug usage. However, these can become lost. Increasing the label size by using fold out labels and tag designs as described in section 3.6 enables pictorials to be added to facilitate understanding. Pharmaceutical pictorials need to be tested for comprehension and legibility as well as recall of information contained on the label. The tag designs also enable larger print sizes to be used (Kalsher et al, 1996).

Wogalter and Sojourner (1999) make several recommendations for the design of pharmaceutical labels:

- Labels should be designed in a way that captures attention. This can be achieved increasing the overall surface area of the package.
- Pharmaceutical information should be iterated by simplified wording and organising the material using headings and pictorials.
- Pharmaceutical information should contain persuasive, assertive statements to ensure that readers form the correct belief or attitudes.
- Information printed on the label should motivate people to comply. The cost of compliance needs to be low and the consequences of non-compliance should be stated explicitly.

Whilst these recommendations have been suggested, Wogalter and Sojourner (ibid) acknowledge that trade-offs have to be made in order to accommodate the appropriate combination of desirable features. For instance, the recommended explicit warnings require more space than less explicit warnings. There is also a need to test the labels using various methods which might include subjective ratings, legibility assessments, comprehension tests and behavioural compliance. Whilst this discussion applies to over the counter medications (OTC) and outpatients, the basic principles can be applied to medication for use by hospital professionals.

The SHERPA table (table 2.3) highlighted the need for conspicuity of labelling/packaging to address the problems of errors caused by failure to read drug labels. The recommendations in this chapter can be used to develop some form of

novel packaging that incorporates the systematic use of colour. Other features such as the addition of icons should also increase conspicuity of labelling and help in the identification. of drugs. This is the focus of the next chapter.

Chapter 4

Design Solutions

4.1 BACKGROUND

The summary SHERPA table (table 2.4 on page 55) indicated that the greatest number of errors (13) could be solved by employing some form of barcoding system. This will be considered in more detail in Chapter 6. The next most prevalent number of errors that were highlighted (9) in the summary table could be addressed by conspicuous packaging and it is this solution that forms the subject of this chapter. A designer was consulted in order to discuss the issue of presenting relevant information on packaging in a way that would capture the attention of nurses. In light of the recommendations of Sojourner and Wogalter (1990) that pharmaceutical labels should capture the attention, it was felt that a combination of colours, iconography and drug imagery would all be useful eye-catching features as nurses are often presented with a collection of bottles or packages with uniform white labels on which information is printed in small black or grey font sizes as outlined in chapter 2.

The model by Roozenburg and Eekels (1995, p5) in figure 4.1 highlights the importance of analysis of the initial design problem and emphasises the development of criteria for judging the success of the resulting design. The functioning of a potential solution is assessed in a simulation. The observed properties of this solution are used to deduce the properties that might be expected from the actual product still to be manufactured. The match between the expected properties derived from the simulation and those required from the product (the design criteria) determines the quality of the potential solution (Adams, 1999). The analysis used to address the original problem was carried out by the task analysis and SHERPA outlined in chapter 4. The main criteria for any designs were that they could be achieved within the scope of this project. The other criteria were that prospective designs should address the pressing issues of information management and drug labelling and packaging.

4.2 DRUG PACKAGING

The problems of drug packaging were highlighted in Chapter 1. A substantial body of work has been carried out on pharmaceutical labels and information by Morris and Kanouse, (1980); Wogalter et al (1993); Morrell et al (1990), Magurno et al (1994); Kalsher et al (1996); Morrow et al (1996); Ringseis et al (1995); Sojourner and Wogalter (1997); Vigilante and Wogalter (1997); Wogalter and Sojourner (1999). These studies were carried out to address problems encountered by members of the public and many apply to over the counter (OTC) preparations. Nonetheless the same fundamental principles apply in the context of professional users. Wogalter and Sojourner (1999) make the point that pharmaceutical labels are used to

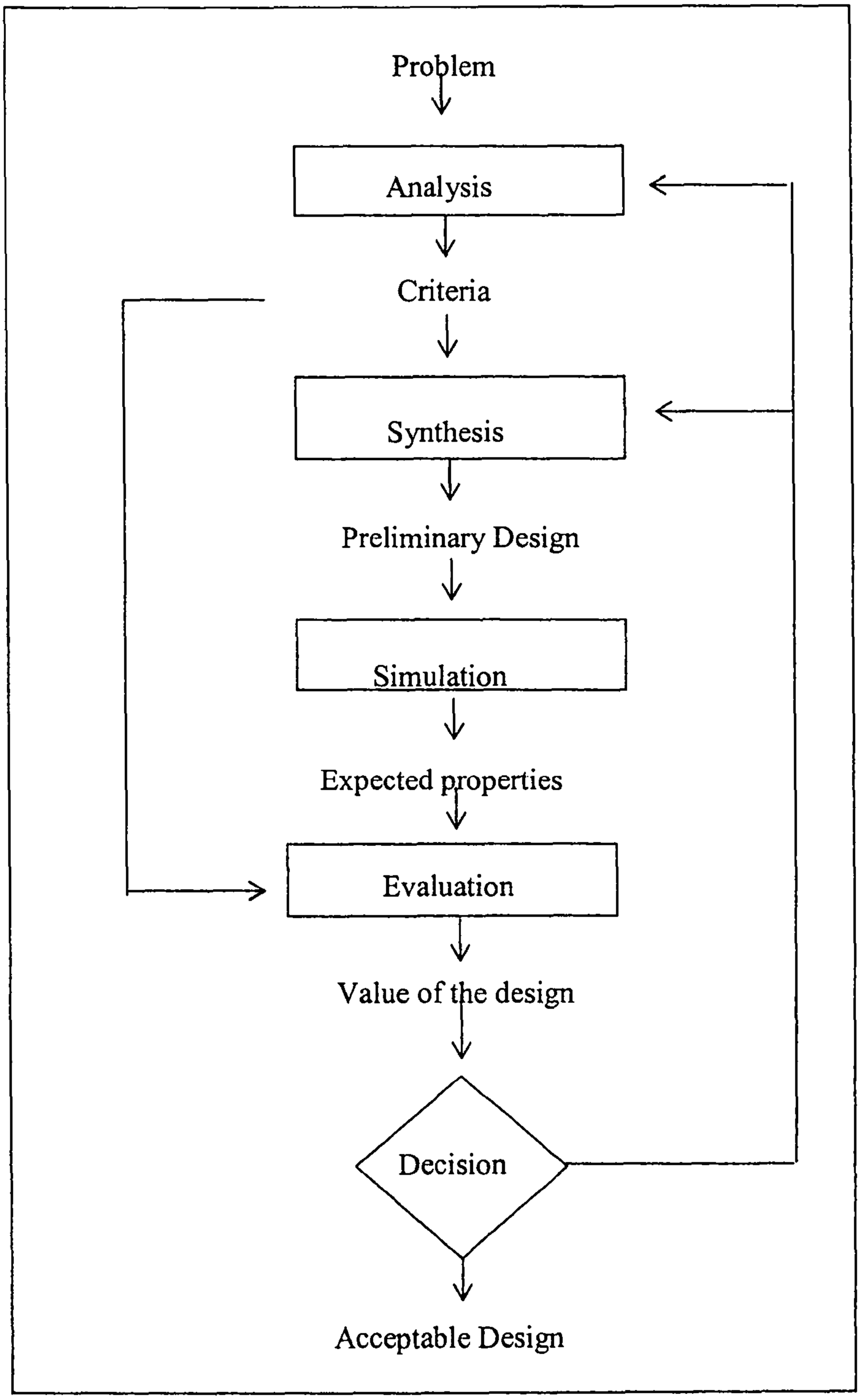


Figure 4.1: The Roozenburg and Eekels (1995) model of the design process

disseminate information about medication uses, indications, benefits and potential hazards and that they are used as a method to influence behaviour. Although

registered nurses are trained in the knowledge of drugs, this should be no less true for hospital staff than members of the public.

4.2.1 Colour

Colour has been used systematically in safety warnings, with red signalling the highest level of hazard, yellow – general hazard, green and blue – instructional warnings to wear goggles or the direction of the nearest fire exits. The European Commission's Safety Signs Directive (92/58/EEC) has examples of these.

4.2.2 Font size

The Medicine and Healthcare Regulatory Authority (MHRA, 2001) recommends that text on medicine labels should be in sans serif fonts at the largest type size possible. The report advises that on smaller packages all the available space should not be used to impart information as this could lead to difficulty in quickly locating and interpreting relevant information.

4.2.3 Original packs

Original pack dispensing has led to the presence of increasingly greater numbers of brightly coloured packages in hospitals with the associated problems of a lack of differentiation between competing colours. As a result of this some manufacturers are reviewing their long-term packaging strategy. Dispensing medicines to patients in original packs which can be taken home when the patient is discharged (combined with storing medication at the patient's beside) has some important cost-saving benefits and is in compliance with the European Commission regulations (EC Directive 92.227).

In hospitals generic drugs are used in 75% of cases because they are cheaper than branded drugs (Audit Commission, 2001). These are often supplied as patient packs which can sometimes cause more problems than the branded drugs due to the similarity of the packaging. Figure 4.2 shows examples of three drugs representing two different types of drugs. Allopurinol is used to treat gout whilst bendrofluazide and furosemide are both diuretics.

Branded drugs are also used because they are in a form that may work better for some patient conditions. For instance, some drugs might only be available in a sustained release (thereby having a longer therapeutic effect) in the branded form. In such cases it might be important to label the drug by the branded name as well as its generic name (its chief active ingredient).

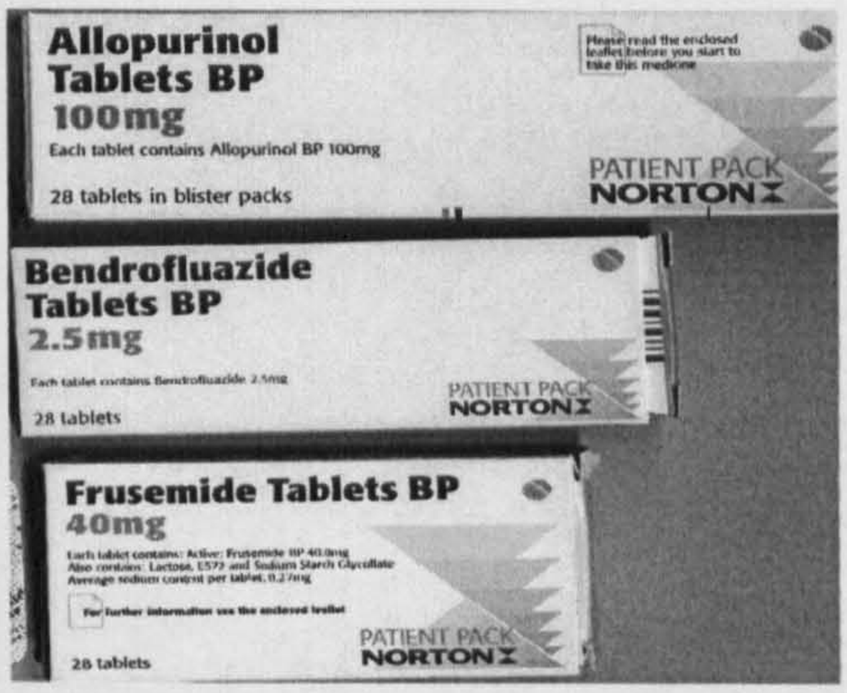


Figure 4.2 Generic drugs in similar packaging

4.2.4 Label information

One of the issues of using branded drugs is that vital information on proprietary drug packaging can often be confusing (Cohen, 1999; Kalsher et al, 1999). Relevant information is sometimes obscured by the dispensing label. This label is necessary because it contains the drug name (generic), patient's name, number of tablets in the

pack and dosing instructions and the address of the pharmacy. It also contains a warning to keep medications out of the reach of children. However it is often printed in small text and is difficult to read. The package might also contain additional warnings. For example, Atorvastatin should have a warning for patients not to drink grapefruit juice whilst taking the medication.

The MHRA (2001) advises that medication packaging should carry a "number plate" of standardised information and that more work should be done on making medicine labels easier to understand. There is also a recommendation to show information in a standard format on both prescription and non-prescription medicines. The key information should be:

- Brand name and generic name in the same font size
- Pharmaceutical form
- Strength
- Dosage (applied by dispenser)
- Warnings (applied by dispenser)

The report calls for manufacturers to leave a clear space on the package, with no text or markings for a standard 70 x 35mm dispensing label.

Label usability research indicates that the most easily readable labels are those that have the minimum required information. Too much information on the label is counter-productive and this applies across all medicine categories as noted by

Australia's Therapeutic Goods Administration (TGA, 2002). Guidance for label design can be found in Rogers et al (1995), Sless (2001) and BS 8501:2002.

4.2.5 Colour Coding

According to Cohen (1999, p13.6) colour coding is the systematic application of a colour system to identify specific products. This is in contrast to colour differentiation in which colour is used to distinguish a single product. Colour coding may be used to help to distinguish drug classes. However as Cohen (ibid) points out the system has not been scientifically tested. Colour coding, along with distinctive background patterns or borders, has been proposed as a way to reduce drug administration errors in anaesthesia (Parr, 1986). In a study of 687 anaesthesiologists, Orser et al (2001), report that only 47% of respondents admitted to always reading the drug labels of the medication they administered. Many responders identified colour as the single most important feature used to identify drugs. When asked to rate the importance of certain features of the package and label they used for identification, colour was the most frequent response. The colour of the ampoule and its label were considered extremely important for drug recognition. Similarly the colour of a vial and cap were considered extremely important. In the case of pre-filled syringes the text colour and external packaging were considered "extremely important".

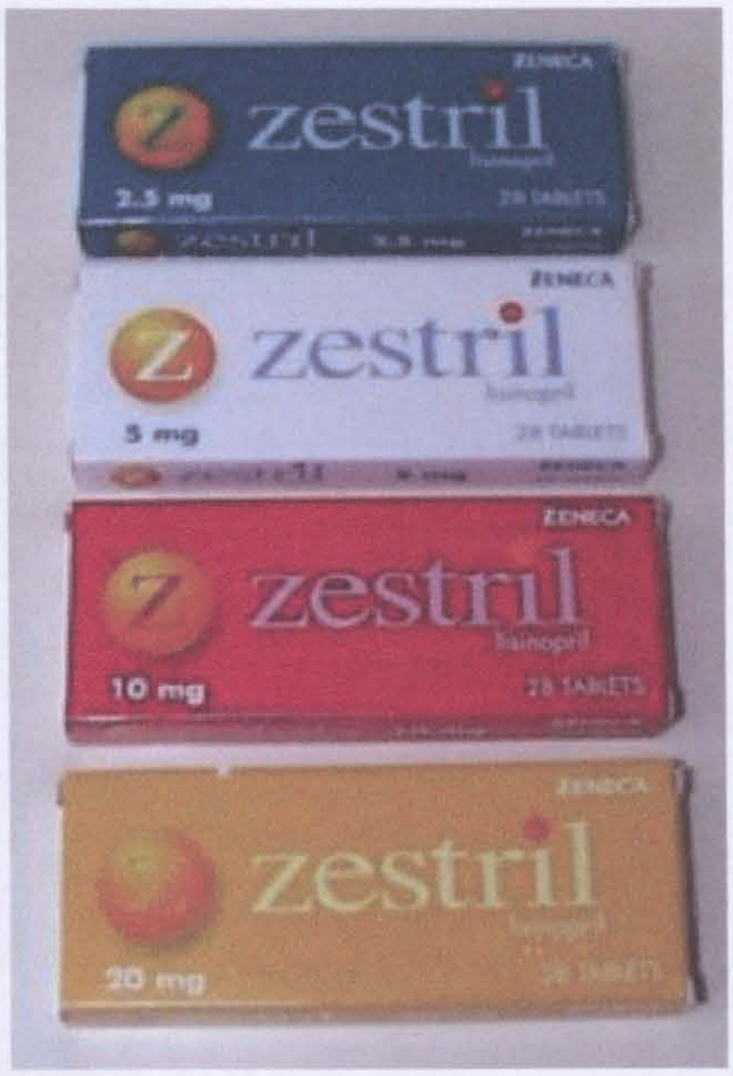


Figure 4.3: Branded drug showing how colour has been used to differentiate between different strengths

Class	Colour	Pantone Number
Anti-infectives	Tan	467
Anti-inflammatories/steroids	Pink	197, 212
Mydriatics and cycloplegics	Red	485C
Nonsteroidal and anti-inflammatories	Grey	4C
Miotics	Green	374, 362, 348
Beta-blockers	Yellow, or blue, yellow	290, 281
Adrenergic Agents	Purple	2582813
Prostaglandin analogs	Turqoise	326C

Table 4.1 Colour codes for topical eye preparations (Source Cohen, 1999)

The American Academy of Ophthalmology has endorsed the use of colour-coded caps and labels on ophthalmic products (table 4.1). The American Society for Testing and Materials (ASTM) has developed a standard for user-applied labels in anaesthesiology. The ASTM standard calls for each colour and border or background to represent a different class of drugs. Under this system induction agents are signified by yellow labels, benzodiazepines are denoted by orange labels and narcotics are represented by blue labels. A similar system is in use in Canada,

Australia and New Zealand (Radhakrishna, 1999). A national survey of anaesthetists by Christie and Hill (2002) has revealed extensive use of colour labels in the UK but these differ from those used internationally. Moreover the drug company Alpharma has taken the decision to colour code all of its products with one of seven colours (pink, blue, tan, violet, red, green or turquoise). Warfarin is the exception with the colour of the boxes matching the colour of the tablets (Pharmaceutical Journal, 2002).

Colour can also be used to differentiate between different concentrations or strengths of the same drug (figure 4.3). However it should be acknowledged that there are disadvantages of using colour coded labels as they may fade over time when exposed to light (Cohen, 1999) and it can be difficult for manufacturers to reproduce standardized Pantone colours from one batch to the next however with modern inks and contemporary printing techniques this is becoming less problematic. Whilst some official bodies endorse the use of colour there is opposition. The American Society of Health System Pharmacists (ASHP) and the MHRA, do not recommend the use of colour coding as a specific way to identify medicines on the grounds that its use may tempt users not to read the label. This, they argue, is because colour can become a short cut to identifying medicines causing people to neglect reading the label text, thereby increasing the potential for error.

4.3 DESIGNING THE NEW PACKAGING

A cursory look at the layout and features of existing drug packaging, reveals that many original packages use colour arbitrarily. The primary function of colour is to emphasise the brand name or to accentuate the name of the manufacturer in an

attempt to make it distinguishable from other drugs. (Kenagy and Stein, 2001). This is demonstrated very well by Nurofen (figure 4.4). This over the counter preparation is the branded form of anti-inflammatory and pain relieving drug ibuprofen. It is marketed and sold by Crookes Healthcare, a subsidiary of Boots Healthcare International. However in this case, unlike many branded drugs, the manufacturer's name is not located in a prominent place on the front of the package. The packaging of Nurofen is now a highly recognised analgesic largely because of its distinctive silver and orange packaging and the heavy marketing it receives. The branding design has become so widely recognised that Nurofen has been acknowledged as an official superbrand by the independent arbiter on branding the UK Superbrands Council. The definition of a superbrand described by the UK Superbrands Council is a brand that offers significant emotional and/or physical advantage over its competitors" (www.nurofen.co.uk/default.asp?nid=15, accessed 16/1/2004).

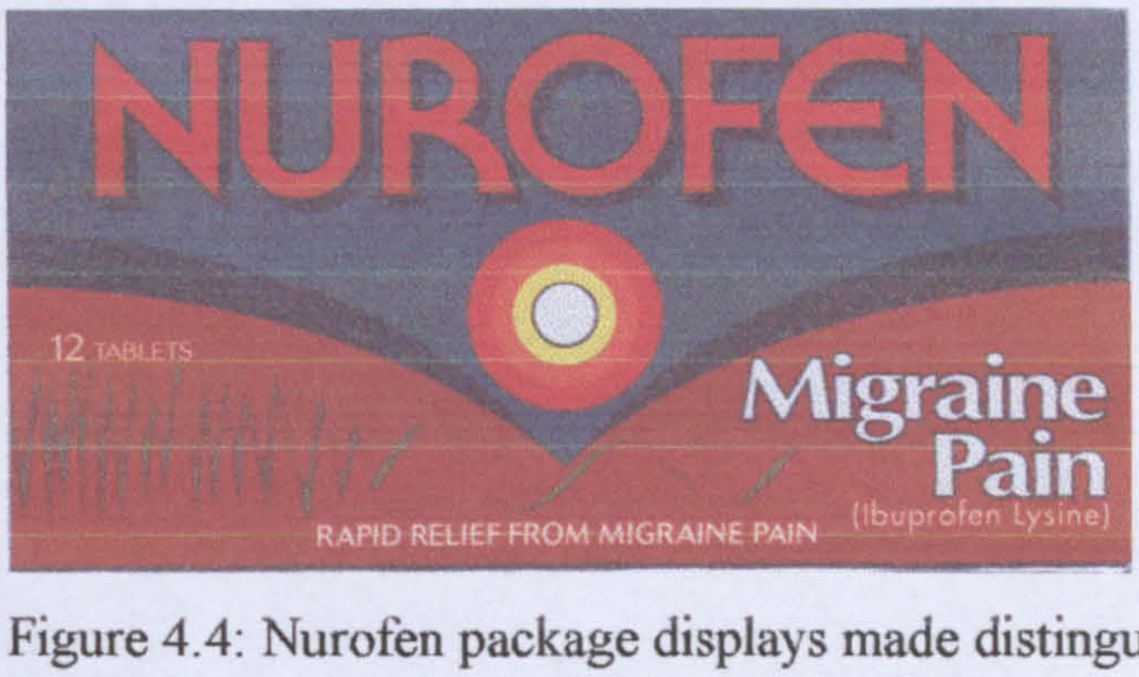


Figure 4.4: Nurofen package displays made distinguishable from other analgesics by dominant use of colour

The process of redesigning the drug packages was to consider what were the salient features used to identify drugs. These are usually colour, positioning and salience of drug name. Using the principles of branding, which typically use dominant colours

and imagery to highlight information the manufacturer deems salient, it was intended to demonstrate that by using similar principles it is possible to draw the user's attention to the drug name of generic preparations.

In designing the new packaging the designer looked at existing drug packaging to see how information was arranged and how colour was used. There was a temptation to classify the drugs according to the parts of the body on which they are used. However this course of action was rejected in favour of categorisation according to the action of the drug in a similar way to the categorization principles of anaesthetists. These categories are given in the British National Formulary (BNF, 2005) but the list produced by the Food and Drug Administration (FDA) is more readily suited this purpose (appendix B). In both cases the drugs are grouped according to therapeutic effect. Using colour to represent categories of drugs is more practical as there are not enough colours to represent each drug individually nor would that be desirable as nurses are likely to use colour as a short-cut as argued above.

The basic premise of the design was to position key pieces of information located in a fixed position on the package label regardless of the drug category. This would enable users once familiarised with the package to become accustomed to looking in a precise location to retrieve the relevant information. A concept package for a box of tablets is illustrated in figures 4.5. and 4.6.

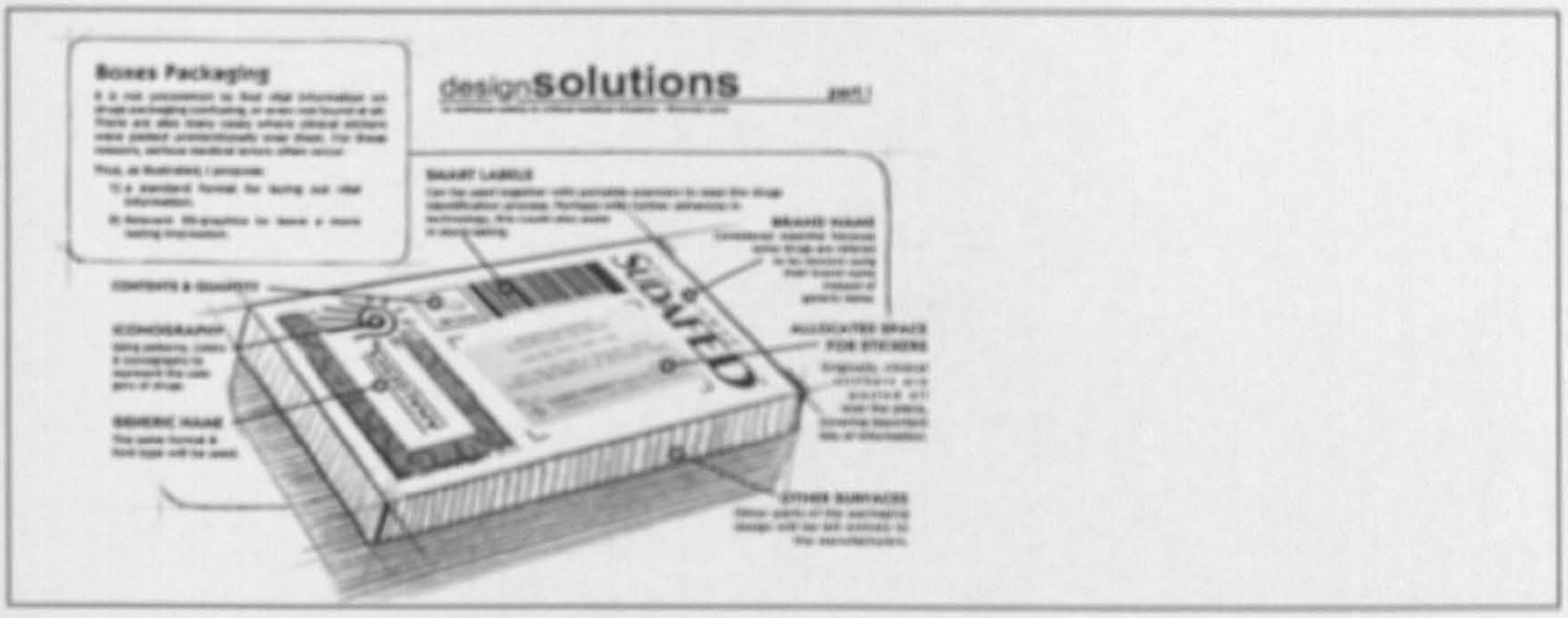


Figure 4.5: Preliminary drawing of the concept design

The generic name by which the drug is most often known is positioned on the left of the label, since in western society, reading tends to be directed from left to right therefore it would seem logical to put the most important information either near the top of the label or on the left. A colour border comprising patterns and colours highlighting the generic name serves to draw the eye to that part of the package. The placement of the icon acts as an additional feature to attract attention to the generic name. A picture of the contents and the number contained in the package appears next to the generic name. Alongside the contents information a barcode or smart label is positioned which can be read by a portable scanner. To the right of the panel is the brand name of the drug if it has one. Space is allocated on the package to enable inclusion of the patient's information when the medication is dispensed for individual patients. This space would also include additional information such as the warning recommended by the British Pharmaceutical Association (BPA) to keep medicines out of the reach of children, the date of dispensing, dosage instructions and the name, address and telephone number of the dispensing pharmacy. The other

surfaces of the packaging would be designed according to the manufacturer's preference. It was envisaged that the design could be produced as a label that could be printed out and applied to boxes as necessary.

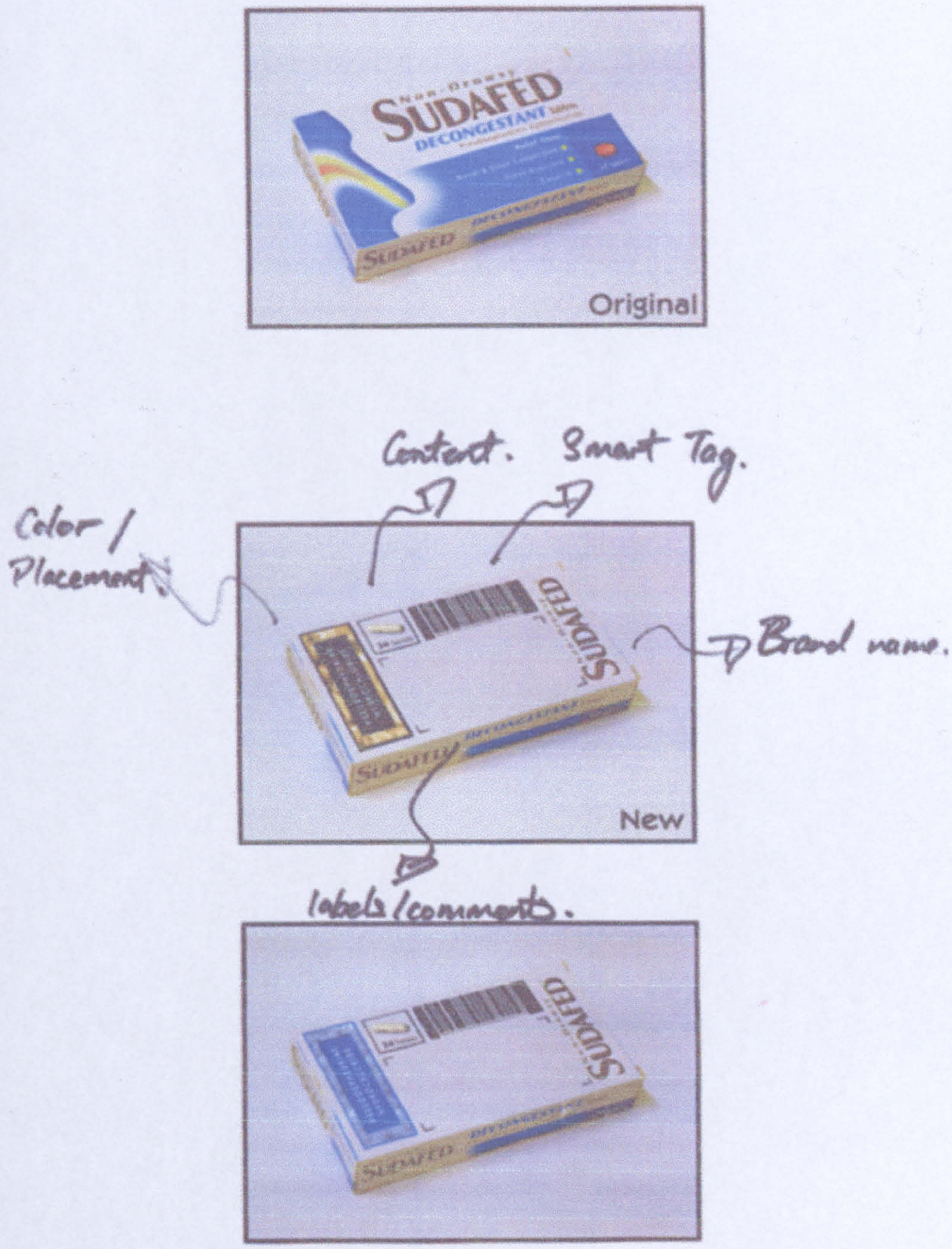


Figure 4.6: Mock-up of the concept design

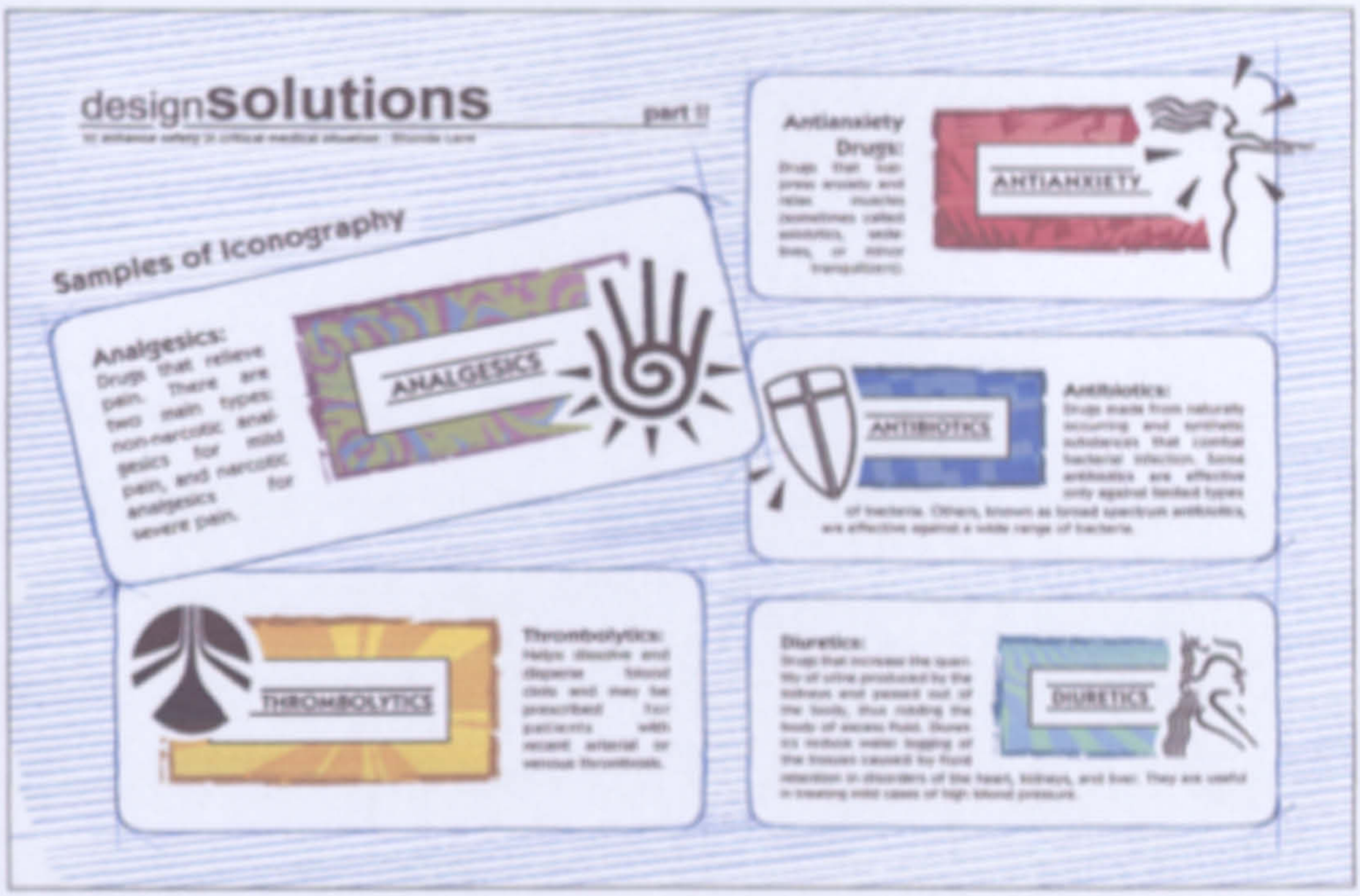


Figure 4.7: Designs for icons and distinguishing colour blocks for five drug categories

4.4 TESTING THE DESIGN

It was necessary to see if the any of the designs were significantly better than existing packages. The simplest way to do this was to test how quickly the printed information could be read.

4.4.1 Participants

A total of 6 participants took part in the experiment, 5 of which were postgraduate researchers. One was a college lecturer. In terms of gender there was one female and 5 male respondents. They ranged in age from 23 to 43 years.

4.4.2 Materials

Five drug categories were selected from the list in Appendix A by the designer. The list was produced by the FDA's Centre for Drug Evaluation and Research. The main

selection criterion for the drug category (given the time constraints) was that it should be easily represented by a pictogram. The categories selected are shown in table 4.2.

A two-dimensional image was designed for each of the five drug categories using the principles of the concept package. This was carried out to enable one face of the package to be shown on a computer screen. The package was designed with a row of text surrounded by a distinctive colour border, accompanied by a pictorial representation (see figures 4.8 – 4.12). The pictogram was intended to reflect the drug category. The shield was intended to represent the protective effect of antibiotics (figure 4.8). In the case of analgesics, the representation of a hand in the 'halt' position' alludes to the ability of the medication to stop the progress of pain (figure 4.9). Pain is signified by the outward facing arrows or spikes encircling the lower portion of the 'hand' in addition to the spiral in its centre. The spikes and wavy lines of the icon in figure 4.10 represents a profile form of the human body in acute discomfort. Figure 4.11 displayed the complex image of a hip joint with water flowing from it and the outline of a woman's face in profile with her hair hanging loose. The image in Figure 4.12 was a depiction of a free-flowing motion along a channel indicative of the action of an anticoagulant.

Drug	**Category**	**Action**
Co-amoxiclav	antibiotic	fight infection
Paracetamol	analgesic	pain relief
Furosemide	diuretic	relieve water retention
Warfarin	anticoagulant	prevent blood clots
Diazepam	anxiolytics	relieve anxiety

Table 4.2 Drug categories used to represent the concept (new) package

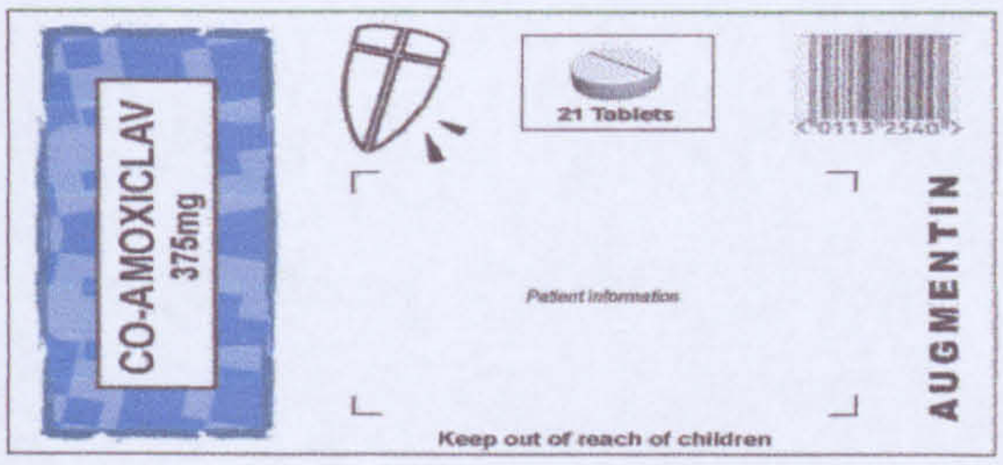


Figure 4.8: Experimental package for the drug category antibiotics

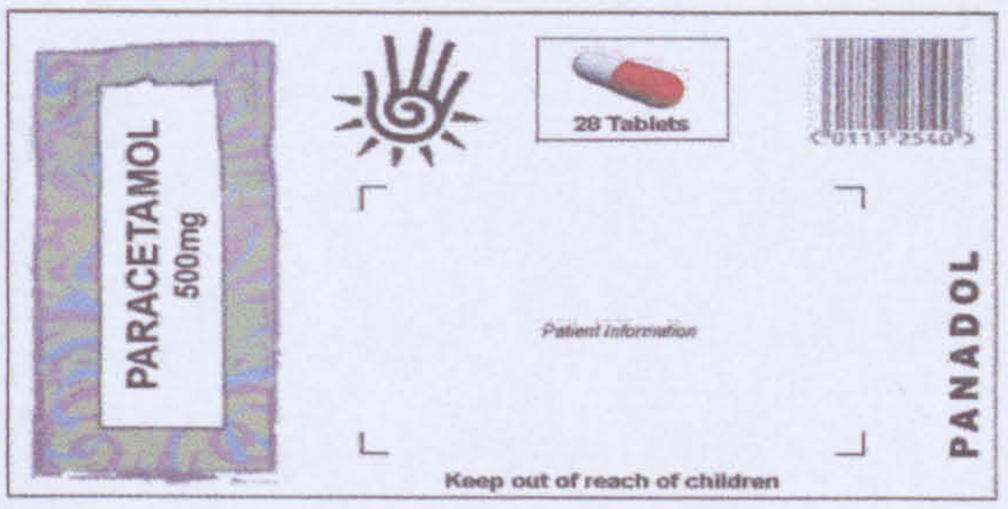


Figure 4.9: Experimental package for the drug category analgesic

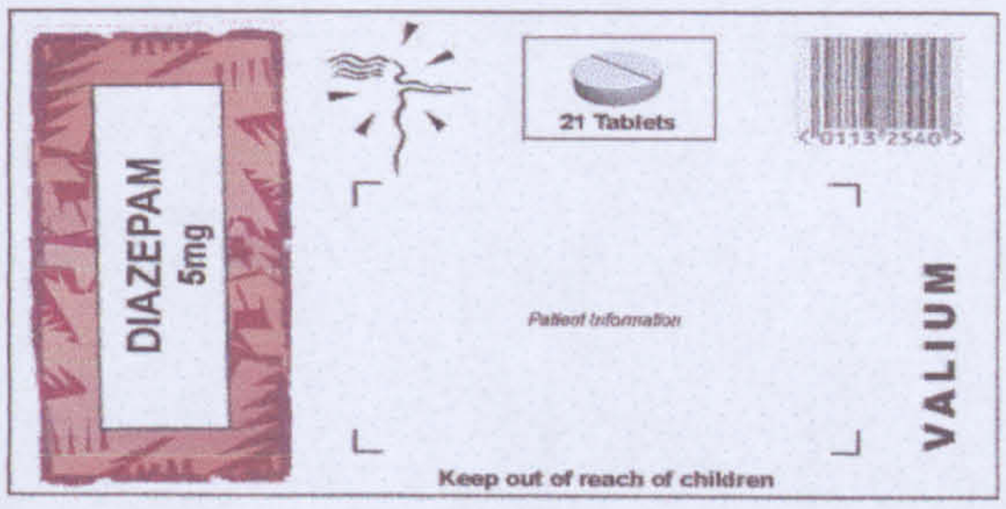


Figure 4.10: Experimental package for the drug category anxiolytic

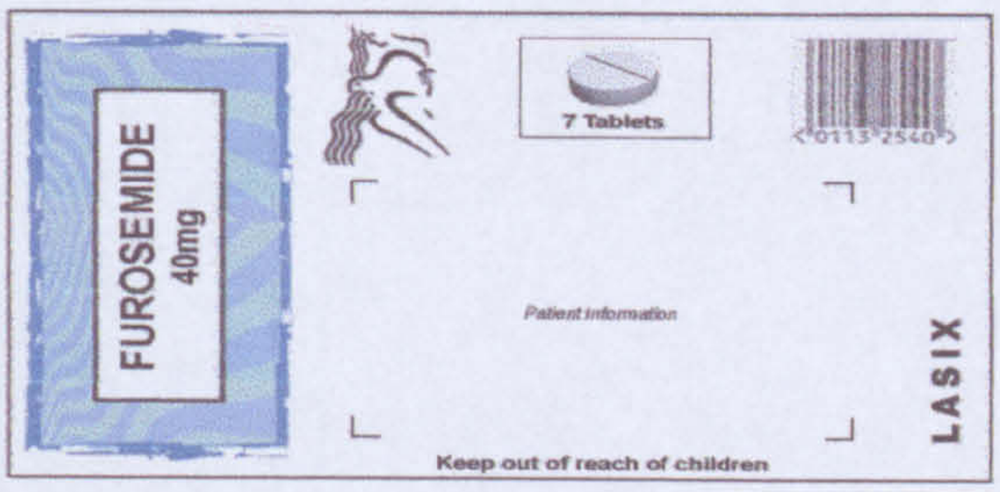


Figure 4.11: Experimental package for the drug category diuretic

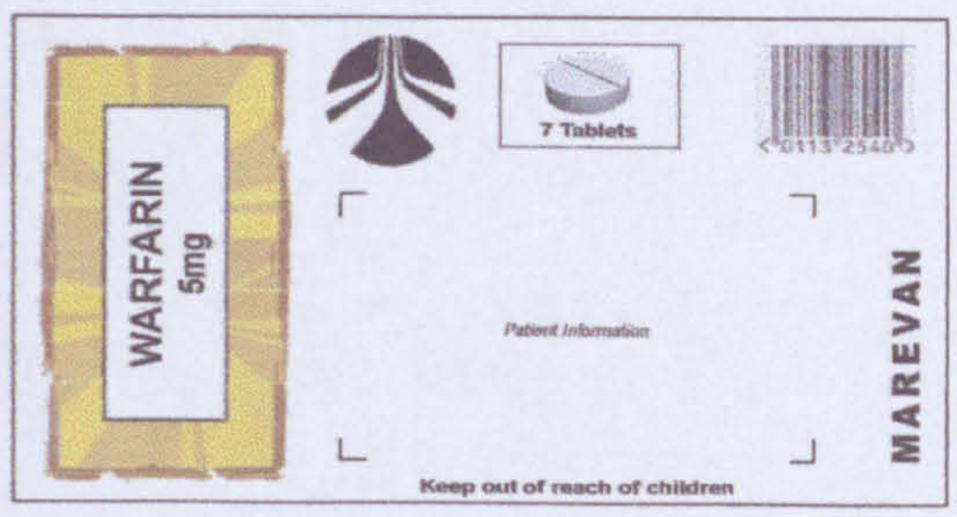


Figure 4.12: Experimental package for the drug category anticoagulant

A picture of the contents and the bar code were included as on the concept package. The branded name of the drug was placed on the right in a vertical orientation as on the concept package. A sans serif text font (Arial) was used throughout the design.

For comparisons with existing packaging, scans were taken of the front face of five branded drug boxes. These were boxes of prescription drugs and were made into a PowerPoint presentation of five slides. The boxes with minimal colour were selected to provide a reasonable comparison with the concept packages. It was not possible to find 5 packages of branded drugs from the same drug categories as the concept packaging as many community and hospital pharmacies now use generic drugs. The drug categories tested were as given in table 4.3.

Drug	Category	Action
Doxazocin	alpha adrenoceptor blocker	lowers blood pressure
Venlafaxine	antidepressant	relieves anxiety
Fenofibrate	fibrate	lowers blood cholesterol
Zopiclone	hypnotic	treats insomnia
Rosiglitazone	antidiabetic	treats diabetes

Table 4.3: Drug categories used to represent existing (old) packages

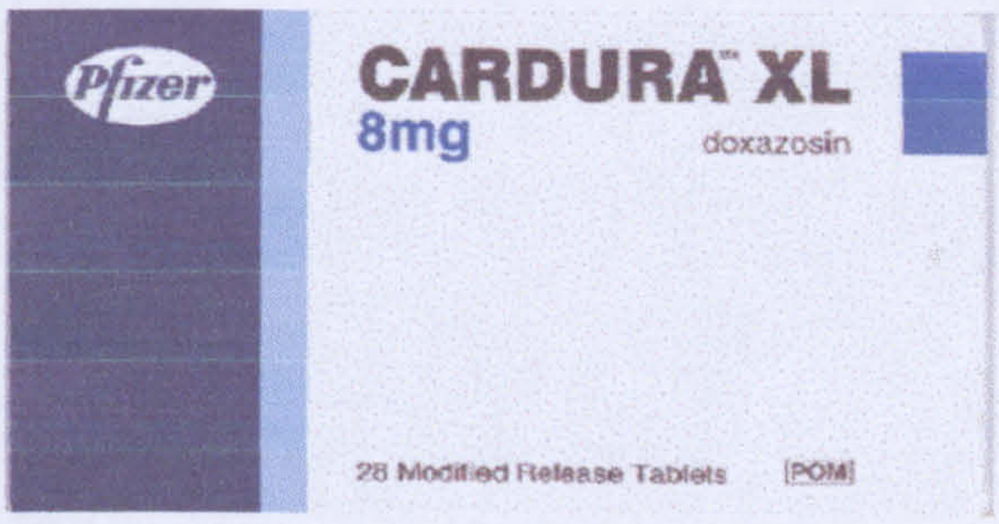


Figure 4.13: Experimental package for the drug category alpha-adreno-ceptor blockers (lowers blood pressure) (Source- Clark, 2000)

Figure 4.14: Experimental package for the drug category fibrates

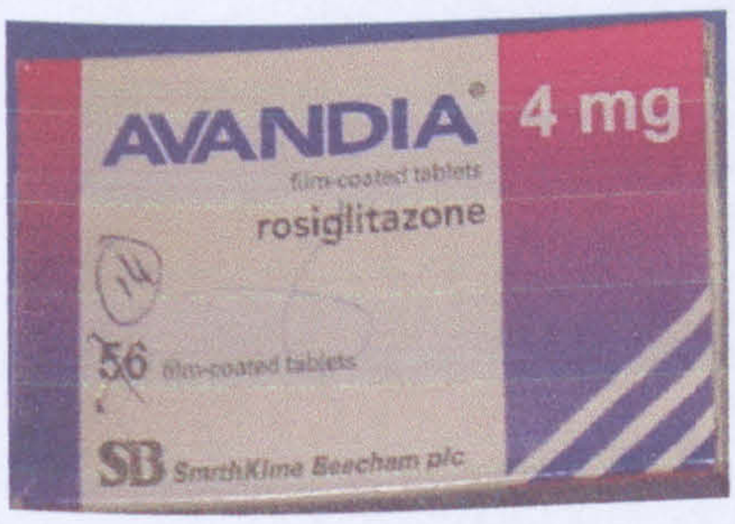


Figure 4.15: Experimental package for the drug category antidiabetics (Source- Clark, 2002)

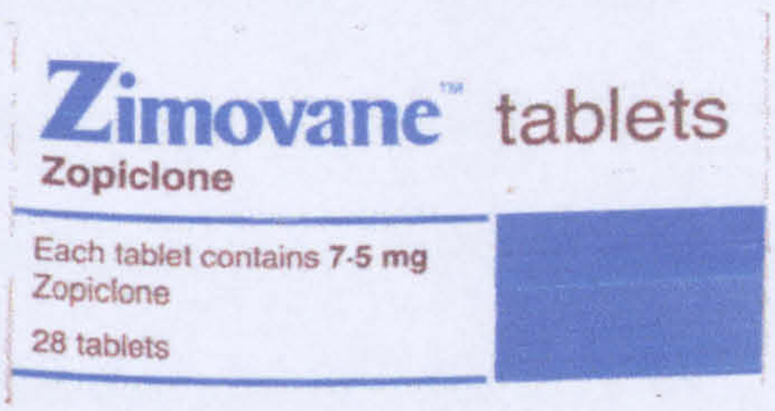


Figure 4.16: Experimental package for the drug category sleeping drugs (Source- Clark, 2002)

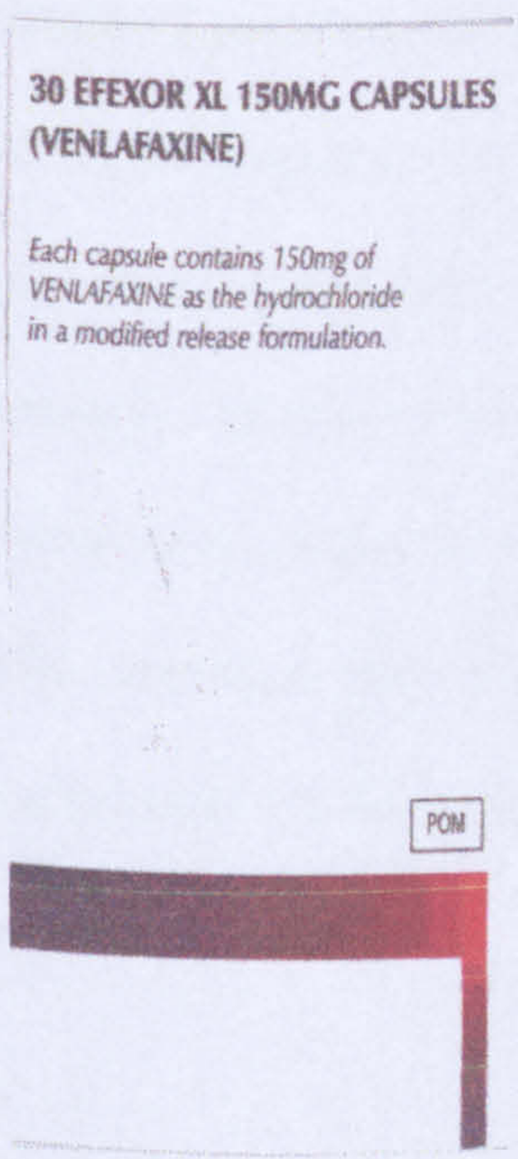


Figure 4.17: Experimental package for the drug category antidepressants

4.4.3 Procedure

Participants were asked if they were prepared to take part in the study and were given a brief explanation of what the task involved. They were told that they would be required to look at slides of drug packaging presented on a computer screen and would be required to state the drug name and the drug strength. As the participants also possessed no specialist knowledge of drugs they some time studying two printed sheets on which were printed the drug names they would be required to state. The participants were also given written instructions (appendix E) and were afforded the opportunity to ask questions before commencing the task.

Microsoft PowerPoint presentations of five slides was prepared for each type of the package (old vs new) with one slide presented on each page. There were four conditions in which the time delay between the slides was varied. The intervals were one second, three seconds, 7 seconds, 10 seconds, giving a 2 (new vs old packages) x 4 (presentation interval) within subjects design. To counteract the effects of practice, the order of the slides within each slide show was randomised for all participants, as was presentation of the timed conditions as well as the label type. Participants were required to state both the generic drug name and the drug strength. It was expected that higher scores would be recorded for both drug naming and drug strength naming with the new packages in all conditions. It was also expected that scores would be higher during the longer intervals as participants would have longer to look at the packages.

4.4.4 Results

Participants were required state the drug name and the drug strength. Scores were recorded by measuring how many drug names and drug strengths participants were able to state in each condition and recorded separately. Thus for each presentation of slides shown during a timed interval the participants could score a possible maximum of 5 correct responses. The results are summarised in figure 4.18 and figure 4.19. Tables of results are listed in appendix F. As expected, participants were able to pick out more information in the 7 second (T3) and the ten second (T4) conditions than in the one second (T1) and three second (T2) conditions. Participants were able to state more drugs names from the new packages than the old packages in all but the shortest time interval (figure 4.18). In the shorter time intervals (T1 and T2) participants performed better with the old labels. A Wilcoxon signed ranks test was carried out on the data (Greene and D'Olivera, 1993) but none of the results reached a level of significance.

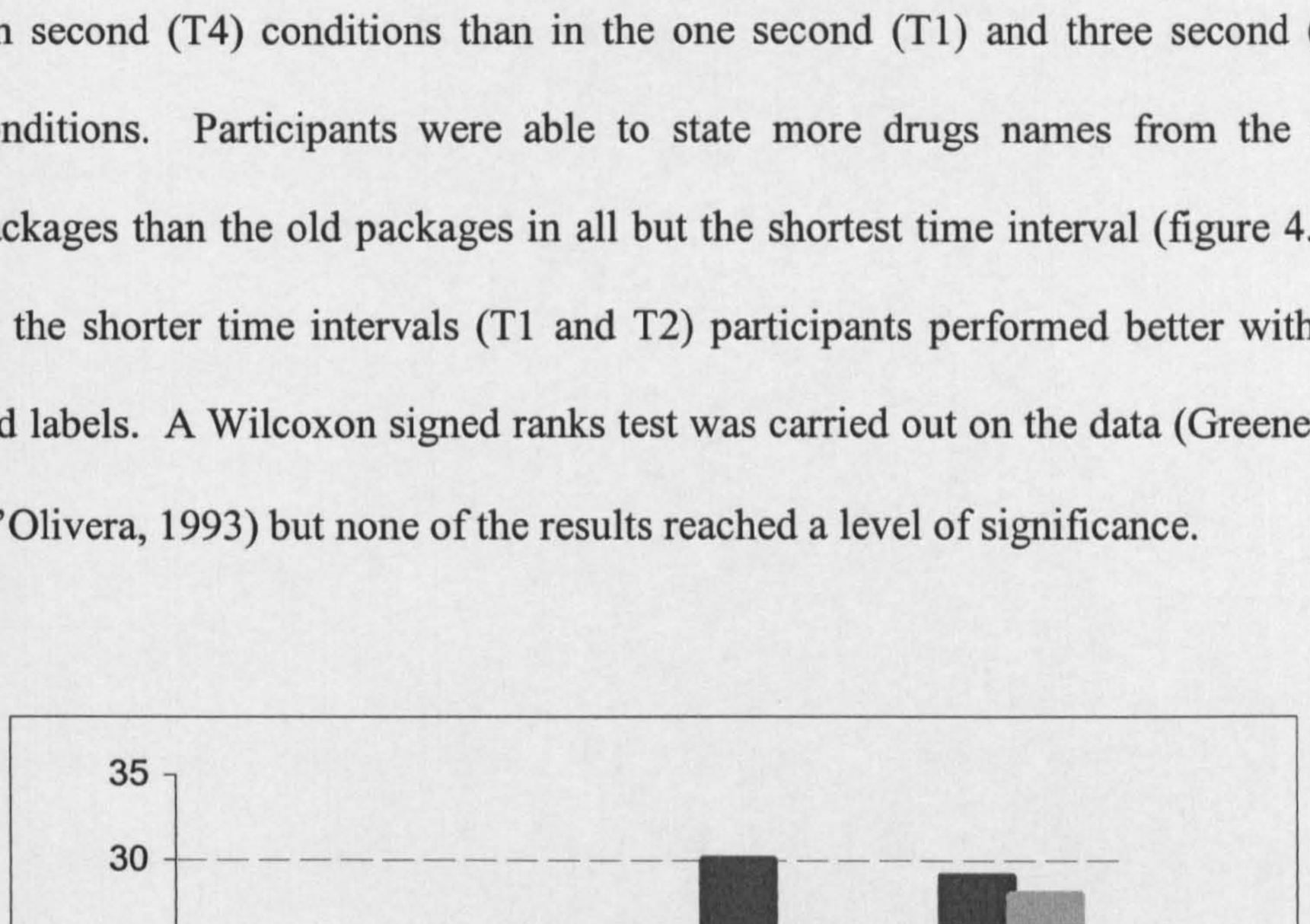


Figure 4.18: Results for drug naming – comparison between existing

(old) and new (concept) packaging

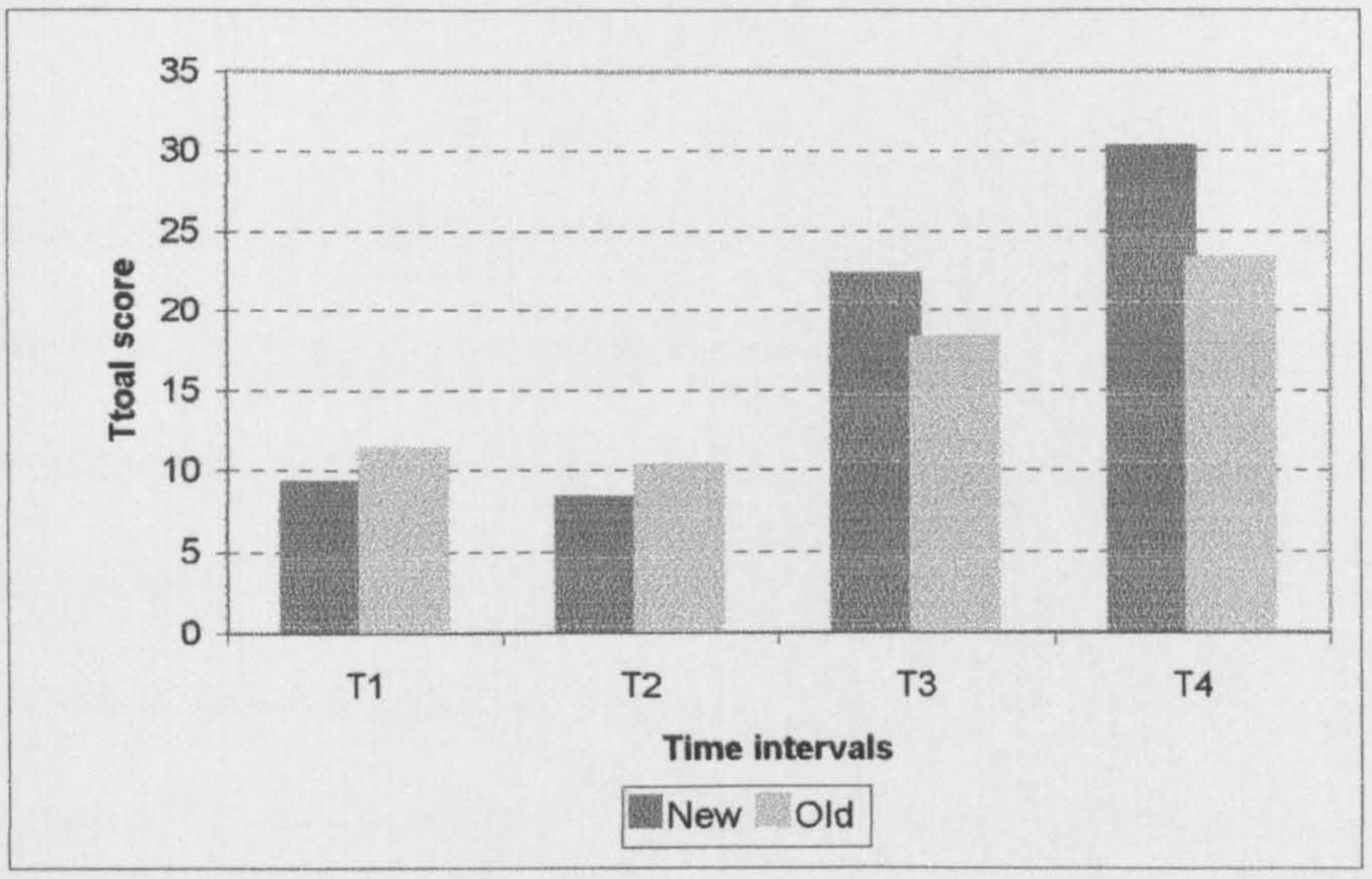


Figure 4.19: Results for drug strength naming- comparison between existing (old) and new (concept) packaging.

4.4.5 Discussion

One of the reasons for the lack of significant differences between the existing and concept packaging was the orientation of the text within the colour panel. It would have been better to have positioned it horizontally rather than vertically. For comparison purposes this represented a confounding factor. In real world terms the vertical positioning of the drug names is not problematic as many boxes are turned on their sides for ease of storage. The vertical orientation should not present difficulty as the pack would be rotated when picked in order to check the patient information. In the present experiment the vertical orientation of the concept packaging slowed recognition of drug strength naming.

It is also possible that the mixed colours of the panel served to distract respondents, a finding reported by Wogalter et al (1999). The white space around the text could have been manipulated as part of the experimental procedure.

However this would have been likely to produce no more than a minimal effect (Adams and Edworthy, 1995).

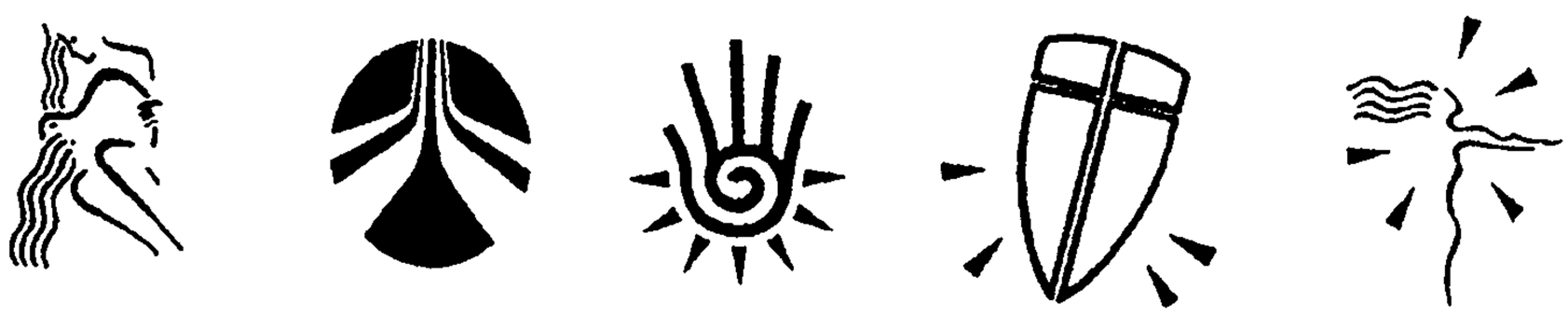
It is likely that the distance between the brand name and the generic name was a major factor in the lack of significant results. In the case of the existing packages although the brand name is much larger than the generic name with the exception of venlafaxine, the generic name is printed close to it. Thus the brand name acts as the target attracting the viewer's attention to its position. This effect is enhanced by the colour print of the letters. Since the generic name is not separated by a great distance as in the case of the concept packaging it is easily picked out. In the case of the concept packaging the viewer has to search a greater distance in order to reject the incorrect drug name. The use of capitals may have made the text prominent but may also have slowed down reading times, thus the labels would have to be redesigned to address these shortcomings.

Interestingly, in the case of the fenofibrate package (figure 4.14) subjects were unable to pick out the drug strength even though it featured prominently on the front of the pack in orange. Comments made were that the 200 seemed more like part of a brand concept than a source of useful information. This supposition becomes more apparent when consideration is given to the way that the drug strength is signified on the other packets in much smaller print.

The lack of significance of times upon naming was due to the effect of practise. This is was most evident in cases where the longer time intervals were presented first followed by the shorter intervals, participants seemed to make a concerted

effort to give both the drug name and strength than when the shorter intervals were presented first. Although the slides were randomised within the presentations and the order of the slide shows varied, participants saw the same 10 slides in each presentation. The rationale of the tests was to elicit a forced response. As the interval in the one second condition was so short that participants did not realistically have time to give their response, the most salient aspects of each label type should have stood out. Those participants who were presented with this condition as their first task showed signs of being flustered. However this was not the case for all respondents. One participant memorised the words and gave his responses completely retrospective to the presentation. The practice effect could be overcome by increasing the number of drug categories represented. Alternatively using a between-subjects design may have yielded significant results.

Another way to improve the design of the experiment would have been to display the slides for the relevant period of time and record response latencies - the time taken for participants to respond before showing the next slide.



a b c d e

Figure 4.20: Drug category icons

One of the difficulties with this exercise was the lack of recognition of the icons on the new package. Not one of the participants was able to state a drug category for all five of the images. Those who did recognise the shield were at a loss as to

what it might represent in terms of drug categories (figure 4.20d). The anticoagulant icon (figure 4.20b) was also not associated with anything either within the context of drug categories or elsewhere, however one participant did think it resembled a company logo. The icons for the anxiolytic (figure 4.20e) and the diuretic (figure 4.20a) had to be rejected as they were originally designed to be used elsewhere.

The icons were included to provide a level of redundant coding in accompaniment to the text as recommended by Wickens (1992); the different formats intended to emphasise different properties of the information. In this case highlighting the drug category whilst the text accentuates the drug name. If icons were to be featured on the new packaging, they would need to be redesigned and this is discussed further in Chapter 5.

4.5 THE THREE DIMENSIONAL DESIGNS

4.5.1 A description of the 3D design

Medications are frequently supplied in bottles therefore the designer adapted the concept so that it could be applied in a more three-dimensional format. The information on the concept label was rearranged so that it would fit onto a 'collar' that could be placed around the neck of the bottle allowing information to be read from a 'bird's eye view' as well as in the standard way when the bottle was picked up (figure 4.21). The icons were translated into three-dimensional tactile features so as to become an additional source of information.

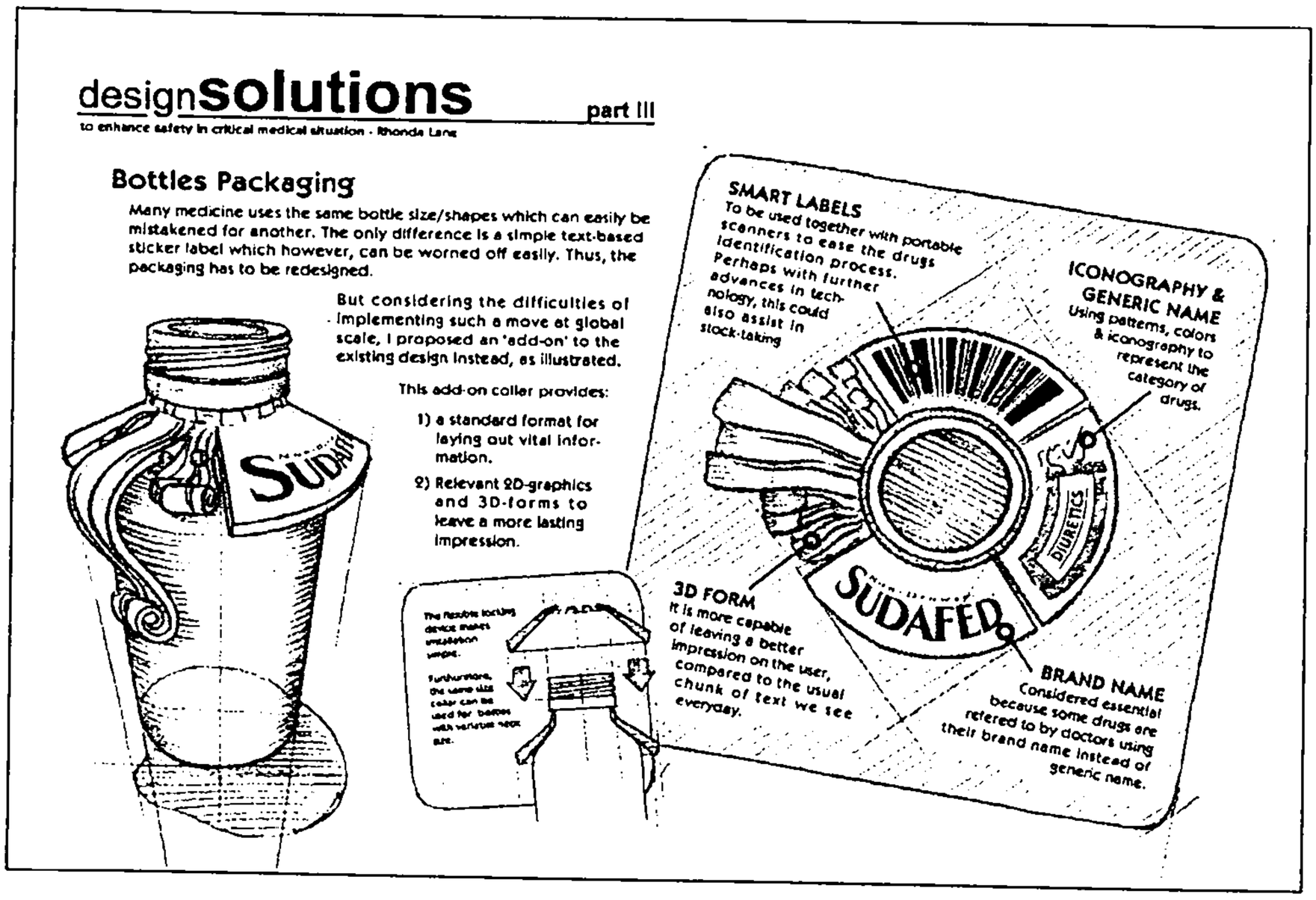


Figure 4.21 – Prospective design for a drug information collar

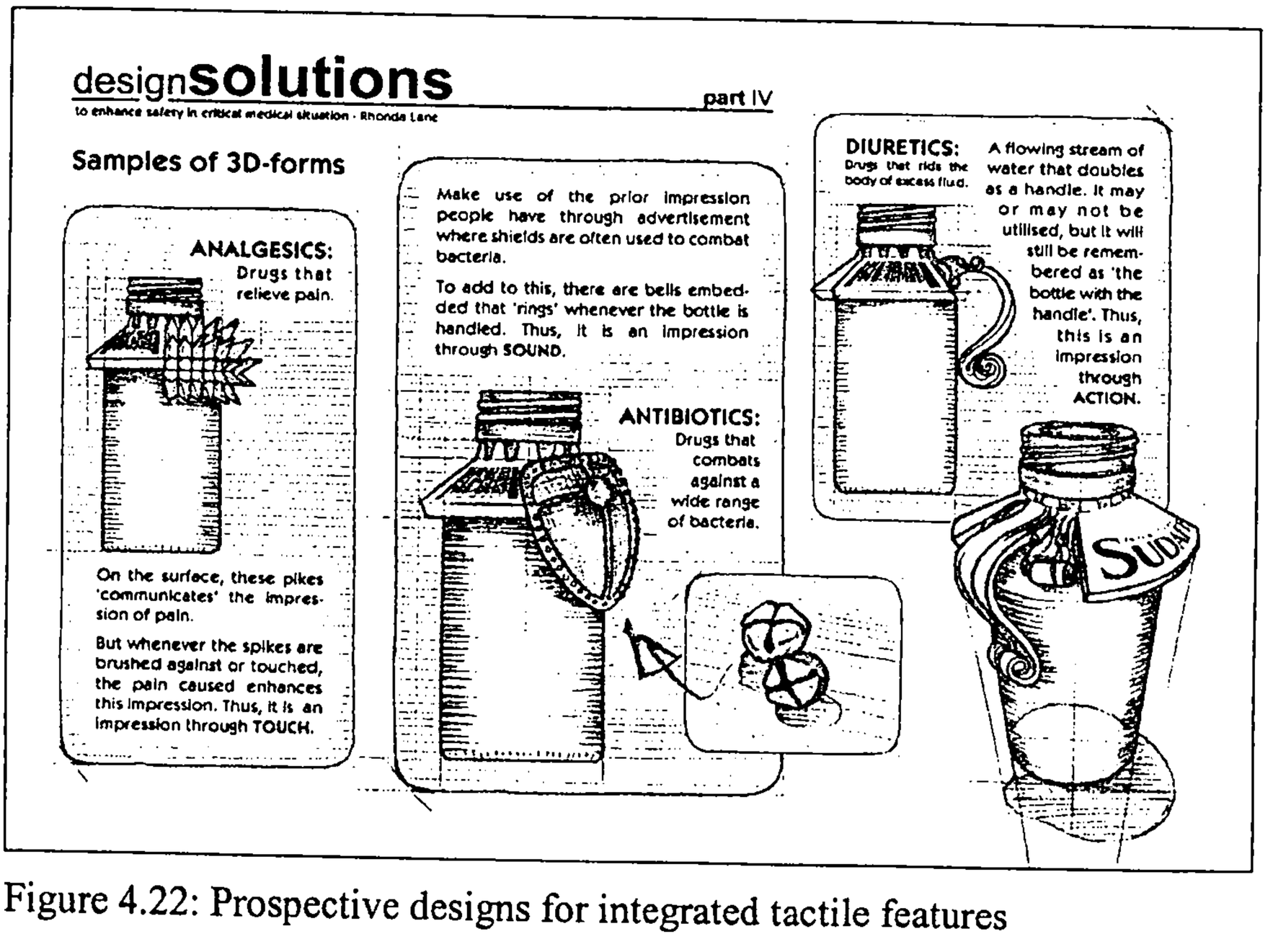


Figure 4.22: Prospective designs for integrated tactile features

Adding tactile cues to aid identification were considered useful as suggested by Sanders and McCormick (1993) and illustrated in figure 4.23. In industrial settings the tactile sensations act as an addition source of information. A similar principle could be added to bottles for medication preparations as a means to

distinguish different types of medication (Cohen, 1996, p3.7). The textures would not be replacements for conventional means of identifying drugs but would serve as purposely redundant features used in addition to the label.

The swirl depicted on the bottle shown in figures 4.22 is intended to be a three-dimensional representation of the diuretic icon (Figure 4.20a) and to evoke an association with water (diuretics are used to regulate fluids).

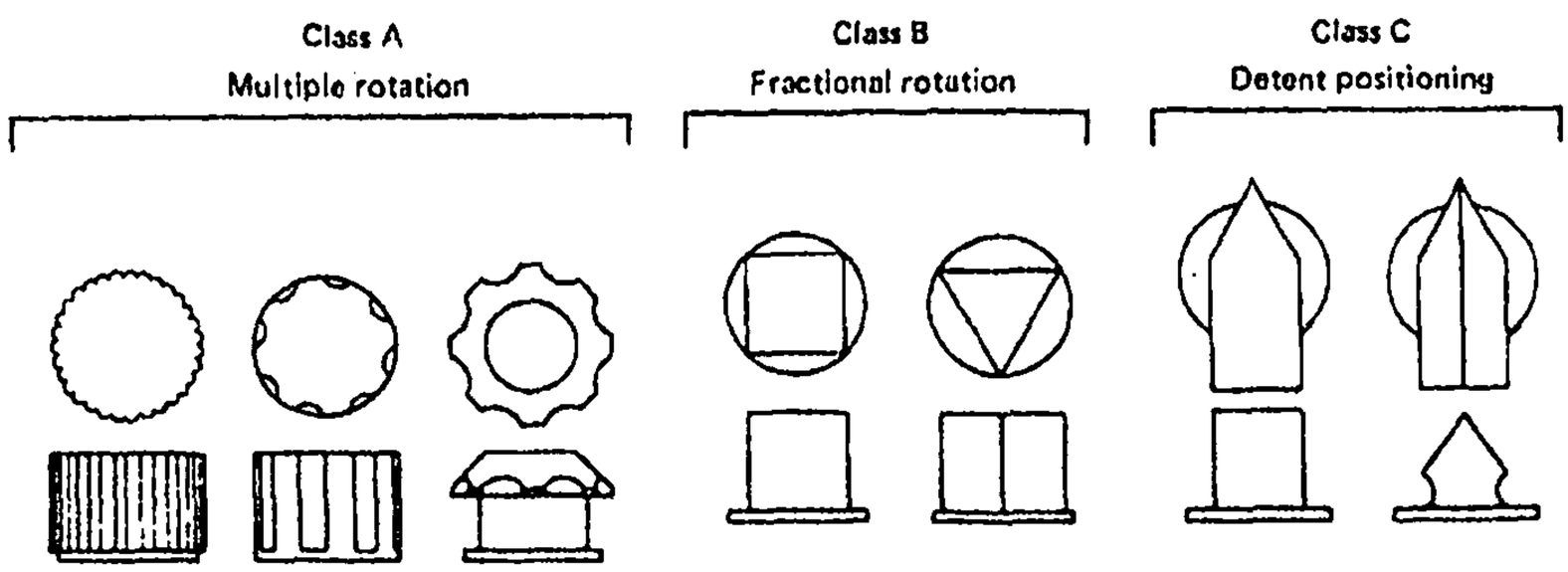


Figure 4.23: Examples of knob designs for three classes of use that are seldom confused by touch.

The original intention was to manufacture a bottle that would incorporate the tactile feature on the main part of the bottle. A more elegant solution was to design a collar incorporating the haptic feature that would fit over the neck of a standard medicine bottle. In this way manufacturing costs could be kept down. However some manufacturers supply the medication in small polypropylene bottles which could be modified to incorporate the elements of the concept design.

Three of the designs were produced as engineering drawings in the CAD package ProEgineer (ProE) (appendix B). One of the challenges with the tactile features

was how to model the elements of the less concrete images (figure 4.20 a and b) with (ProE). The wavy lines of the diuretic image (figure 4.20 a) had been used to signify both hair and water. For the three dimensional representation this was simplified to three vertical wavy lines denoting water. The thrombolytic icon did not have any features that would afford a meaningful three dimensional representation. Models of the collars were made in ABS using a Stratasys fusion deposition modelling rapid prototyper (model FDM3000) and are shown in figure 4.24.

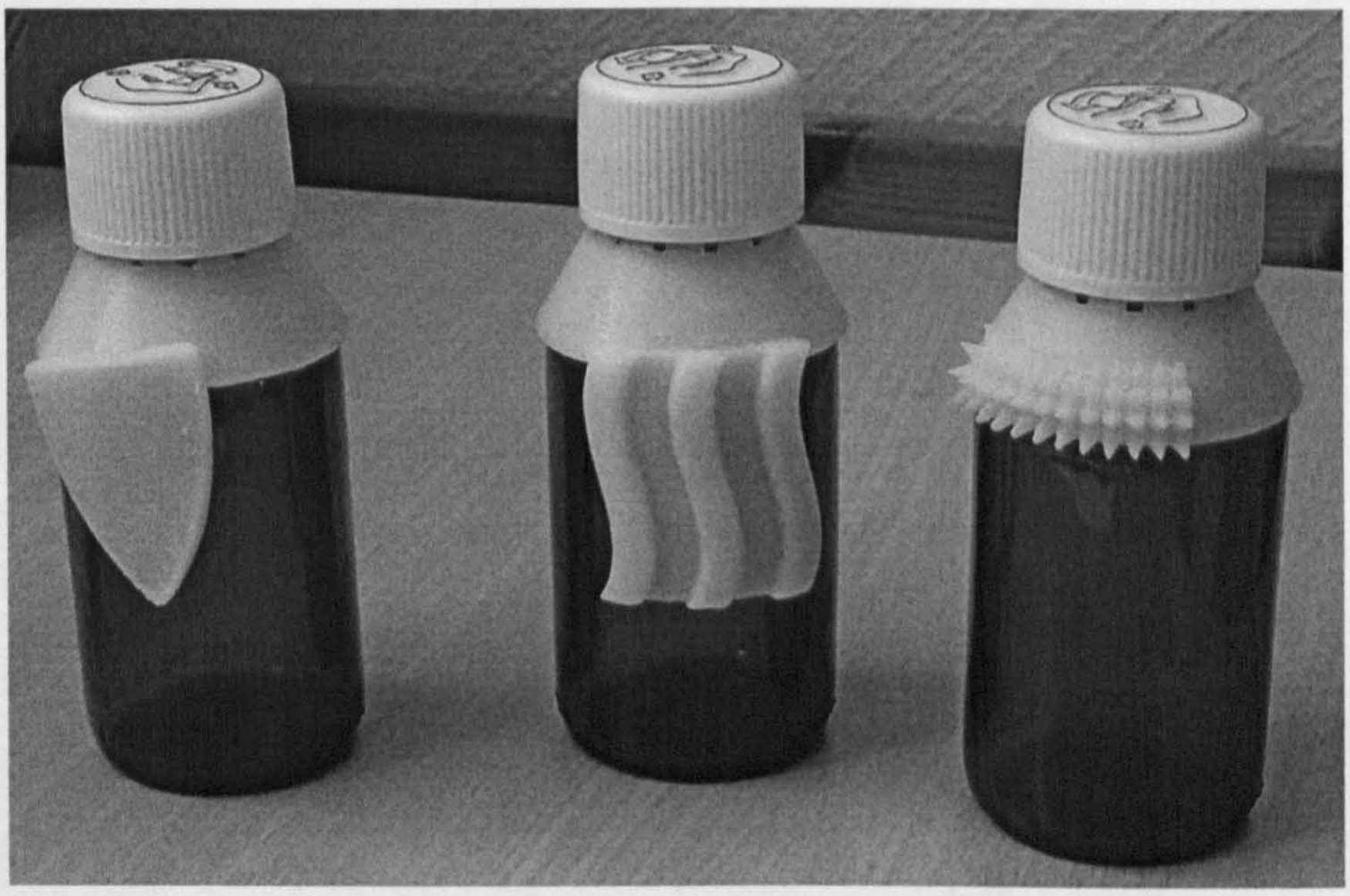


Figure 4.24: Prototype of the medication collar incorporating tactile features

4.5.2 Testing the 3D design

4.5.2.1 The training session

It was assumed that participants would be able use the tactile features to associate the drug categories with their shape. However, participants would need a brief period of training in order to associate the shape with the drug. This was carried

with a group of 25 Further Education students ranging in age from 16 years, however no demographic data were collected. The students were informed of the purpose of the task, that it was a short memory test involving tactile features on medicine bottles. The bottles were shown to the students as part of a psychology class and the shapes were described using a drug name as an example. It was stressed that it was not the drug names that were important but rather the association they made with the shape and the drug group it denoted. The students were able to look at the bottles and pass them around and ask questions for clarification. It was explained to them that they were required to make an association between the shape and the category of the drug. It was pointed out that the drug name had been included as an example and that on the following day they would be required to make a selection of the bottles without looking at them.

4.5.2.2 A test of the blindingly obvious

The following day the students were required to perform a repeated measures blind touch test. Three bottles with collars were placed in a small cardboard box inside a black plastic dustbin liner. This procedure was repeated but with three standard medicine bottles without a collar. Participants were asked to put their hand in the first bag and select the drug category requested and to do this without looking. The bag was held so as to provide a small opening through which a hand could be inserted. They were required to repeat the process for the second bag. The order of the bags from which they made their selection was alternated, as were the drug categories to control for the effects of learning. A total of 12 students took part in this selection test and were debriefed after the task..

4.5.2.3 Results of the 3D test

Without any tactile cues there was a probability of one in three that the participants would be able to select the correct bottle. All 12 participants correctly selected the collared bottles on demand. In the absence of the collars five bottles were correctly selected. A Wilcoxon signed ranks test was carried out on the data in table 4.1 and achieved a level of significance (W= 3.5, <p.01).

Subjects	Collar	Standard
1	1	1
2	1	0
3	1	1
4	1	1
5	1	0
6	1	1
7	1	1
8	1	0
9	1	0
10	1	0
11	1	0
12	1	0
	12	5

Table 4.4: Results of the 3D touch test

4.5.2.4 Discussion

This test indicated conclusively that tactile coding enabled participants to make the correct drug selections. No errors were made during the selection which accords with the findings of Sanders and McCormick (1993). The test also demonstrated that the 3D features could be easily learned. Further testing could be carried out to establish how long people are able to retain the information and the number of symbols they are able to remember before they suffer decrements

in performance. Similarly the effects of stress whilst making selections may have an influence on how well individuals are able to perform.

Since the participants were able to effectively use the tactile cues to help identify drug categories, when used in conjunction with the labels the tactile features are likely to increase noticeability of the drugs. Given the success of this trial, judged by the ease with which participants learned to recognise the meaning of the shapes, there is scope for further development of the principle to include other categories of drugs.

The 2-dimensional images on which the tactile features were based were not so readily recognised. This may have been due to general lack of the participants' knowledge of drugs. The use of icons was intended to increase conspicuity of the packaging as outlined in the SHERPA table in chapter 2 and to provide an additional source of information (drug category) on the drug package. It was therefore decided to generate more icons in the hope that these would prove more meaningful imagery.

CHAPTER 5

Designing and testing icons

5.1 GENERAL POINTS

There was poor recognition of the original icons illustrated in chapter 3. It was hoped that using some of the principles outlined in chapter 4 would produce icons that were both noticeable and meaningful. It was, therefore, decided to generate further icons for testing using the model outlined by Zwaga and Easterby (1984) and illustrated in Figure 6.1. Within the context of public information symbols, the first part of the procedure, the production test, should be undertaken by users of the facilities. These individuals might be limited by their drawing ability therefore in the present study the decision was made to use designers to create symbols as they would be able to produce high quality, representative drawings and were likely to be able to produce several designs in a short period of time. To be considered successful the drawings would have to be tested for appropriateness (how well they fitted the context) and recognisability/comprehension. In this study comprehension – the degree to which the respondent understands the meaning of the symbol - would be more important than recognisability (i.e. the respondent has perceived it before), since the symbols would be created for specifically for the novel purpose of assisting in the identification of identifying medication categories.

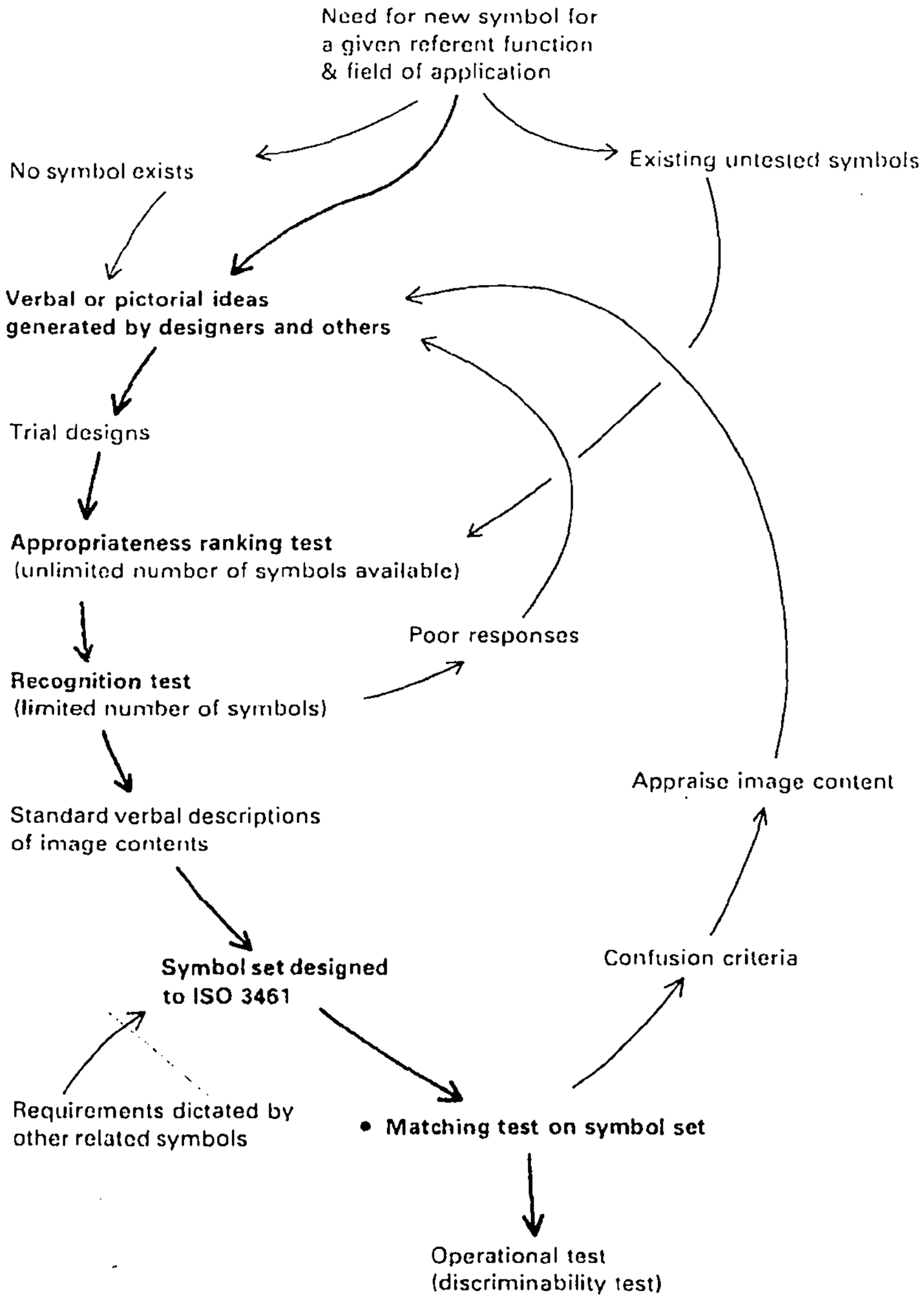


Figure.5.1: ISO procedure for the development of public information symbols Zwaga and Easterby (1984)

5.2 THE DESIGN WORKSHOP

5.2.1 Participants and procedure

Postgraduate designers from the School of Engineering and Design at Brunel University were invited to a one-day workshop for which they were paid £5 and given lunch. Six people attended, having been told previously that the purpose of

the workshop was to design logos for drug packaging. Three of the attendees were postgraduate students with professional design experience and the other three where undergraduate design students. There were three main strands to the workshop. The first part involved the author providing an outline of the research to date in order to provide some context for the task that the designers were to undertake. The second strand was centred on producing drawings representing drug categories, whilst the third area of focus revolved around discussing the drawings and ranking them in order of appropriateness.

The issues surrounding drug packaging design were expounded. The designers were shown examples of existing packaging highlighting factors such as branding, the use of colour, the lack of differentiation between some of the packages and the use of logos. Graphic images, where used, tended to be abstract as shown in figure 5.2 in the case of the imodium package. They also tended to highlight the manufacturer's name or were used to reinforce the brand name of the drug. Whilst the packages demonstrated bold use of colour, this was not done in a systematic way as pointed out in Chapter 4. Figure 5.3 shows the packages of two different generic drugs distributed by the same company. The colours used are quite distinctive but vary only slightly. The strength of the drugs is displayed prominently and is highlighted in both instances by a colour panel. The

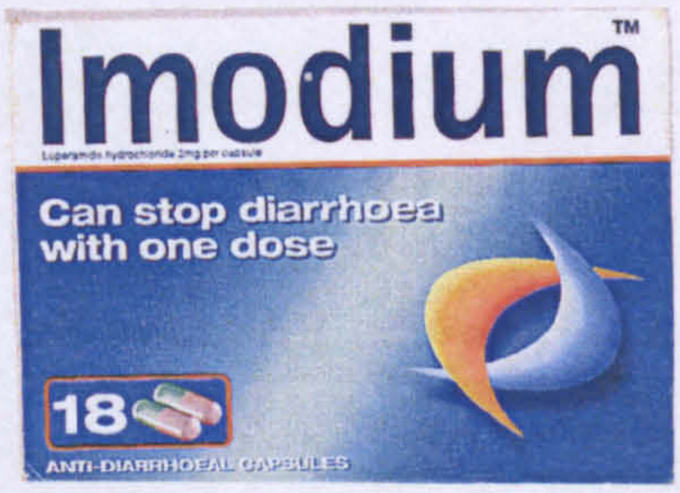


Figure 5.2: An example illustrating the use of imagery on packaging

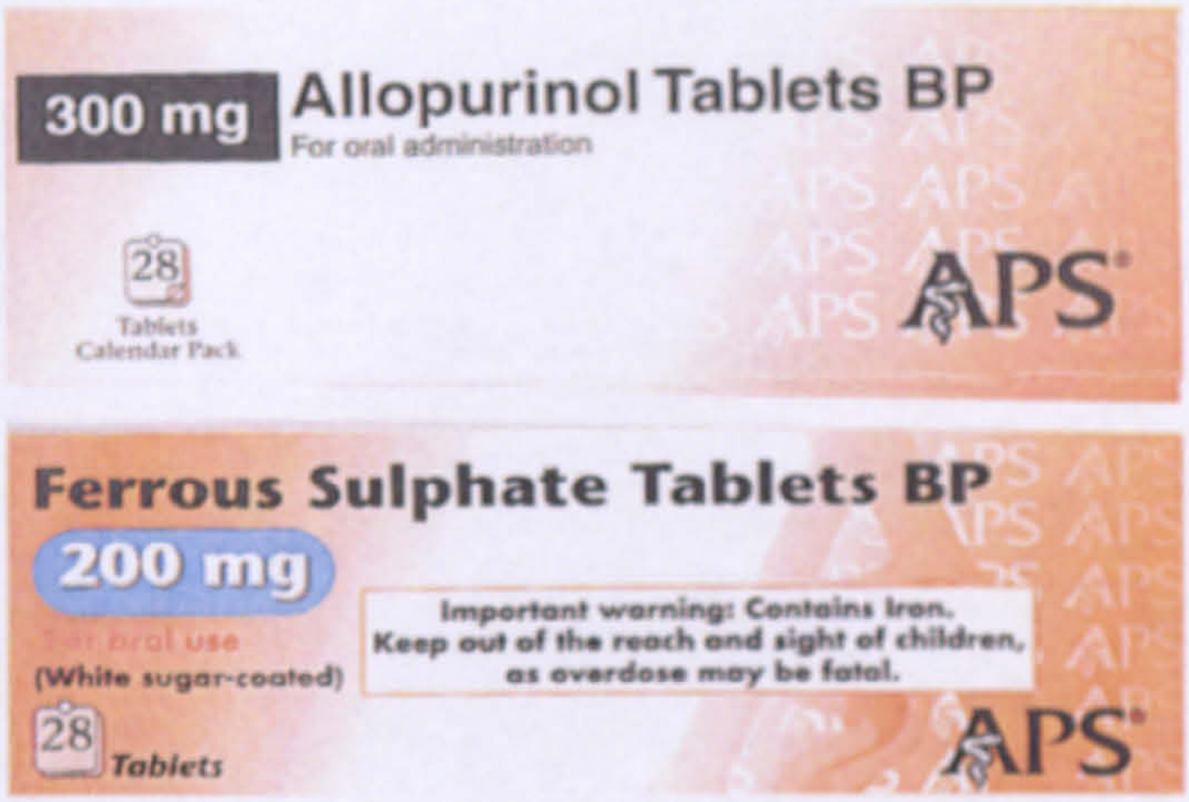


Figure 5.3: Examples of drugs from different categories in similar coloured packaging

manufacturer's logo (the letters APS incorporating the snake) also features. Significantly, when looking at these packages, one of the designers admitted that initially he could not see the difference between the two drugs. His experience emphatically demonstrated the potential for a selection error. It was also pointed out that large amounts of the package space could be used to provide information to assist the task of selection. In the case of ferrous sulphate the manufacturer has used the available space to add a warning to the front of the package.

The designers were shown examples of safety signage and icons from ISO 7001:1990 (the specification for public information symbols) and BS 8501:2002 which contains extensive examples of public information signs. They were advised to try to make the lines of their icons as bold as possible. The designers were then instructed to look at the list of drug categories shown in appendix A, and to select three items from the list to represent. The aim of the workshop was to generate as many drawings as possible from the list of drug categories in appendix A. Using

the descriptions given for the categories the task was to generate icons that reflected aspects of the descriptive paragraph.

The designers worked in two pairs and as a single individual. One designer was forced to leave the workshop to fulfil competing commitments. The remaining designers produced drawings as part of a process of collaborative discussion. First reading through the descriptors of the three categories they had collected (three categories between two). They tried to distil the description into a representative word either by selecting a word or group of words from the paragraph on which to hinge their idea or by thinking of a word that encapsulated the main aspect of the description.

The drug groupings selected were:

- Anticoagulants
- Analgesics
- Anticonvulsants
- Sleeping drugs
- Expectorants
- Vitamins
- Muscle relaxants
- Immunosuppressives

A key feature of the session was the informality with which the designers worked whilst discussing their ideas with each other and with the author. They were free to move about the room and refreshments were available throughout the session. After approximately two hours of drawing and discussion several icons were produced for anticoagulants, analgesics, sleeping drugs, and expectorants. Icons were also produced for muscle relaxants, vitamins and immunosuppressives.

During the drawing phase of the session it was evident that the designers found the task of representing drug categories challenging. One of the main issues that arose out of the drawing session was how to represent an abstract idea in a drawing. However this has been achieved in the domain of public information, consumer products and safety warnings so there was no reason to doubt the success of the process in this case. One designer commented that the design forms he had produced were 'wrong.' Some referents such as expectorants and sedatives, generated as many as 13 icons. This might be taken as indication of how readily these categories lend themselves to representation. But a more likely explanation is that the designers had well-developed cognitive schema for these types of drugs and were able to call upon these in producing the drawings.

All the drawings that were considered acceptable were grouped into their respective drug categories by cutting them from the sheets of paper on which they had been drawn and sticking them onto the relevant sheet of flip chart paper which had been laid out on tables. Intriguingly, this activity revealed how the designers thinking had been directed towards aspects of the descriptors for the categories such that, sleeping drugs became 'sleep', expectorants became 'coughing', anticoagulants became 'clotting' and analgesics became 'painkillers'.

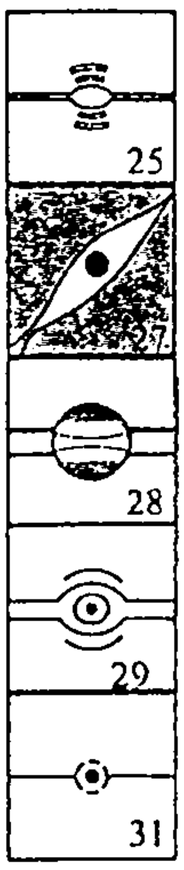
5.2.2 Explaining the conceptual ideas behind the icons

5.2.2.1 *The process of choosing*

There are different definitions for the graphical representations pictograms, symbols, icons and icons but for ease of discussion in the present study these terms will be used interchangeably to mean the same thing.

There were two rounds of discussion during which the 5 designers and the author took part. The purpose of the first round of discussions was to give all five of the creator designers the opportunity to explain the reasoning behind their designs and to allow their colleagues to comment on the drawings whilst the author took notes and asked for clarification when necessary.

The second set of discussions progressed with the three professional designers as the undergraduates were unable to devote any more time to the project at that time. It was during the second round of discussion that the final designs for the referents were chosen. For ease of discussion the standardised versions of the drawings are shown in figure 5.4 and some of the rough drawings and the drawings put forward for assessment but later rejected are shown in appendix G.



5.2.2.2 *Anticoagulants*

Central to this group of symbols was the notion of blockage which was represented by a circle that was shaded in some cases. Icons 28 and 29 and to a lesser extent icons 25 and 31 introduce the idea of the vein as a blocked tube. The designers were aware that their symbols signified the opposite of the descriptive passage and admitted this was because the idea of 'blockage' was more easily conveyed than 'blockage released'. For instance, the arrow in icon 31 was described as '*pointing at the problem'*. Another reason for the difficulties experienced was that the referent had been simplified to clotting which put a different emphasis on the concept. Icon 27 was described as being: '*a stylised version of a vessel with something open in the middle.*' The depiction of free-flow is shown in figure G.3

(A and B) in appendix G and in the same figure the idea of a blockage being broken (C and D) is illustrated but these icons were not submitted for consideration. It did occur to the designers that icon 26 (figure 5.5) was similar in appearance to the ISO symbol for meeting point (figure 5.6) and therefore was not included among the icons put forward for appropriateness testing.

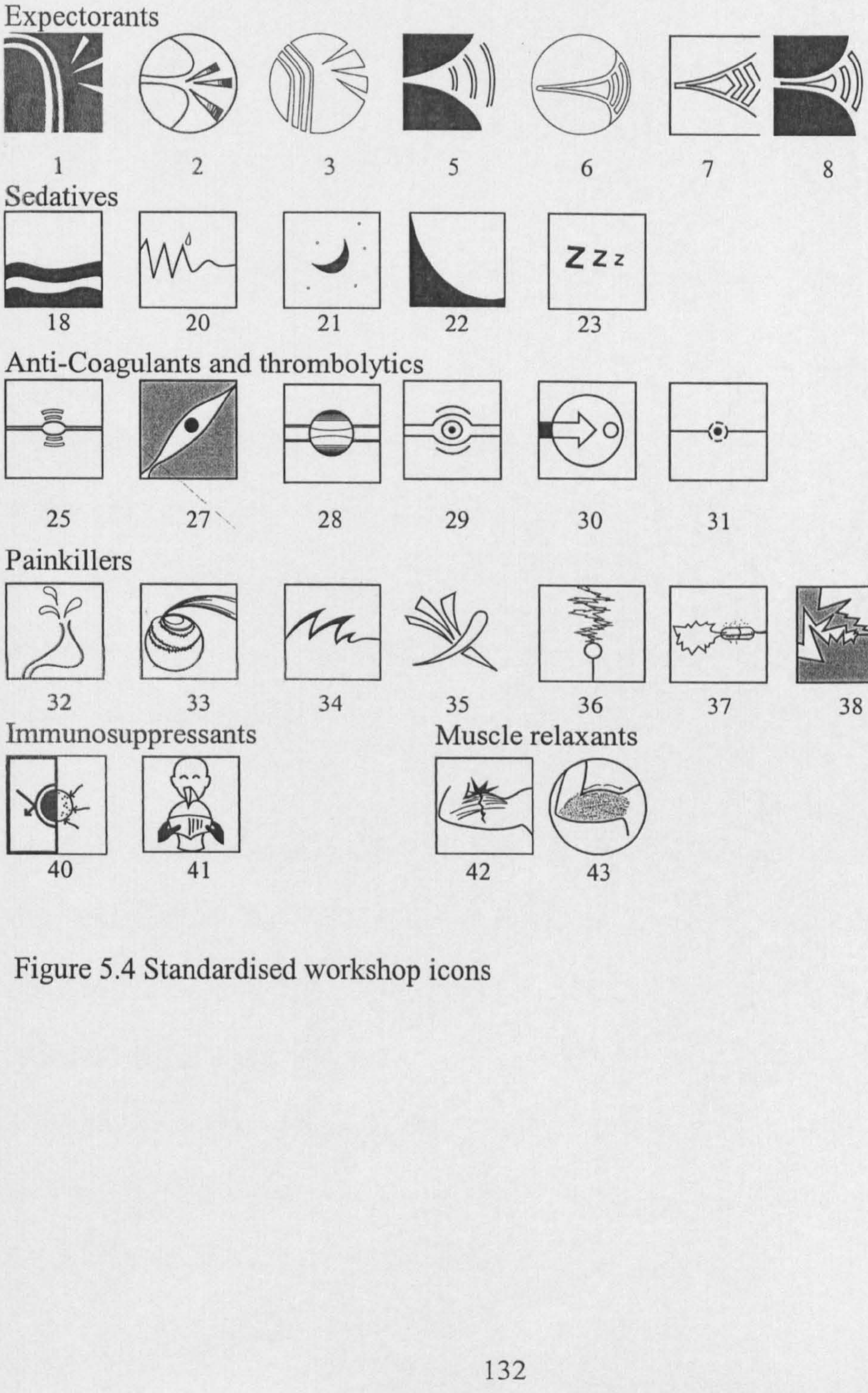


Figure 5.4 Standardised workshop icons

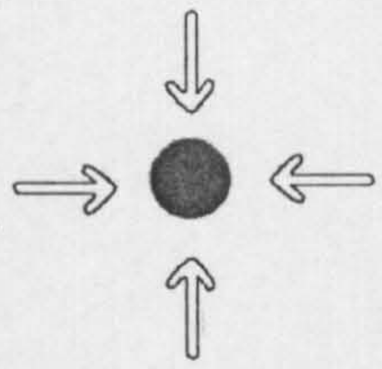


Figure 5.5: Anticoagulant icon 26 (rejected)

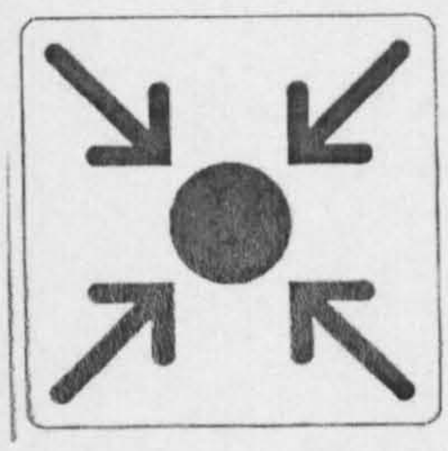
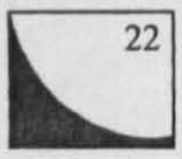


Figure 5.6: ISO symbol 7050 for the referent meeting point

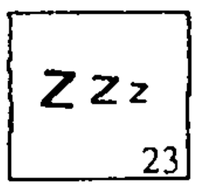
5.2.2.3 *Sedatives*

The idea of sedation was symbolised by gentle undulations in icon 18 (figure 5.4), which was intended to invoke comparisons with calm water as a metaphor for a state of tranquillity and repose. The bottom part of this icon was thought of as conveying the idea of relaxation, as the icon designer remarked: '*Things at the bottom are more relaxed*'.

Icon 20 was based on the notion of hospital monitoring machines used to measure vital signs such as heart rate and blood pressure. Though it was commented upon that sleep is not normally measured like this. The peaks and troughs represented alertness which was interrupted by the introduction of the medicine (depicted as the drop) which induces sleep as indicated by the near flat line of the display. Icon 22 also depicted movement from a state of alertness towards sedation. In this icon the key feature was the contrast between the high and the low point.



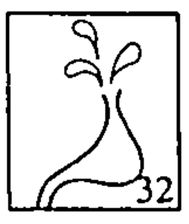
The moon was instantly recognizable in icon 21 (see also appendix G, figure G.1) but was considered by the designers as potentially frivolous given the serious nature of the task. They felt the icons had nursery connotations and a similar criticism was levelled at the rejected icons (shown in item 24 appendix G, figure G.1). This was felt to be particularly the case for those images portraying clouds as seen through a bedroom window.



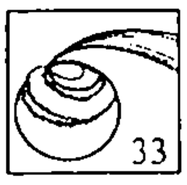
Icon 23, though considered frivolous, was not rejected. The icon commonly signifies sleep in cartoons and comic books and for that reason was deemed to be instantly recognisable. Nevertheless, doubts about its suitability were expressed in terms of how well it would be accepted within the present context. Two of the designers were Korean nationals and pointed out that the moon is not an icon traditionally associated with sleep in Korea. However many Koreans have learned to recognise it and attach the correct connotation to the symbol through the influence of western media.

5.2.2.4 *Painkillers*

Although readily selected by one of the designers, this category was difficult to represent, with only four icons originally put forward into the general pool for



consideration. It was difficult to convey the notion of relief. Icon 32 was created to represent a non-descript 'bag' of discomfort on the verge of an explosion. The drops above it were intended to convey the action of the medication.



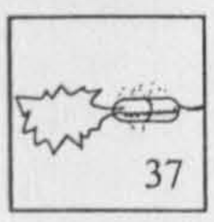
Icon 33 was a representation of a blue spherical object with its outer red layer, signifying pain being stripped away. Red was chosen to convey the intensity of pain whilst blue represented the calmness of relieved pain. Interestingly, many existing analgesic packages incorporate a circle as part of their iconography.

The jagged waves of pain were depicted in icon 34 with the shading emphasising the intensity and the crest of the waves indicating its rising and advancing nature.

Icon 35 is based on the Chinese characteristic for the whole person. The element in the bottom left/top right orientation representing the drug breaking the pain which is the dominant element and represented by the character underneath in the top left/bottom right orientation. This was depicted as being 'split.'

Discussions about how to represent pain dominated the second round of discussions. This was because although the designers agreed that it was possible to signify pain in drawings, the situation became more complex when attempting to convey the relief of such an abstract entity. Part of the difficulty was attributed to the fact that we tend to think of pain as associated with parts of the body, that is headache, stomach ache, toothache, arthritis and so on.

As there were only four icons for this category, it was felt that more icons would be better for appropriateness testing. Thus, in a short 10-minute brainstorming session the remaining three designers were asked to quickly create more icons without too much regard for form or structure. One designer, intending to emphasise a soothing effect of the medication drew a pair of pictures; one depicting a clenched



fist with shards of pain escaping from it whilst the second picture showed a soothing open hand was drawn (appendix G, figure G5 (B)). The images were considered tenuous and were not put forward for assessment. Icons 36, 37 and 38 resulted from the doodles shown in (appendix G, figures G.4 and G.5). Icon 37 represented the drug as a bullet smashing through pain. This was considered ironic by the designers as bullets predominantly have the opposite effect. The jagged edges of icon 38 are illustrated as being broken by the action of the drug.

5.2.2.5 *Expectorants*

This category of drugs stimulates the flow of saliva thereby promoting coughing, however the coughing is essentially a secondary action produced by the drug and it was this that emerged as the main feature of the icons produced. Figure G.3 in appendix G shows the evolution of icons 1 and 3 which depict a cross-sectional view of the upper respiratory tract with an explosion of air outside the mouth. In the early drawings the profile of a nose helps the viewer identify the icon as a human head in cross section. With these drawings as a basis it is easy to recognise stylised versions of these concepts in the icons. The other icons are representations of expulsion of air from the mouth, again in cross section. In discussing these icons, the designers expressed the difficulty they experienced when attempting to depict air. They pointed out that the elements depicting the expulsion of air could equally be representations of sound. But since the production of sound is commonly represented by air movement, this might not be entirely unacceptable, as coughing is accompanied by sound.

5.2.2.6 *Muscle relaxants*


42

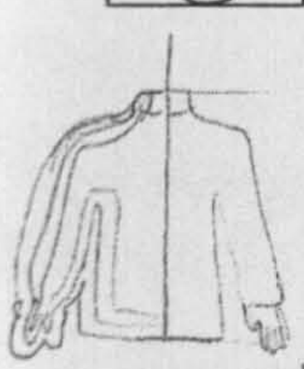

43

The muscle relaxant (icons 42 and 43) were considered ambiguous in that the imagery could represent a product that might be used to enhance physical strength or as a muscle builder. These depictions were drawn as pictograms and the designer was unable to think of a way to simplify the drawings. They were submitted to the final set of icons to see if they would be recognised. Icon 42 shows the muscle under strain whilst icon 43 indicates a relaxed muscle.

5.2.2.7 *Immunosuppressants*


40


41


IS3

Icon 40 depicts an object seen in cross-section that is vulnerable on its right side and under attack from an external source. The left side has a protective covering that acts as a defence. The rough drawings for icon 41 are shown in appendix G, figure G.6 and are based in the notion of lowered protection (represented by removing the armour). Icon IS2 was not selected for testing as it was felt to be too tenuous.

5.2.2.8 *Vitamins*


35

The symbol for vitamin (figure 5.7) was very similar to icon 35. Again it was based on Chinese symbolism. In Eastern tradition Man is believed to be inextricably tied to vitamins which are held to be his life-force and it is this belief that is represented in this symbol. The larger element on the left represents Man and the smaller element on the right is the vitamin. This drug category was perhaps the most difficult to represent and the designer who selected this referent was unable to produce further icons for vitamins. Interestingly, a logo was found

on the packaging of Boots effervescent vitamin C that incorporates the notion of protection depicted in the immunosuppressant icons discussed in paragraph 5.2.2.7. This is conveyed by the faint outline surrounding the representation of the human form (figure 5.8). Vitamin C is recommended as an aid to boost the immune system and is commonly held to act as a defence against colds and flu

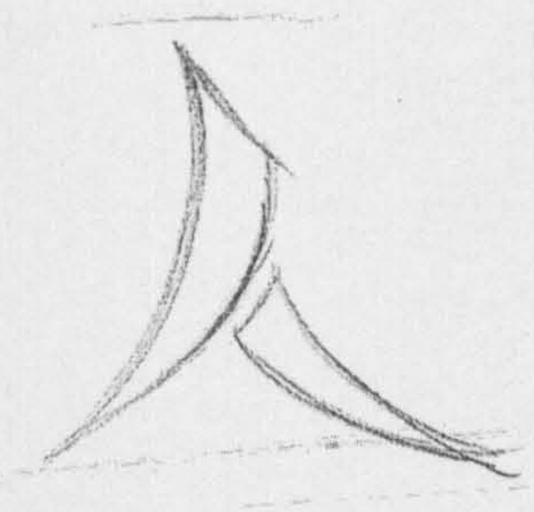


Figure 5.7: Chinese symbol for vitamin

Figure 5.8: Logo used on existing vitamin package

5.2.2.9 *The Anticonvulsant icon*

Another professional designer who was interested in the project and prepared to help with the designs but had been unable to attend the workshop looked at the designs and commented on the anticonvulsant icon. This was left as the original pictogram as there were no alternative designs for this category. The designer, D5, observed that although the picture told a story and did indicate the condition the drug would be used for, a symbolic representation would be more recognisable but would not give as much information about the drug grouping as the pictogram.

When asked what the pictogram in figure 5.9 might represent D5 remarked: '*it looked like someone having a fit'* and correctly identified the drug category as anticonvulsant, as the original designer had intended.

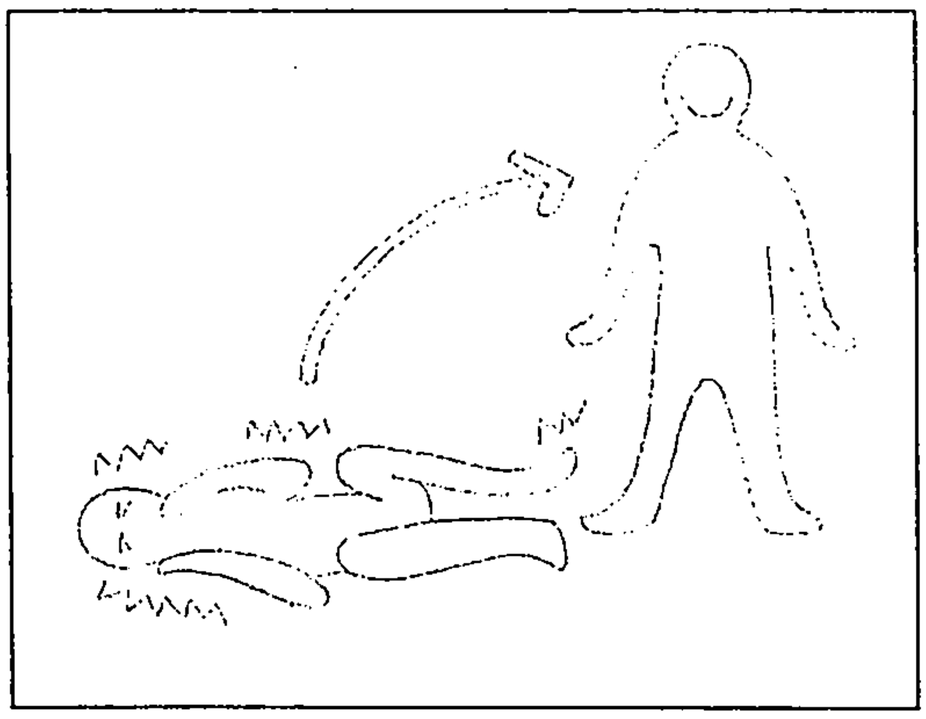


Figure 5.9: Anticonvulsant icon

5.2.3 The designers' assessments

Both pictograms and symbols were present in the drawings – as the designers pointed out there should be some consensus resolution. In order to resolve this conflict there needed to be a decision to use either pictograms or symbols and to adopt a single style so that the icons looked similar. Another pointed out that if people were to use the icons to cluster together pieces of information then in terms of cognitive processing their task would be made easier by the use of symbols as these tend to be simpler and therefore are more readily recalled. Similarly, designer D5 said that whilst a pictogram could convey more information than icons or symbols it would be easier for people to remember symbols.

What did become apparent among the professional designers was that they attempted to invent some kind of 'vocabulary' to express aspects of the drug categories and whilst this might have been more readily achieved in other domains

it was hampered in this context by their general lack of knowledge of drugs. The discussion frequently, though not unexpectedly, centred on their own experiences of over the counter (OTC) preparations. There was an impression that the symbols should have some kind of extrinsic meaning in the same way that the logos of international consumer brands evolved significance beyond their visual appearance. The example was given of the Nike 'swoosh' which was said to have become associated with perceptions of high quality and technical expertise. '*...These things are brought to mind by the appearance if the brand symbol,*' (D3). It was felt that a similar process should prevail in the case of medication icons.

Lin (1992) suggested that there are six important items and three cognitive factors of importance in the design and comprehensibility of icons. The important items are that the designs should be: associable, symbolic, meaningful, concise, eye-catching and identifiable. The cognitive factors are related to these and the first one, communicativeness comprises *identifiable* and *meaningful.* The second – design quality relates to *concise* and *eye-catching* and the third – icon function is linked to *associable* and *symbolic.*

After some time spent discussing the features of the designs and how best to represent the drug categories the designers were asked to rank the icons for appropriateness (to select the icon that they think best represented that drug category in terms of conveying information). One of the undergraduates from the first workshop session returned to do this and a professional designer (D5) who did not take part in the workshop agreed to assess the drawings. The results are shown in figures 5.10 – 5.13 and appendix I.

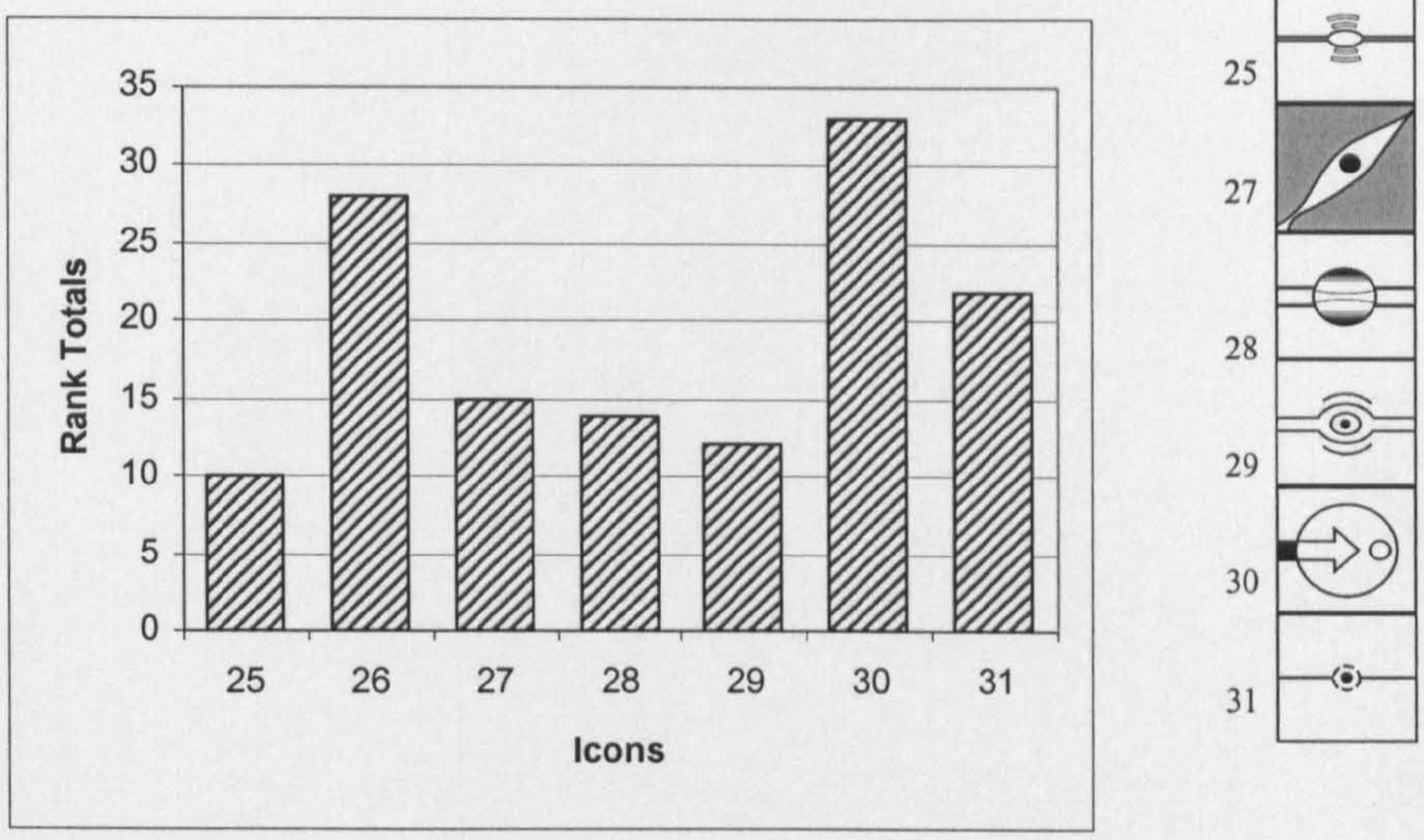


Figure 5.10: Designers' rank totals for anticoagulant icons
The lowest total represents the preferred icon.

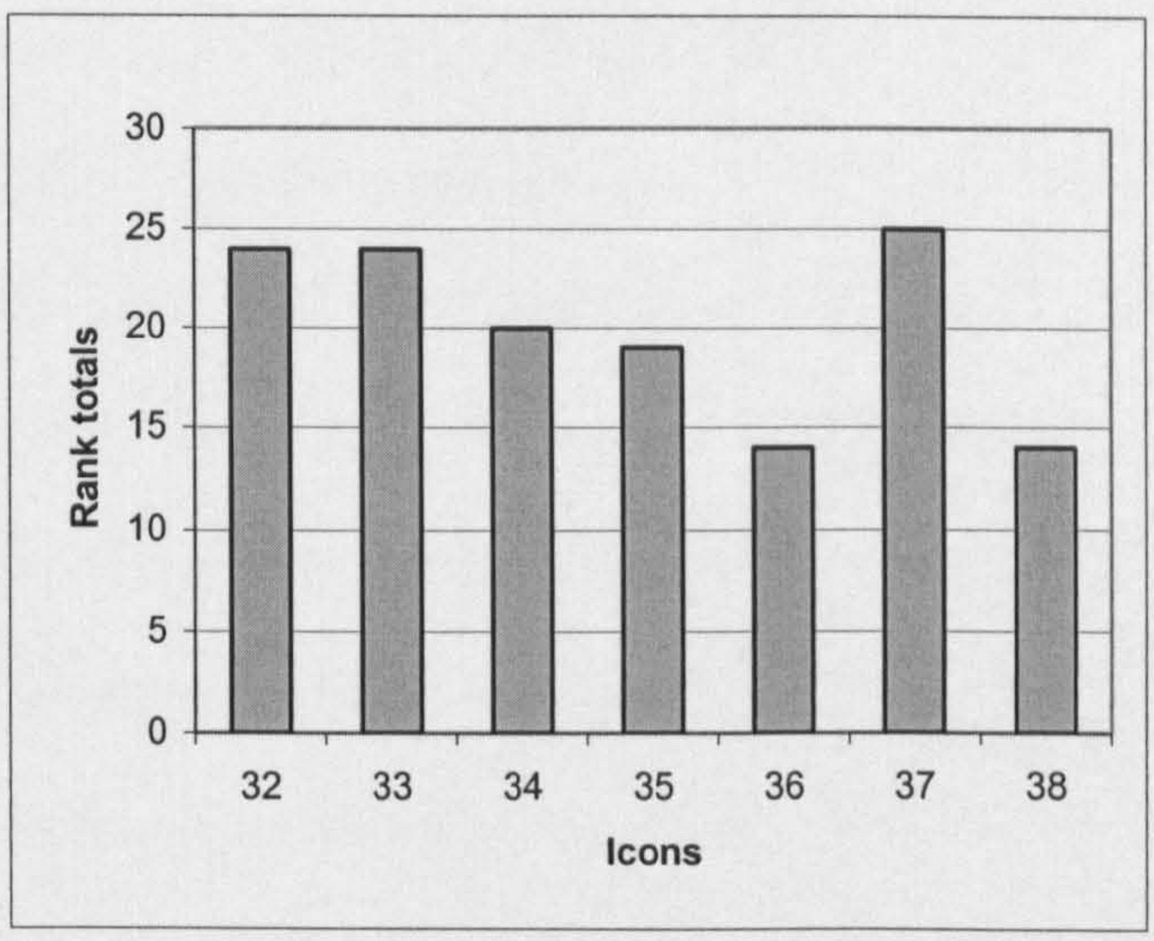
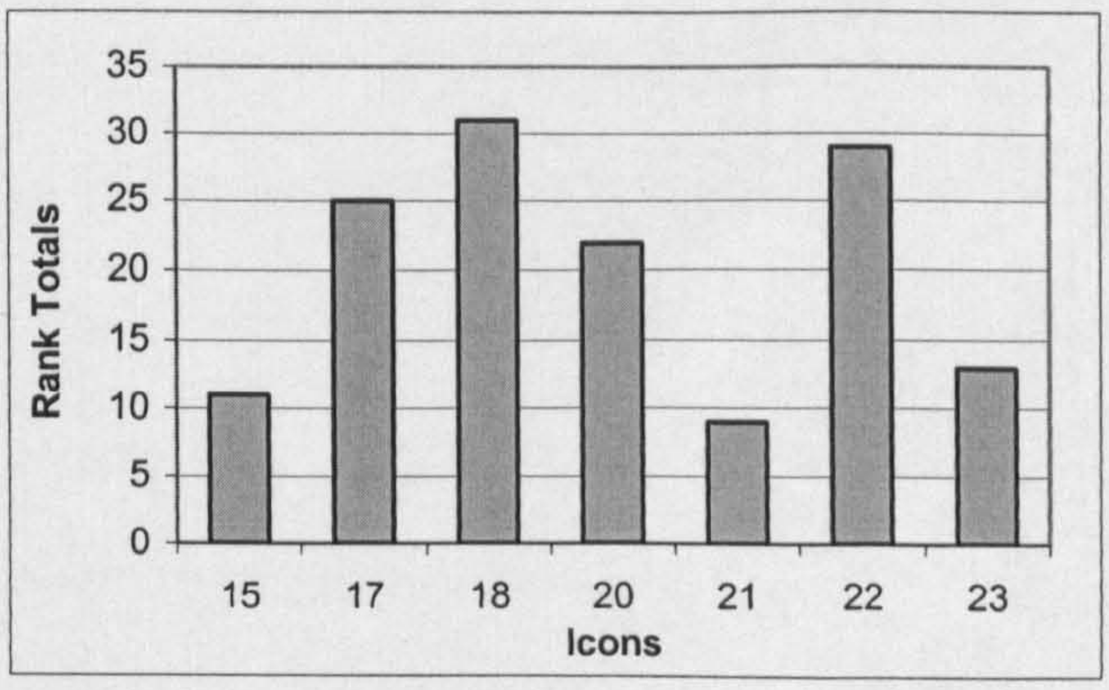


Figure 5.11: Designers' rank totals for painkiller icons



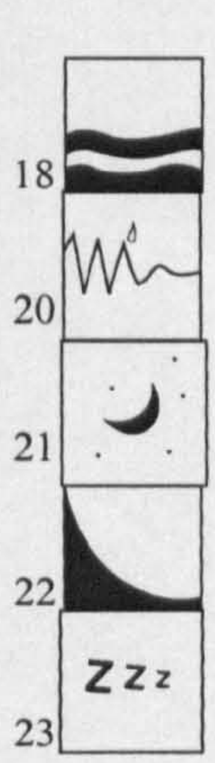


Figure 5.12: Designers' rank totals for sedative icons

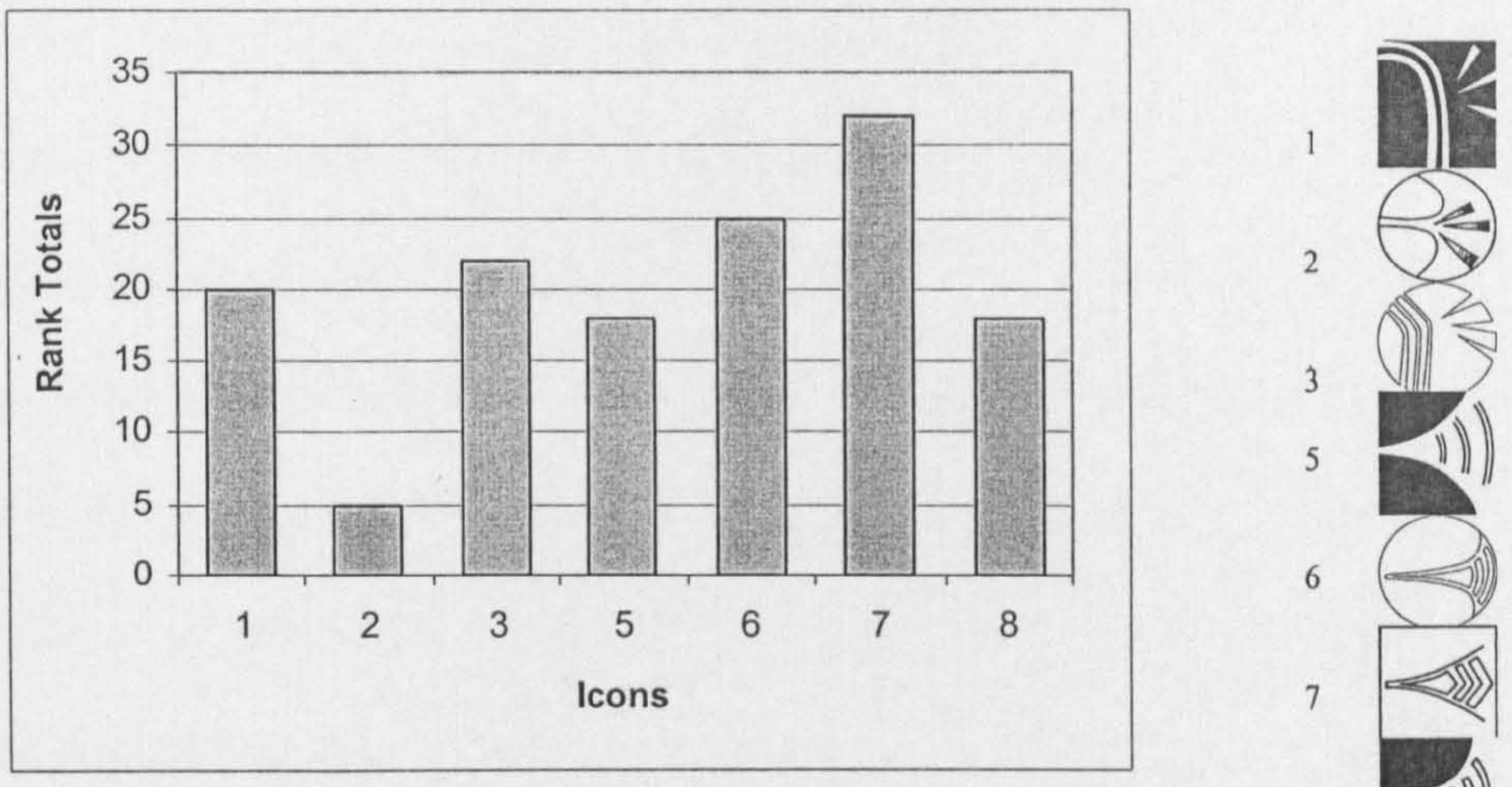


Figure 5.13: Designers' rank totals for expectorant icons

5.3 APPROPRIATENESS TESTING

5.3.1 Former Approaches

The next stage was to see how well the icons represented the referents and to test if people would be able to understand the meaning of the symbols. Many studies have used paper and pencil methods to evaluate symbols, as these are generally inexpensive and easy to administer. Dewar and Ells (1974) employed a series of studies to investigate the suitability of symbols. Their first procedure designed to test the comprehension of 70 symbolic traffic signs entailed using open-ended responses. Subjects were required to indicate the meaning of each symbol projected as coloured slides on a screen. A second technique involved a matching procedure in which subjects were required to indicate which of the three symbols represented a specific message. The third approach required subjects to choose the correct interpretation from a set of four meanings for a specific symbol. The results of these tests indicated general agreement across the three methods of measuring comprehension of symbols.

Symbols have also been evaluated by rating procedures, in which participants were asked to make a selection of which symbolic version of a message they think most adequately conveys that message. During this process participants may be required to select the symbol they like best, or they may be asked to rank the target symbols in order of preference. Yet another method might be to ask participants to rate the 'clarity of meaning' of symbols, to indicate how well symbols convey their intended meanings.

Easterby and Zwaga (1976) in an evaluation of public information symbols, used a rank ordering technique to select three versions of each of several messages for further testing by the recognition/comprehension and matching procedures. The preferred symbols were then tested for comprehensibility with a new set of participants. The symbol was deemed acceptable if it was identified correctly by 50% or more of the participants (ISO, 9186: 2001).

5.3.2. Methodology

A total of sixty participants were selected at random from among the undergraduate and postgraduate students and staff at Brunel University. Several staff members at Farnborough College of Technology also took part and were given the assessment sheet shown in appendix H.

Participants were asked for their verbal consent and the purpose of the task was explained to each participant individually; namely, that it formed an assessment of part of a PhD thesis regarding assessment of a set of icons that might be suitable for use on drug packaging and that their task was to rank the icons in order of how well they thought the pictures fitted the given description of types of medication.

Most of the assessment sheets were completed in the presence of the author and participants were given clarification of the task if this was requested. However there were several instances in which participants were unable to complete the sheet at that time and these individuals were directed to return the form using the internal post. Only one assessment sheet was returned by this method and one by email.

5.3.3 Results

Of the 60 forms given out 50 were returned and two were discarded because one had been partially completed and the other contained tied ranks. The demographic analysis of the remaining 48 participants revealed a mean age of 26.76 years with a standard deviation of 10.05 .The minimum age was 18 years and the maximum was 52 years. Although randomly selected, 31 males and 17 females took part.

The results are summarised in figures 5.14 – 5.17. The lowest total represents the more favourably ranked icons, thus if all participants ranked an icon in first place it would obtain a maximum total of 48.

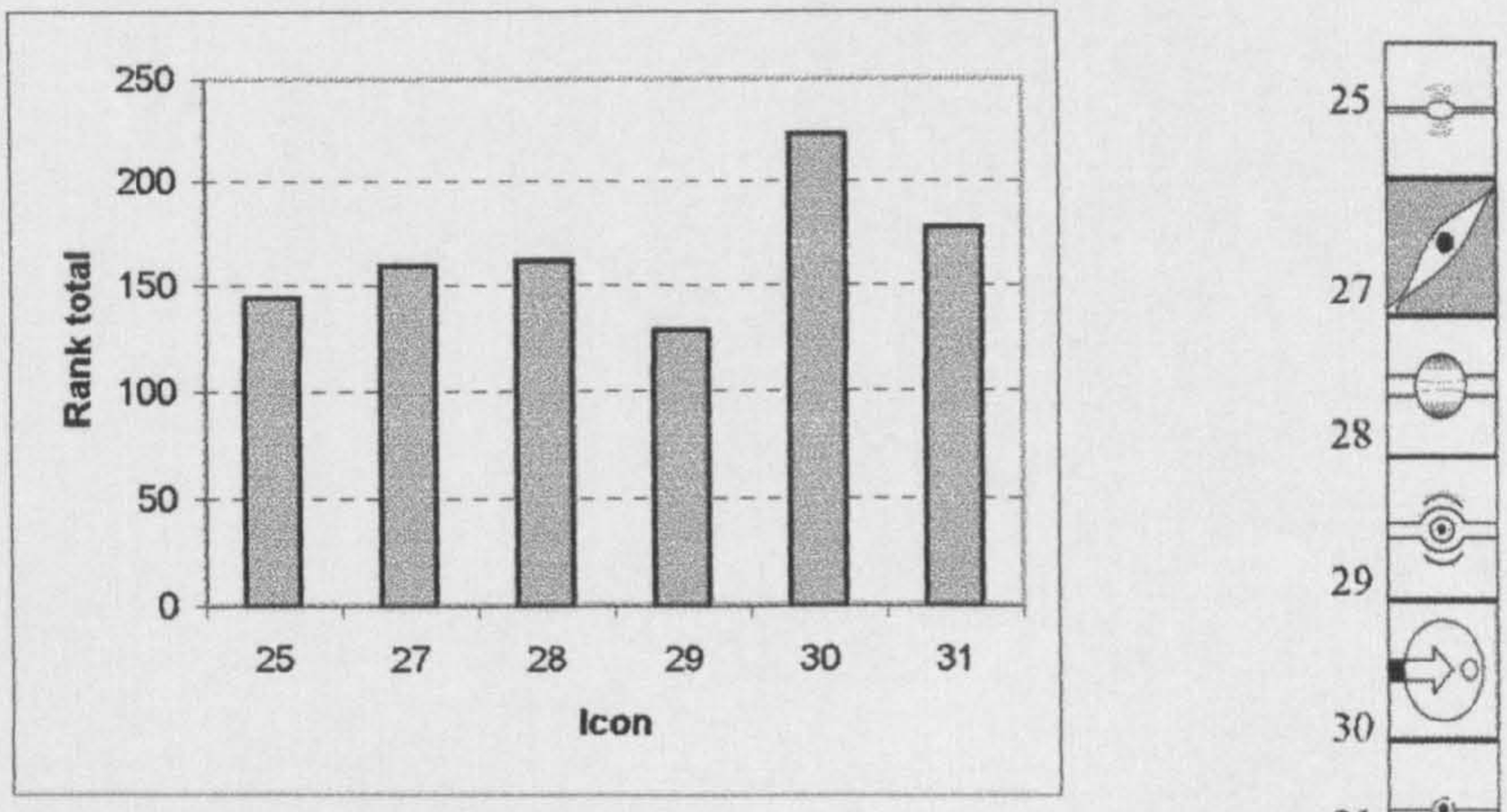


Figure 5.14: Appropriateness ranking of anticoagulant icons by the experimental group (n=48)

Figure 5.15: Appropriateness ranking of sedative icons by the experimental group (n=48)

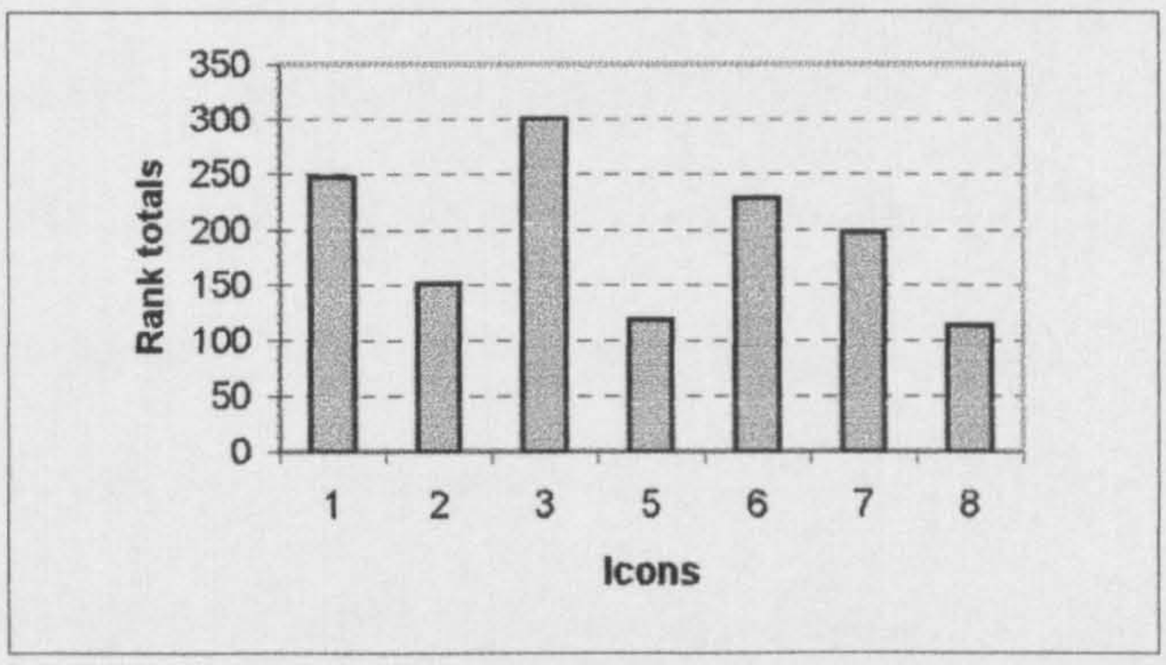


Figure 5.16: Appropriateness ranking of expectorant icons by the experimental group (n=48)

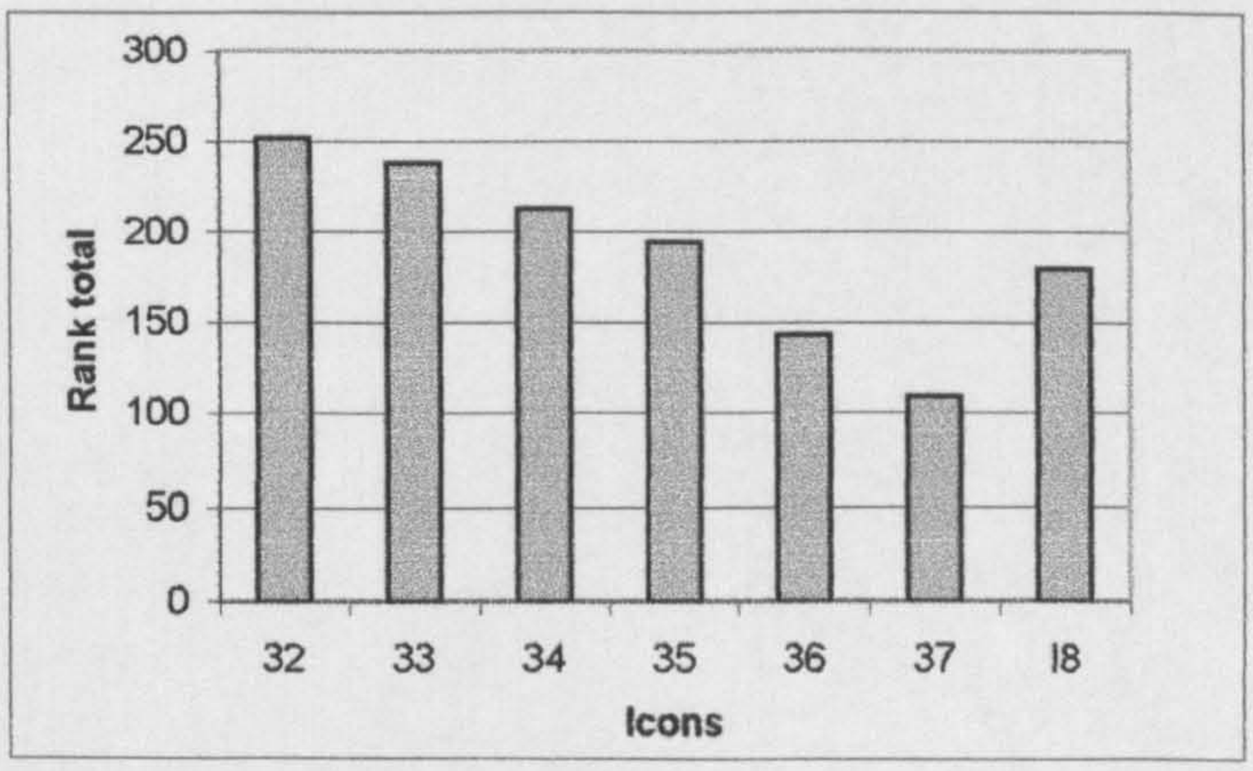
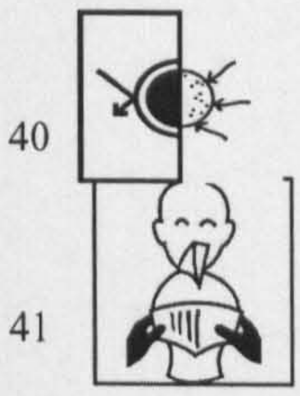


Figure 5.17: Appropriateness ranking of painkiller icons by the experimental group (n=48)

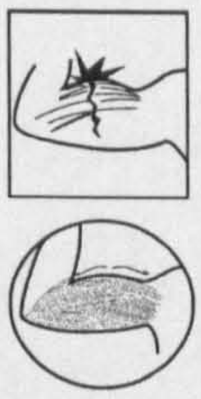
the experimental group (n=48)



87.5% (42)

12.5% (6)

Figure 5.18 Preference for immuno-suppressant icons



75% (36)

25% (12)

Figure 5.19 Preference for muscle relaxant icons

Appendix I shows the ranks assigned by each participant to the icons listed by category. The degree of agreement between the participant rankings reflects itself in the variation of the rank sums. In the case of maximum disagreement the rank sums will be equal or thereabouts. It is this circumstance that provides the basis for the definition of a coefficient of concordance. Kendall's Coefficient of concordance (W) was carried out to determine the variance within each of the categories expectorants, painkillers, anticoagulants, and sedatives. The concordance among the sets of ranks may be described by calculating Spearman's rank-order coefficient (Ferguson and Takane,1989). Both sets of results are given in table 5.1.

Referent	**W**	$\overline{\rho}$
Anticoagulants	0.134	0.118
Expectorants	0.456	0.454
Painkillers	0.241	0.230
Sedatives	0.630	0.635

Table 5.1: Kendall's Coefficient of concordance (W) converted to Spearman's Rho ($\overline{\rho}$)

A chi square test was carried out to test the value of W using the formula:

$$X^2 = N(k - 1)W$$

Sedatives: $X^2 = 48(5\text{-}1)0.63 = 120.96$

Expectorants: $X^2 = 48(7\text{-}1)0.456 = 131.28$

Painkillers: $X^2 = 48(7\text{-}1)0.63 = 69.4$

Anticoagulants: $X^2 = 48(6\text{-}1)0.134 = 32.16$

The values obtained were significant for sedatives df_{47}, $p < 0.001$, expectorants df_{47}, $p < 0.001$ and painkillers df_{47}, $p < 0.005$ indicating that there was significant agreement among the participants with regard to these icons but not for painkillers.

Kendall's Coefficient of concordance was carried out on the data as recommended by Ferguson and Takane (1989). A Friedman test would have been equally applicable to this type of data. The test looks for variance in the ranked column totals, an indication of bias towards one particular design. This was observed for sedatives : W= 0.63 but less so for expectorants: W= 0.46, painkillers: W= 0.24 and sedatives: W= 0.13. If all the participants were in perfect agreement on the degree to which the icons represented the category they would rank the icons in the same order and the value of W would be 1. Inability to agree that any of the icons were appropriate indicators of their category would yield a W value of zero. The values obtained indicate that there was a good level of agreement for sedatives and that the designs ranked lowest (those ranked in first or second place) were considered the most appropriate. There was less agreement of the placing of the icons in the other groups, an indication that the participants' choices were not directed towards any particular design.

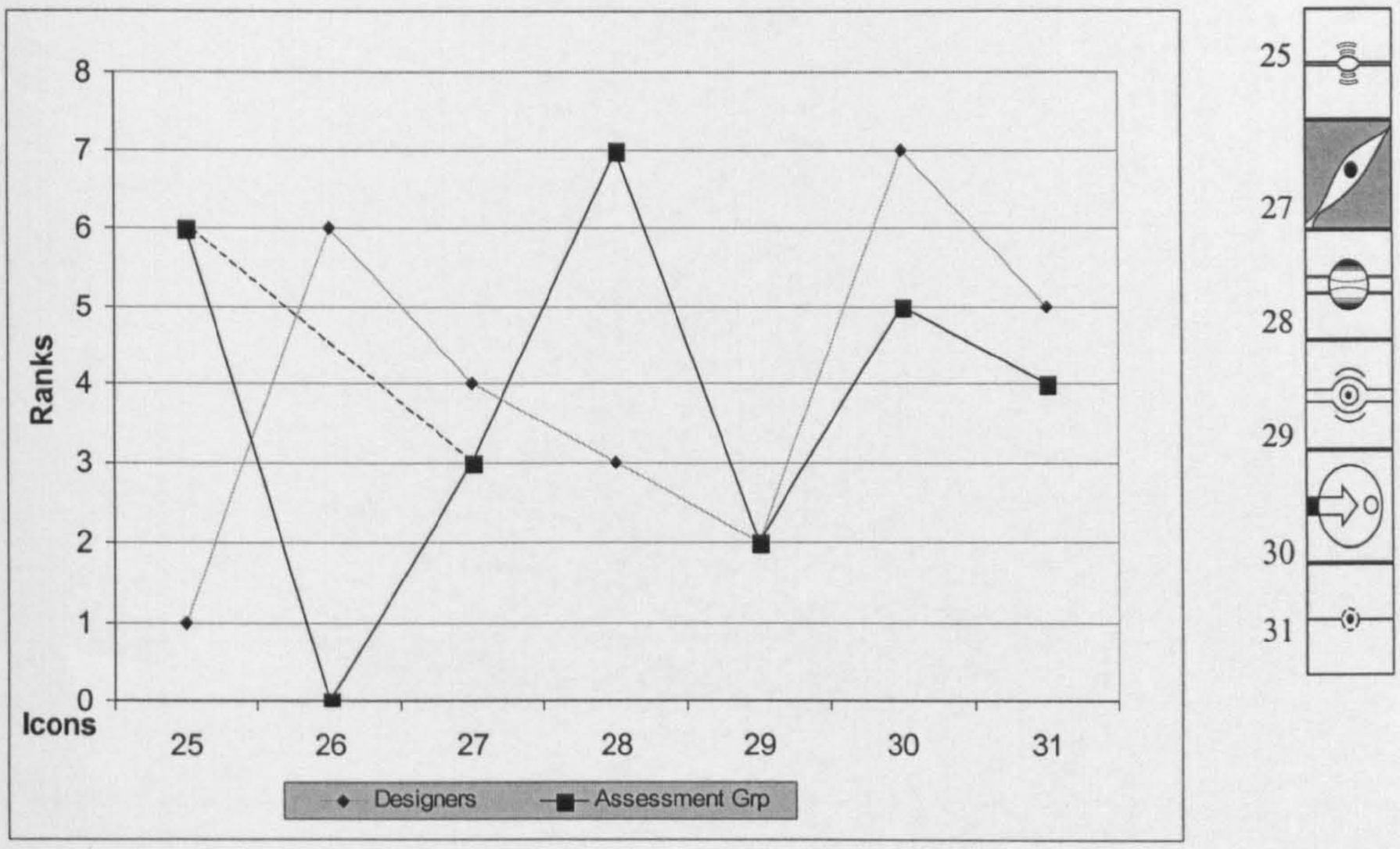


Figure 5.20:Comparison of median values for anticoagulant icons
Zero value due to icon 26 not being submitted for assessment. Dotted line indicates the adjusted plot line

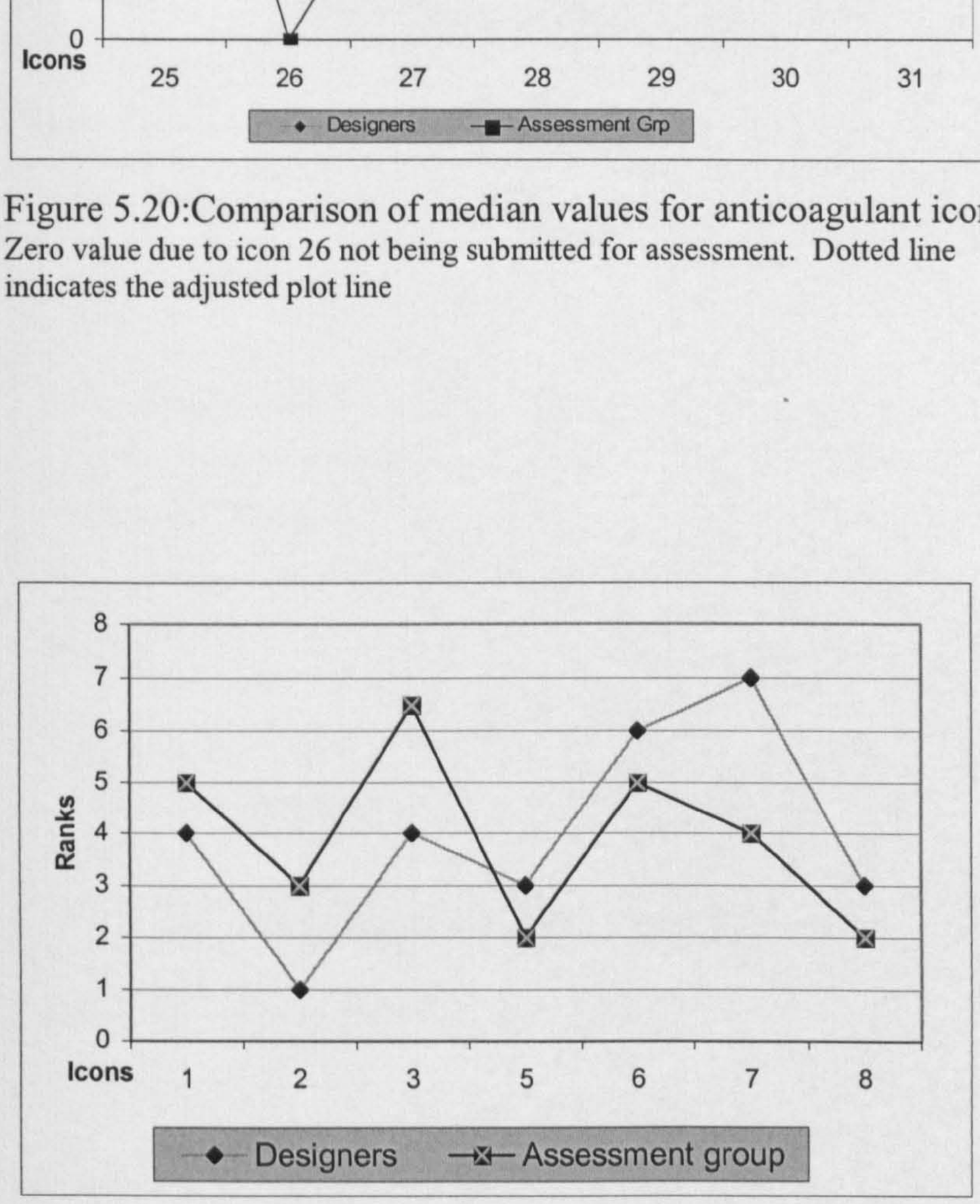


Figure 5.21: Comparison of median values for expectorant icons

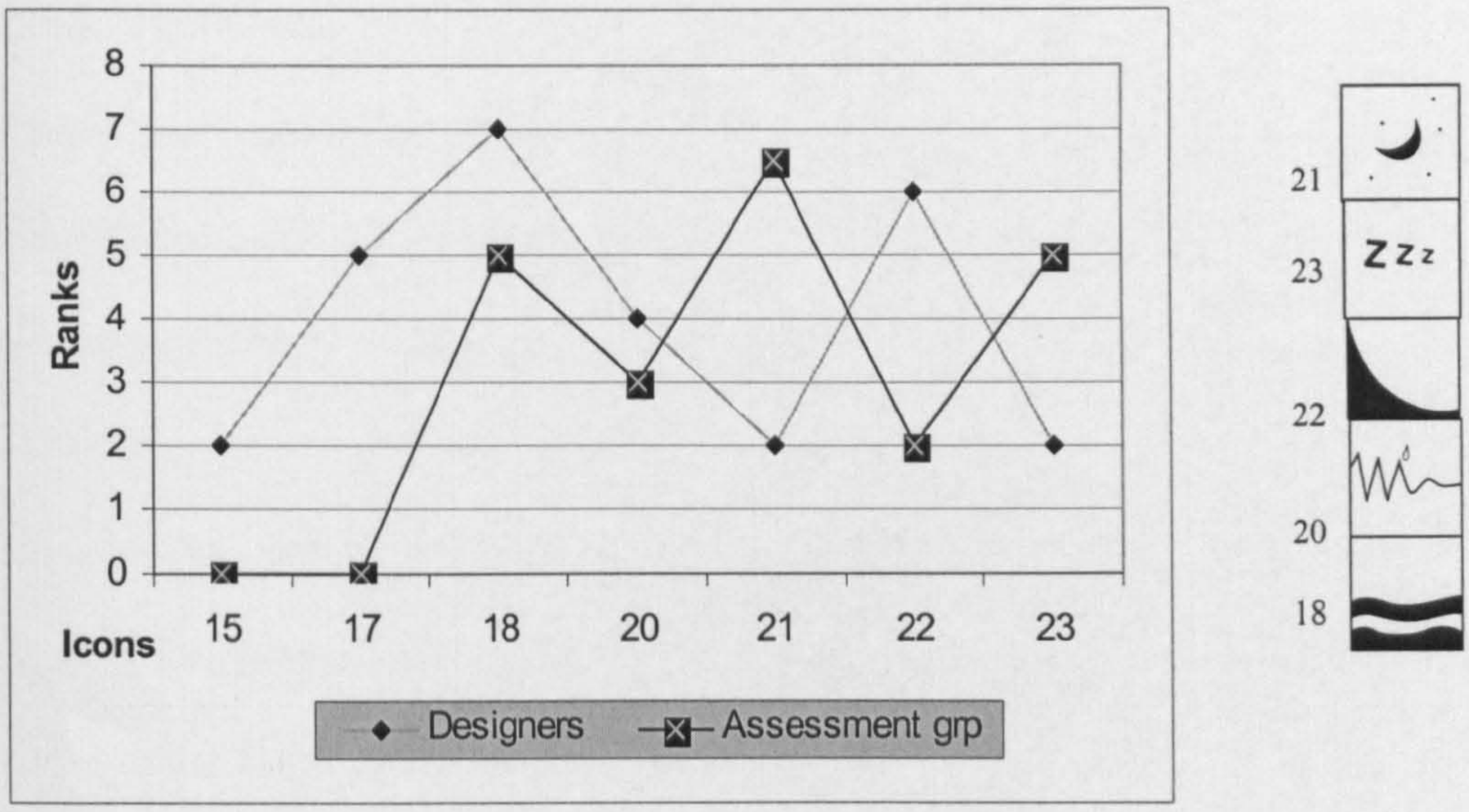
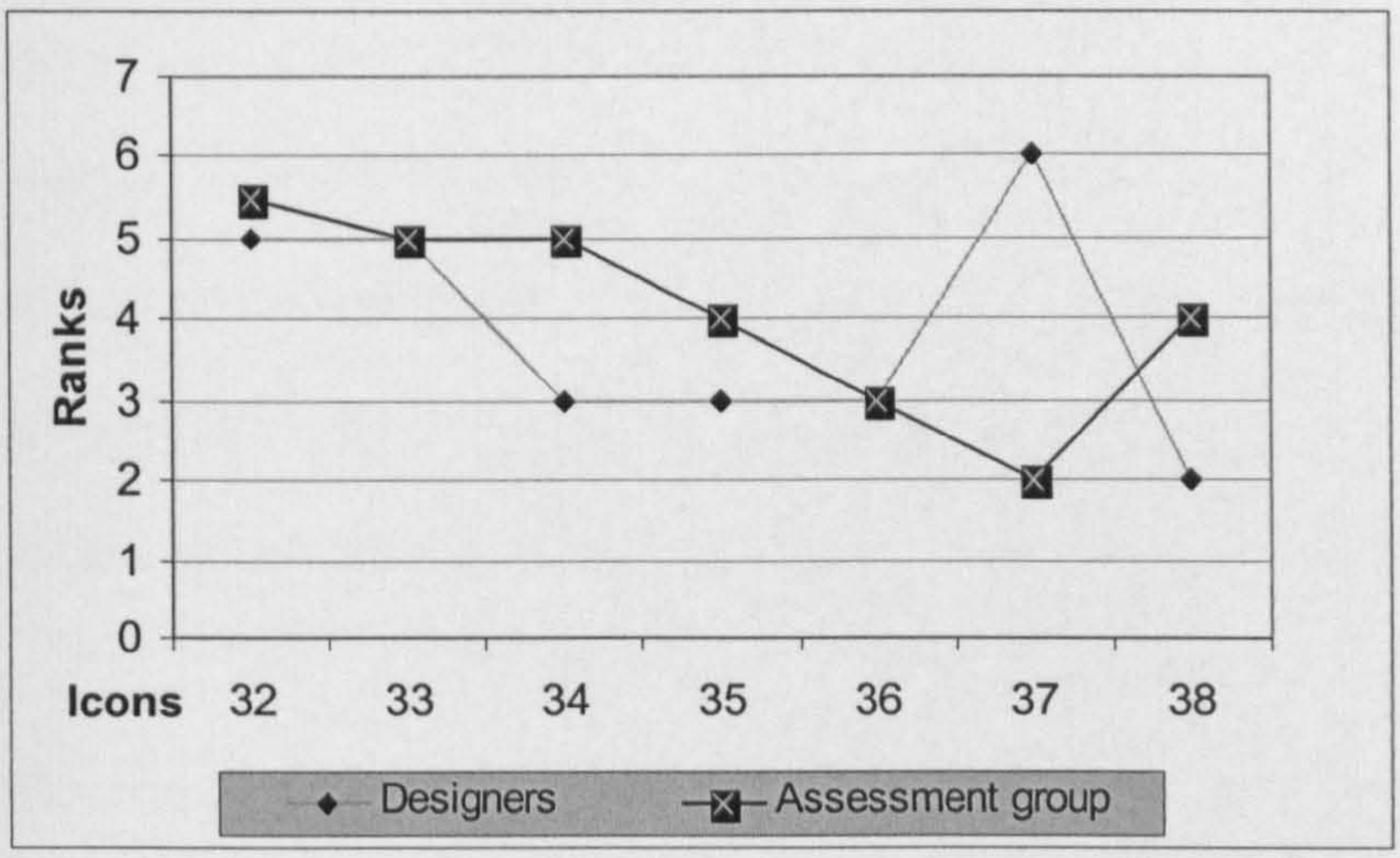


Figure 5.22: Comparison of median values for sedative icons
Zero values recorded because icons 15 and 17 were not submitted for assessment ranking



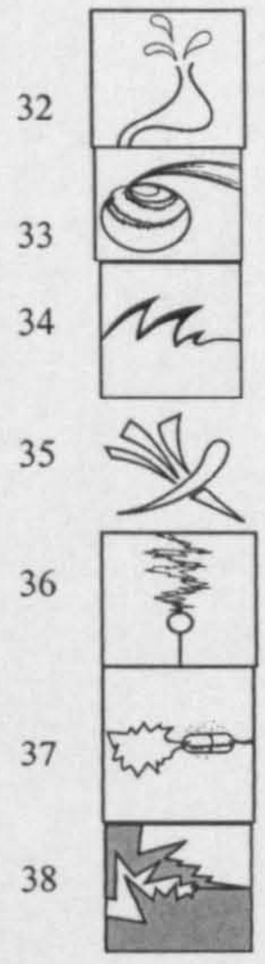
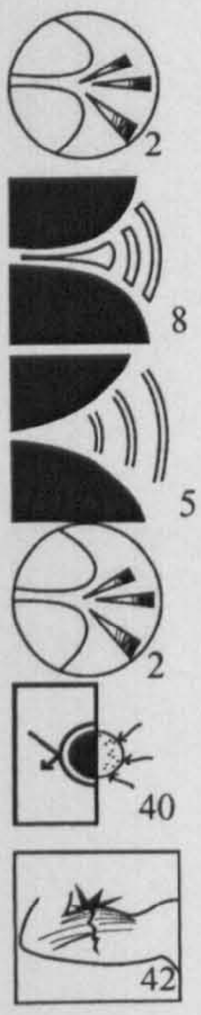


Figure 5.23: Comparison of median values for painkiller icons

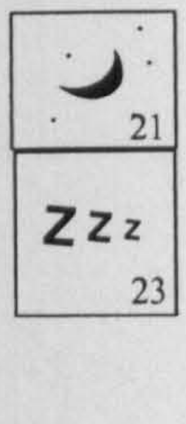
The results for immunosuppressants and muscle relaxants were analysed as percentages asere were only two designs for each category. Over 87% of participants considered icon 40 better than icon 41 and 75% preferred icon 42 over icon 43.

5.3.4 Discussion

There was significant agreement between the judges for the categories for sedatives, expectorants and anticoagulants. Comments made by participants during the appropriateness ranking task were that within the categories one or two symbols stood out as being significantly better than the others. They then struggled to order the others among the lower ranks as the icons were considered to have equally indefinable characteristics. This was that there was low discriminability between the lower ranking symbols or low levels of associability.

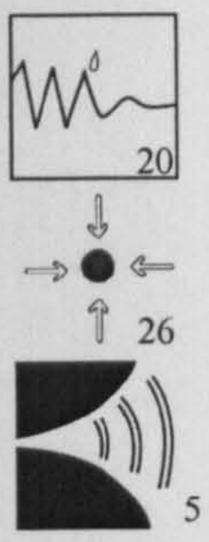


Icon 23 was the preferred icon among the sedative category and achieved a high number of first place rankings. Icon 21 was ranked second by 75% of the participants a clear indication that these were considered most representative of the category. There were only two icons to choose from in the immunosuppressant and muscle relaxant categories. Among immunosuppressants participants preferred the symbolic representation over the pictogram. The muscle relaxant images are similar but preference was shown for the image showing the distressed muscle.



There were differences in the preferred icons of the designers and the larger test group (table 5.2). Icon 2 (expectorants) achieved a mean rank of 1 among the designers who had created the images but only 3.15 among the larger participant group. Whilst icon 21 (sleeping) achieved a mean rank of 1.8 whereas icon 23 was preferred in the appropriateness test (mean rank 1.25).

The asterisks in table 5.2 indicate the icons that were not standardised for the appropriateness ranking test, as they were considered too similar to others within



the set. For instance icons 15 and 17 (appendix G) were similar to icons 21 and 20 respectively (figure 5.4). Icon 26 (figure 5.5) was rejected as unsuitable to the general context for the reasons highlighted previously in section 5.2.2.2.

5.4 THE COMPREHENSION TEST

5.4.1 Icon selection

There was a wide variation among the designers and the large participant group regarding the appropriateness of the icons. Therefore it was decided to select the two items from each of the categories expectorants, anticoagulants, painkillers and sedatives for comprehension testing; that is, the two icons from each category with the highest number of first and second-place rankings appendix I. Among the expectorants icons 8 and 5 each recorded the lowest median ranks of 2. However due to their similarity it was decided to substitute icon 2. Icon 8 received a higher number of second place rankings (41.7%) than icon 5 (27.3%) and was thus retained. Icon 5 was rejected in favour of icon 2 (median rank 3). A single icon was included for each of the referents immunosuppressants and muscle relaxants (icons 40 and 42 respectively).

The assessment sheet used for the comprehension test is shown in appendix J. The majority of subjects who carried out the appropriateness test were design students most if not all of who had no medical training or specialist knowledge of medications. As the icons were primarily intended to assist nurses it was decided to enlist nurses to carry out the comprehension test. Fourteen test sheets were left at general practitioner surgeries in the Fleet area of the Blackwater Valley and Hart Primary Care Trust. These were left for the practice nurses and were accompanied by letters outlining the purpose of the research (appendix J). A further 36 test

sheets were left in the training room of the Great Western Hospital, Swindon for nurses to complete. All the sheets were accompanied by stamped addressed envelopes to facilitate prompt return.

5.4.2 Results

A total of thirty three assessment sheets were returned from a total of 50 sent out, giving a response rate of 66%. Participants were asked to indicate the number of years they had been practising and of the 19 who responded to this question, 6 had been practising for more than 20 years. The mean was 12.66 years (median 10 years, st dev 7.38).

The table for the comprehension test results can be seen in appendix J and is presented in summary form in figure 5.24. Icons correctly identified were marked with '1' whilst errors and missing responses were signified by dashes. Icons 21 and 23 (sedatives) were the most universally understood, scoring correct responses of 88% and 100% respectively and were the only symbols to reach the minimum 50% recognition/comprehension rate recommended by BS ISO 9186. Icon 40 (immunosuppressants) achieved a comprehension level of 48% and icon 42 (muscle relaxants) reached 45%. The least understood were the symbols for anticoagulants, icons 25 and 27 which as many as 60% of respondents left blank (figure 5.25). Similarly the painkiller icons generated a comparable level of blank responses.

A Cochran Q test (Cohen and Holliday, 1996) was carried out to test whether the frequency of responses differed at a significant level. The value of chi square *df* 9,

74.56 <0.001 demonstrated that icons 21 and 23 (sleep) were better understood than the other icons.

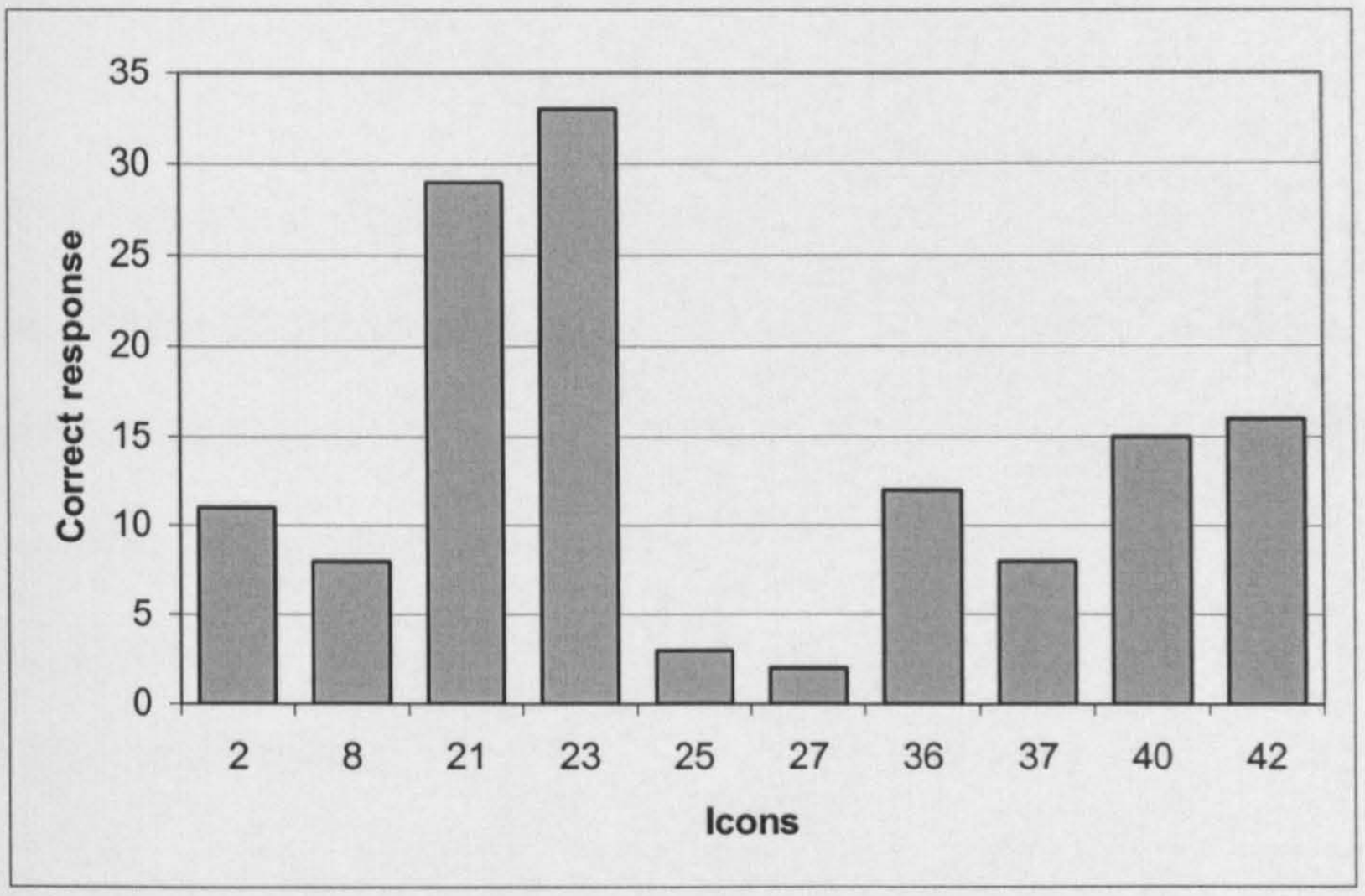
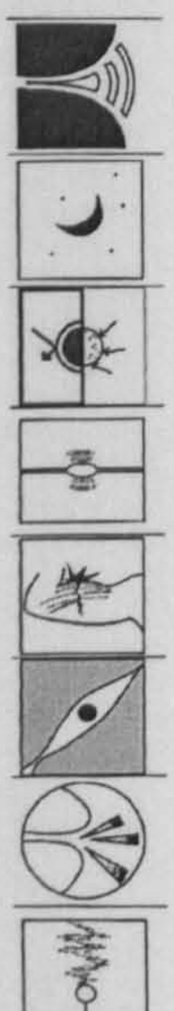


Figure 5.24: Comprehension test results (n=33)



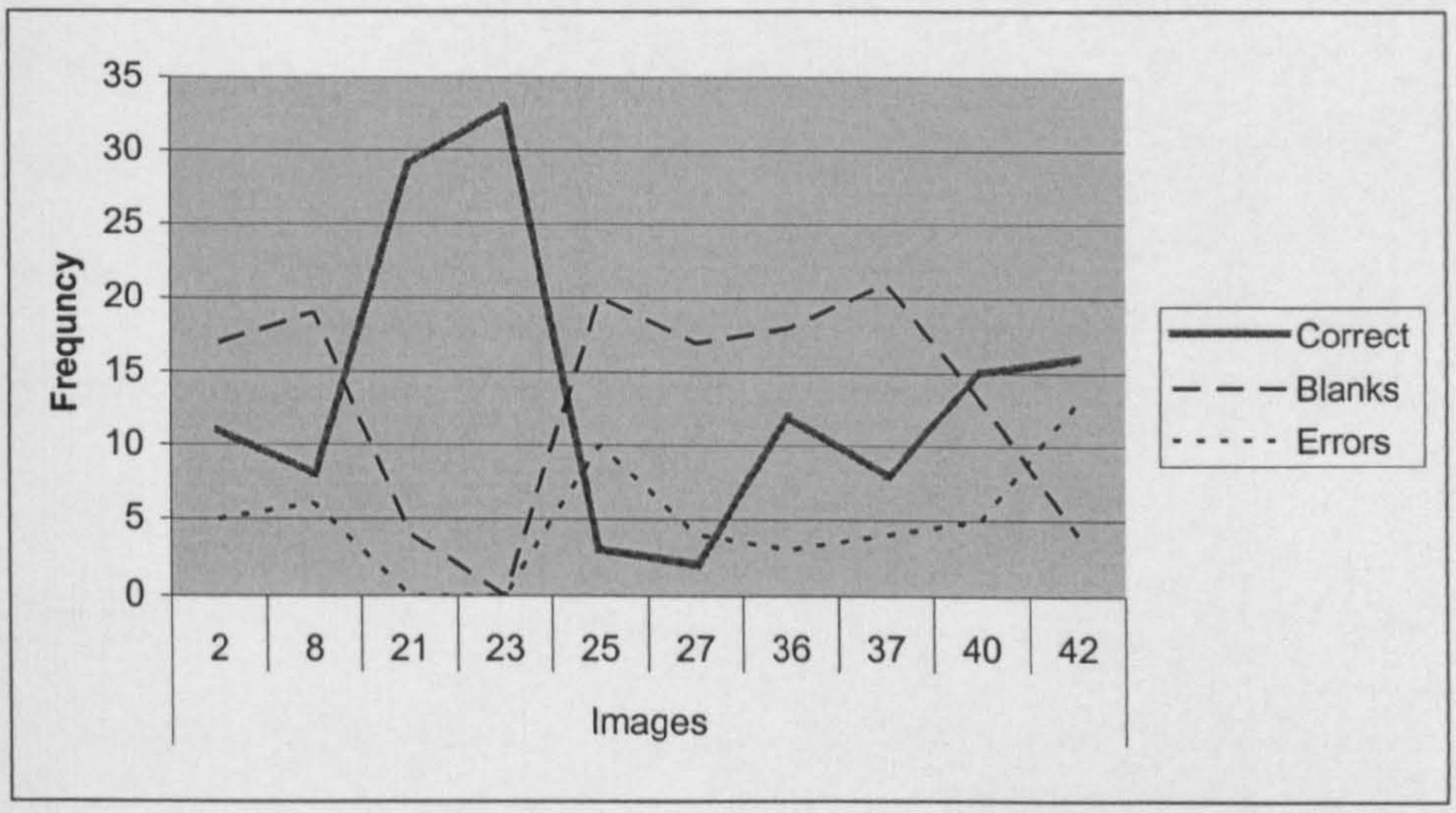
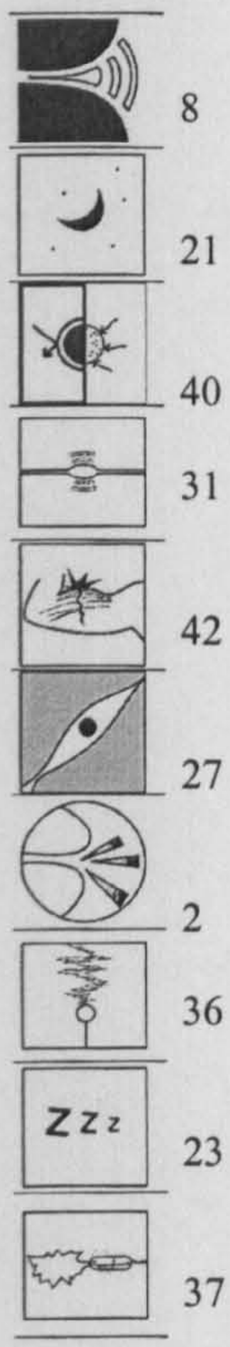


Figure 5.25: Comprehension test - comparison of responses (n=33)

5.4.3 Discussion



There was significant agreement between the judges for the categories for sedatives, expectorants and anticoagulants. Comments made by participants during the appropriateness ranking task were that within the categories one or two symbols stood out as being significantly better than the others.

The sleep icons 21 and 23 were readily recognised despite initial concerns among the original designers that these representations might be considered too frivolous within the context of medication labelling. Icon 42 for muscle relaxants was often mistaken for a painkiller (12 occasions) whilst icon 27 was erroneously assigned to the muscle relaxant category in 15 instances. The possible reasons for these errors are discussed below.

The relatively high proportion of blank spaces on the assessment sheets indicated that participants felt the symbols were inappropriate to the descriptive headings given. Talking about the icon designs with one of the practice nurses revealed that they did not convey any meaningful information and consequently many of the symbols were not assigned to a category. This nurse offered ideas about how two of the icons could be redesigned.

The following remark was made by a 60 year-old full-time dermatological nurse: '*I am afraid these icons totally foxed me!*' The comments received from other participants were in the same vein:

S13: *'I don't think any of these symbols are any good, except 1* (icon 23) *and 7* (icon 21) – *all very difficult to understand.'*

S26: *' Sorry couldn't make out some of the icons.'*

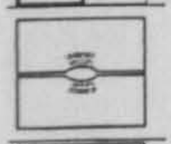
S12: *'I find them very confusing.'*

One of the reasons for the low comprehension rate for painkillers is that the

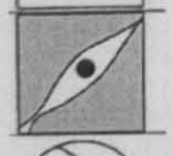

8


21

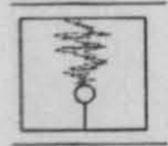

40


31

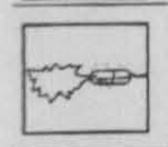

42


27


2


36

23


37

symbols were created in a post hoc manner largely to balance the number of referent icons. Therefore it was surprising that in the appropriateness ranking test icon 36 received a median rank of 3 and icon 37 a median rank of 2. As individuals most of us struggle to find words to describe the nuances of pain, therefore it is almost impossible to convey to others levels of pain relief. Without a highly defined semantic representation it is difficult to depict such a highly subjective entity. As referred to above, pain is often related to aspects of the body which may explain why icon 42 with its clear depiction of a body part caused people to think of pain and its associated relief. The anticoagulant symbol (27) has the appearance of a muscle fibre, hence the attribution of this symbol to the category muscle relaxants.

The form in which the comprehension test was administered makes the assumption that the drug category headings used had the same meaning for each person. As the participants were trained in the knowledge of drugs, it might have appeared patronizing to supply a descriptive phrase for each category, as was the case in the appropriateness ranking. However standardized descriptions for symbols have been advocated by ISO 7001 and may have helped participants in this test to think

of aspects of the drugs the symbols might be attempting to represent. This lack of a formal description may have influenced responses.

There seemed to be differences in the way the nurses thought about drug categories. Most lay people are familiar with OTC preparations such as cough and cold remedies, painkillers and prescription drugs for relatively minor ailments such as antibiotics and all of which tend to be self-administered. This causes them to think of drugs differently to professionals. Nurses, on the other hand need to be aware of both a drug's therapeutic effect as well as contraindications both in terms of the patient's immediate condition and in the event of underlying physical states. Many patients take several drugs and this would have a huge impact on how they are construed by nurses. Consequentially nurses may not cluster drugs together in such neat discrete categories.

Figure 5.26: Alternative design for expectorants

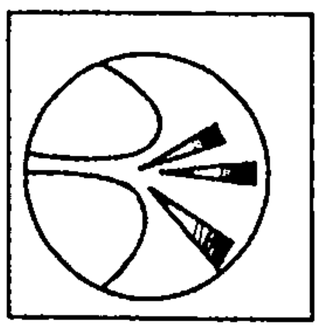


Figure 5.28: Icon 2 tested for comprehension

Figure 5.30: Alternative design

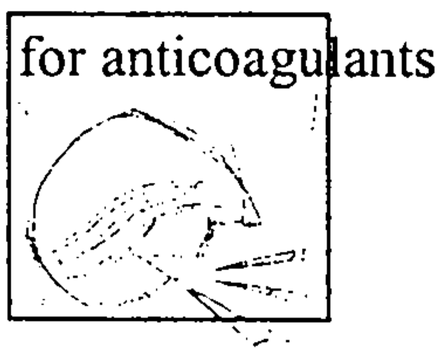


Figure 5.27: Rough design for expectorants

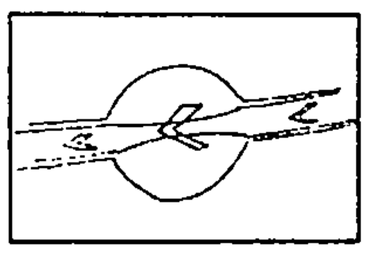


Figure 5.29: Rejected design for anticoagulants

Alternative symbols for two categories (expectorants and anticoagulants) were drawn by a nurse and are shown in figures 5.26 and 5.30. Intriguingly, the icon in Figure 5.26 is pictorial rather than symbolic but does possess similar elements to those of one of the rough designs for expectorants from the workshop that was not put forward for appropriateness ranking (figure 5.27). This symbol was simplified giving rise to icon 2 (figure 5.28), a depiction of a mouth in the action of coughing and perhaps too concise a depiction to be recognised by the comprehensibility testers. As pointed out in section 5.3.4, this icon was highly rated by the designers. Figure 5.30 has similar elements to figure 5.29 (also shown in appendix G, figure G3). This rough drawing was not submitted for appropriateness ranking but shows arrows indicating blood flow in common with the alternative design of figure 5.30. Figure 5.30 differs in that the walls of the vein are emphasised and balanced against the notion of the impending blockage rather than dominated by it.

Participants had been asked to indicate the number of years experience they had and in the cases where this was given it seemed to have little impact on ability to comprehend the icons.

The comprehension test may more accurately be considered a matching test as the participants were required to match the symbols to the correct drug category. The test might have yielded a greater degree of recognition if participants were asked to consider only one example symbol of each category as in the case of muscle relaxants and immunosuppressants, which would have entailed using a greater number of participants.

5.4.4 Improvements

There are several ways the design of this study could have been improved. A commercial designer would spend several months developing icons of this nature whereas those designed and tested in the present study were designed in a single 2-hour session. With more time it would have been possible to design more icons and to involve nurses in this process.

Many of the participants in the appropriateness-ranking test were designers they could have been asked to draw symbols they considered appropriate for the drug categories. Similarly the participants in the comprehension test could have been asked to design representative symbols. This would have given some insight into how nurses conceptualise drugs and it might have proved a more effective strategy to have involved them at the earlier stages of design and appropriateness ranking.

A paired comparison technique might have yielded significantly better results as candidates would have been forced to make a choice. However as many people felt the designs were inappropriate in the first instance it is doubtful whether this method would have been an improvement.

A major factor for both assessors of appropriateness and comprehensibility was the lack of context. Had the icons appeared on the packaging of the relevant drugs, a greater degree of association may be been observed between the drug categories and the symbols.

Despite the advantages afforded by symbols there are still several problems associated with their design and use. Many are too small, have indistinct detail and are difficult to see clearly from a distance or they have small and unnecessary detail. Similarity between the icons and lack of syntactic and semantic rules such as those in verbal language often leads to confusion. Considering that symbols are often intended to be used to convey information to people regardless of their language, this is a major drawback (Dewar, 1999, p289).

In the present study symbols were not to be used in the absence of text, however they would appear to do little to reinforce the identification of drug categories. This may be due in part to the fact that drug categories are highly abstract in nature and contain few discernable elements that are universally acknowledged. A parallel situation has existed for some time in computer applications and more recently in telecommunications messaging. Within these contexts icons are used to represent abstract information and in most cases individuals learn the meaning of these by associated action. The same success rate might reasonably be expected within the present context. The icons were added to the concept packages as recommended by the SHERPA analysis (chapter 2) to increase conspicuity in order to prevent errors associated with reading labels. However, further work needs to be done to explore the conceptions nurses have about drugs and drug categories in order to develop suitable semantic terms with which to assess the imagery and to test the effects of training on ability to learn the symbols. The SHERPA analysis also recommends the use of technology to resolve the issue of reading labels and this is the subject of the next chapter.

Chapter 6

Applying technology to the problem

6.1 BACKGROUND

This chapter considers how technology has been used to address errors and describes the design and development of a novel technological device. Technological solutions such as bar coding were suggested by the SHERPA analysis in chapter 2 to mitigate the errors associated with: reading medication label or the medication chart, giving medications to the wrong patient and failing to check the patient's identity. The summary table (table 2.4) highlights that technological solutions address the greatest number of errors. RFID tagging systems were suggested for locating charts in the SHERPA analysis however in practice these are more likely to be used as part of a larger automated process. Tagging systems have been used in various aspects of medication management most notably at the prescribing and dispensing stages. Computerized physician order entry (CPOE) systems have been used in Brigham and Women's hospital, Boston and have been cited by Bates et al (1999) as contributing to a reduction in

medication errors of over 80%. Similarly, Ragan et al (2005) and Potts (2004) have reported lower error rates after the introduction of computerised systems.

6.2 BAR CODING SYSTEMS

Barcoding has been used successfully for some time in retailing and in health care for labelling blood products. With a view to improving medication error rates in US hospitals the Food and Drug Administration (FDA) published a final rule entitled Bar Code Label Requirements for Human Drug Products and Biological Products (FDA, 2004). This rule obliges manufacturers to ensure that all prescription and certain non-prescription drugs are bar coded. The rule requires that manufacturers comply within two years. Although bar coding technology is not mandatory the Commission on Accreditation of Healthcare Organizations (JCAHO) has noted a decrease in medication administration errors that is attributed to its use (JCAHO, 2004). When used with a scanning system and computerised database the steps are as follows:

1. The patient is admitted to hospital and is given a bar-coded identification bracelet that links with his or her computerized medical record.
2. Prescription drugs and certain over-the-counter drugs would have a bar code on their labels. The drug is identifiable by it unique NDC number.
3. The hospital's bar code scanners or readers linked to the hospital's computer system of electronic medical records enable identification of the required drug regime.

4. The patient's bar code is scanned before the drug is administered enabling the computer to access the patient's computerized medical record.
5. The nurse worker then scans the drug(s) dispensed by the hospital pharmacy for that patient. This scan informs the computer which drug is being administered.
6. The computer looks for a match between the patient's medical record and the drugs being administered. If there is a problem, the computer sends an error message, and the nurse worker investigates the problem.

The system is intended to ensure the requirements of drug administration are fulfilled:

- The appropriate medicine
- In the appropriate formulation
- By the appropriate route
- At the appropriate dose
- At the appropriate time
- At the appropriate rate
- For the appropriate duration of the therapy (Dougherty and Lister, 2004).

In the United States, the Veterans Health Administration (VHA) has used a bar code medication administration (BCMA) system for some

time. Between 1993 and 1999 a 64.5% reduction in errors was observed (Johnson et al, 2002). Currently, over 150 VHA use BCMA systems. Sublett (2002) describes how a barcoding system operates in practice at 350-bed acute hospital in a 38-bed urology and nephrology ward where up to 450 medications are dispensed each day.

6.3 RFID

RFID point of administration systems are currently undergoing trials in the UK although they have been used in the US for some time and work in a similar way to bar code systems. Fowlie et al (2000) describes how an electronic prescribing and administration (EPA) has been used effectively in a British hospital. The Swedish company Cypak has developed a form of intelligent packaging system that is able to monitor the patient's drug usage and can alert the user with an auditory signal when the next dosage is due. Each time a dose of the medication is pushed out of the packaging the event is recorded. Information from the packaging can be retrieved by placing the package on a scanner connected to a PC.

6.4 IBUTTONS

An iButton is a mobile memory silicon chip encased in a stainless steel covering that communicates by touch. The casing gives it the advantage of durability which means it can be mounted on almost any surface and is able to withstand harsh indoor or outdoor environments such as high temperatures or high humidity. This is an important consideration for use in a hospital identity bracelet as in a health care environment these items can come into contact with various bodily fluids and

hospital chemicals or drugs and remain attached for bathing. The bracelet might be dropped, knocked, scratched or stepped on, therefore a robust design for the memory is of considerable importance.

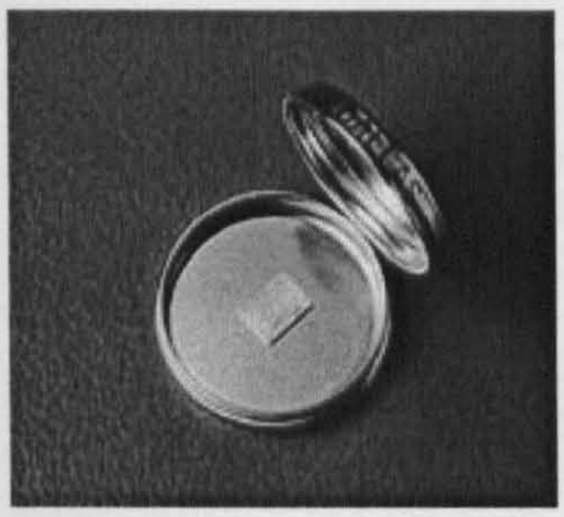


Figure 6.1: iButton

The computer chip possesses a unique identity and depending on the type of button selected can be used in to various applications. Information can be written to, read from it and stored in accordance to the size of memory. Ibuttons are low-cost, use low power and are able to operate as a mobile database, either as standalone devices or as part of a networked system. They have various capabilities such as a microprocessor, clock or environmental sensors and might typically be used as a key to control access, as a location identifier for route compliance or equipment identification for inspection tasks.

NVRAM iButtons are read/write devices available in sizes from 1K bits to 64K bits used in applications where the data need to be updated frequently and the memory is capable of being rewritten millions of times. Memory updates, once initiated, will always be completed because the power to finish the transfer is supplied by the integrated lithium cell, not the reader/writer therefore these devices are useful in conditions of intermittent power.

EEPROM iButtons are read/write devices available in sizes from 256 bits to 32K bytes but have a lower write cycle limit than NVRam iButtons. They are used for applications that need data updated on a less frequent basis than NVRAM type applications, but can be used for over 10 years. Given their characteristics iButtons are a good alternative to barcoding and RFID identification systems.

Ibuttons connect with other components through a 1-wire MicroLan which is an inexpensive, easy-to-install network standard with multi-drop capability. It uses a microcontrollers as a master, and can supply both data and power over low-cost twisted-pair cable. It has a multi-drop capability and an identify and read 1-wire devices permanently attached to structures along the bus, as well as roving devices such as ID tags or decoder rings. One-wire parts with memory capability allow data to be collected off a bus and transferred to the computer master by touching a port somewhere along the MicroLAN bus. Functionally, a port consists of little more than elegant exposed sections of the twisted pair constituting the bus that touches both the lid and case of the iButton or decoder ring. When connected, the master can address and begin transferring data with the device in about 7 ms (Awtry, 1997).

6.5 BRILLIANT

6.5.1 Outlining the technology

This chapter now goes on the describe an intelligent hospital identity bracelet which was designed and assessed by Claire Dunne (2005) in consultation with the author who provided the literature sources and the background information relating to the

problems of medication administration errors that enabled the designer to devise a preliminary questionnaire that was circulated to nurses. The author advised on the physical dimensions of the device and the type of information that would need to be displayed. The testing methodology was also devised by the author, whilst the ensuing discussion and evaluation of the design by the author brings the chapter to its conclusion.

The bracelet named Brilliant uses iButton technology to make a direct link between the patient and the drug packaging (figures 6.2 and 6.3). The patient's details such as name age, hospital number and medications are programmed into the bracelet. The drug package contains the iButton which is programmed with the drug name and dosage. When the drug bottle or box containing the selected drug is touched against the reader in the patient's identity bracelet the system checks the stored data looking for a match between the drug name and dose. If the drug selected by the nurse is the correct dosage and the drug name are shown on the screen, the date and time, of administration are recoded and stored to enable comparisons to be made when the drug is next scanned into the device. In this way the system prevents a possible overdose. The medication administration record is stored in the device and can be can be downloaded to a computer at the end of the patient's stay.

The bracelet possesses two LCD screens to enable both the nurse and patient to observe and become involved in the medication administration process. In this way the patient becomes involved with the procedure. The double screens also enable the bracelet to be worn on either wrist.

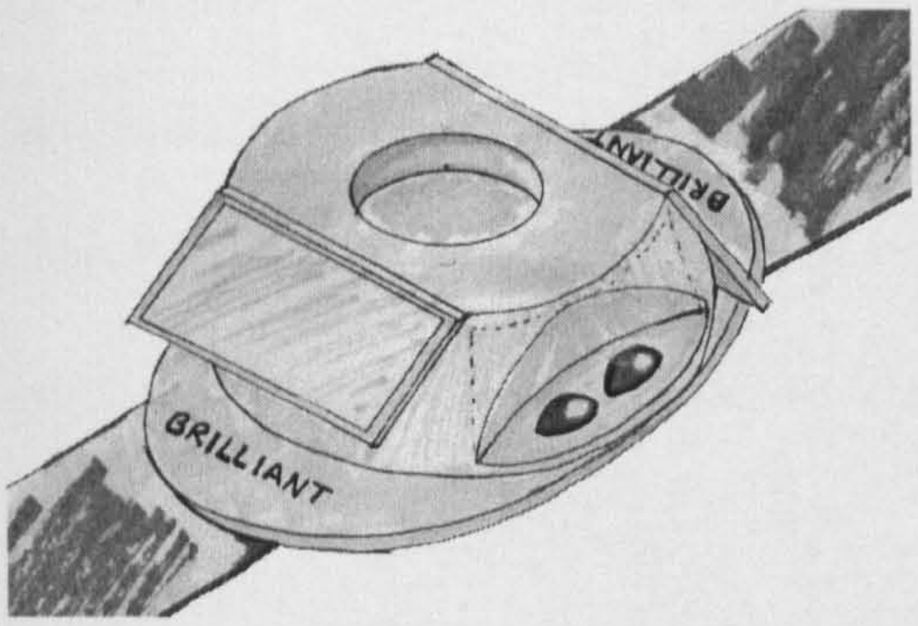


Figure 6.2 Drawing of 'Brilliant' - the intelligent hospital identity bracelet

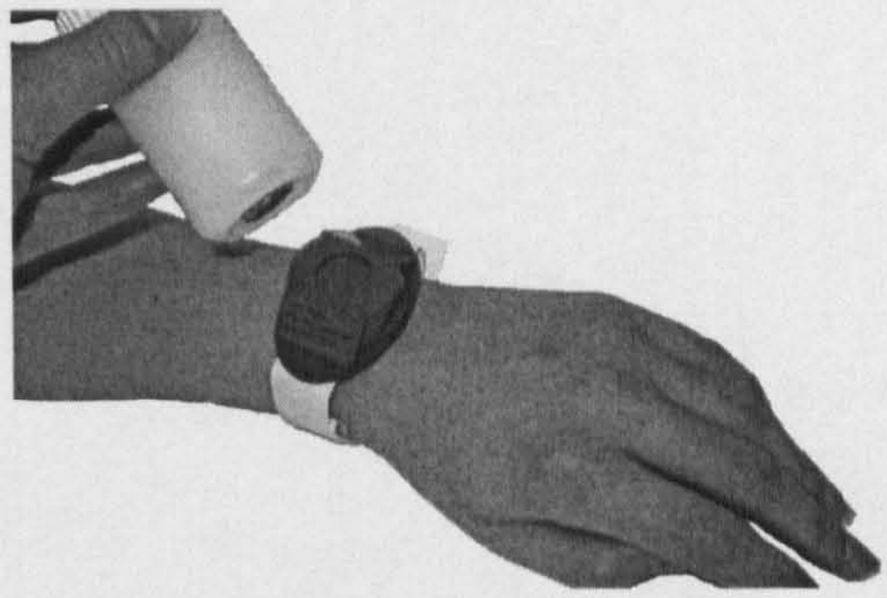


Figure 6.3 Aesthetic model of 'Brilliant'

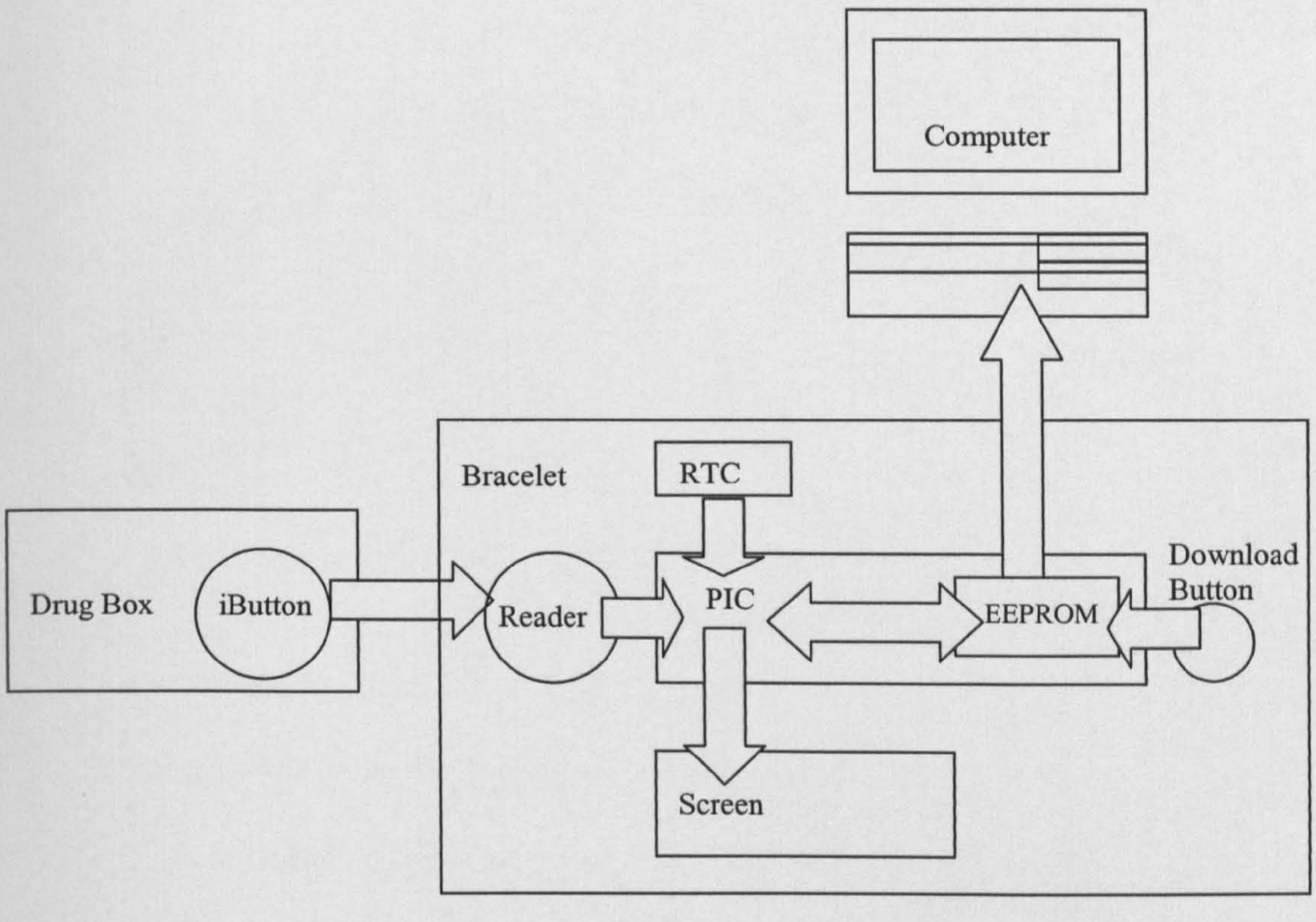


Figure 6.4: The system diagram for'Brilliant'

6.5.2 The Design

The design of the system is shown in figure 6.4. The iButtons used in the system were identifiable by a unique factory assigned serial number which enabled them to

be used to represent medications. They were then read into the PIC so that each could be identified. A small circuit was created with the iButton reader connected to the PIC. The artwork for the printed circuit board can be seen in appendix L. The PIC was programmed to accept the serial number matching that which had previously been programmed. A Real Time Clock (RTC) was incorporated as a separate chip to record the patient's date of admission and the duration of stay in hospital. Its high level of accuracy made it suitable to record medication administration times.

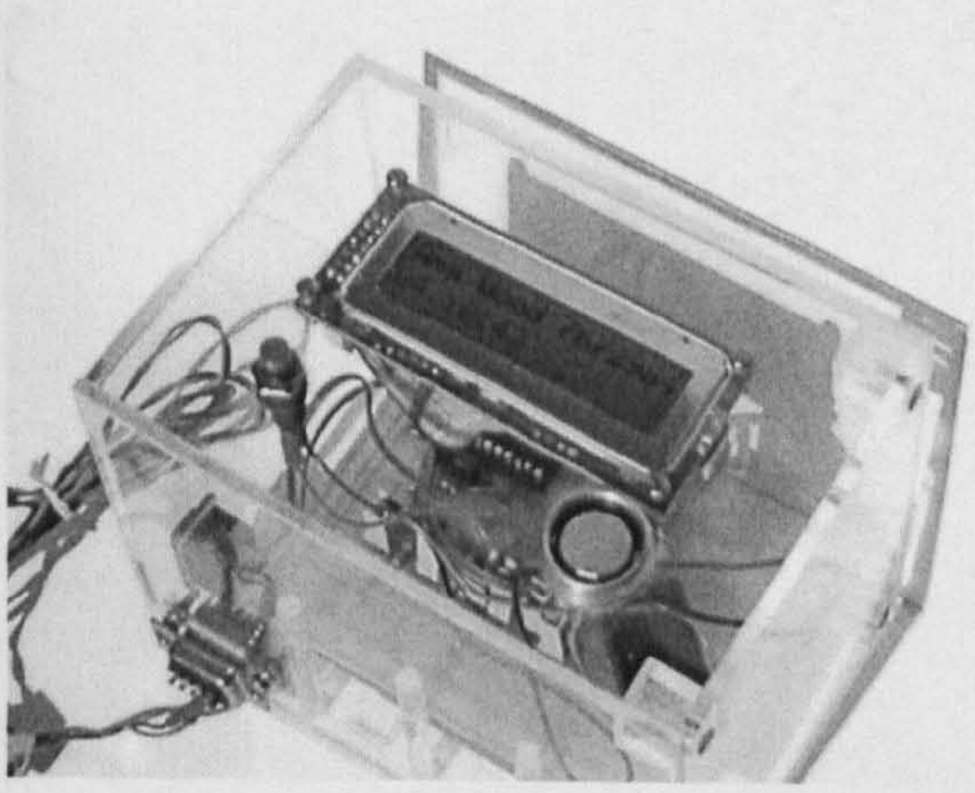


Figure 6.5: The prototype

The circuit board along with its peripheral components was mounted in an acrylic box in order to demonstrate and test the principle (figure 6.5). Using the device it was possible to the to select two drugs from a range. Perhaps most importantly, the system prevented additional doses of the same drug being given for an interval of one minute. This time interval, though small, was sufficient for demonstration and evaluation purposes. For real-world application it would be changed to a more appropriate time interval. The system was able to store logbook information such as date, time, drug name and dose. Data transfer was carried out though a USB port

and could be stored on a computer as a single-button operation and printed out at a later time as necessary for billing or audit purposes. The USB port also afforded the possibility to incorporate the device into other systems to the extent that with suitable modifications and further development, it could be used to display laboratory results from patients' tests.

6.6 BRILLIANT EVALUATION

6.6.1 Test 1 participants

The tests carried out by the designer attempted to create in part some of the conditions that were likely to produce the errors identified by the SHERPA analysis. The initial tests with ten student participants from Brunel University using protocols outlined by the author of this project to determine how easy the device would be to use compared to other types of wristbands. The purpose of the test was to assess whether or not participants were able to use the device to retrieve the salient elements of patient information which is normally found on patient identification bracelets (items such as the patient's name, date of birth and hospital identification number. It was expected that a higher number of correct responses would be recorded for the iButton device.

6.6.2 Test 1 method

A test was devised to assess the performance of Brilliant against 3 other types of wristband. These were write-on, insert and RFID. The participants were presented with the following information on the wristbands:

Wristband	Name	Date of Birth	Hospital Number
Write - on	Ben Howard	16/09/1981	84 579 56
Insert	Julie Redman	23/05/1973	03 764 25
RFID	Michael Cooke	01/01/1956	123-45-6789
ibutton	Amy Wood	04/01/1942	76 429 84

Table 6.1: Patient information given to participants

The participants were asked the following

- w*hat was the patient's first name?*
- *What was the patient's surname?*
- *What date in the month was the patient born?*
- *In what month was the patient born?*
- *In what year was the patient born?*
- *What were the last the last two digits of the patient's hospital number?*

- *What were the last the last two digits of the patient's hospital number?*

The participants were given intervals of one, two, three and four seconds to look at each bracelet and the bracelet was shown four times for each of the intervals. They were then asked to provide a specified piece of information from the bracelet. The order of the questions and the presentation of the bracelets were randomised and the presentation of the intervals was reversed.

6.6.3 Test 1 results

Overall, the highest number of correct responses were recorded with the iButton bracelet (Brilliant) (figure 6.7).

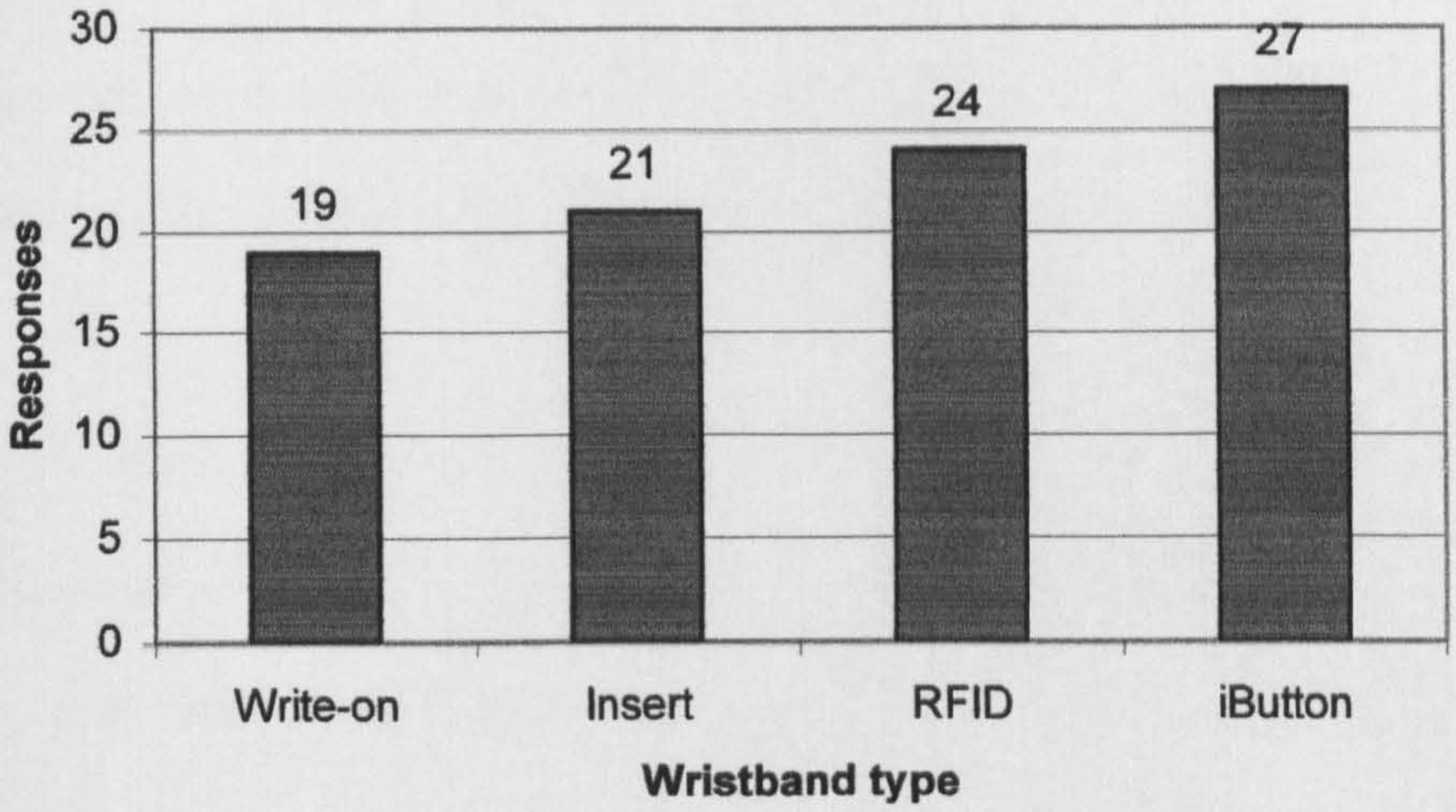


Figure 6.6: Total number of correct responses for each wristband – maximum total score is 40 (n=10)

A Friedman test (Greene and D'Oliveira, 1993) was carried out on the total scores (figure 6.8). The observed value of Chi Square was 6.06 which did not quite reach the level of significance ($p<.1.0$) given as 6.25.

6.6.4 Test 1 discussion

The participants recorded the highest number of correct responses with the iButton bracelet however the differences observed were not significant. This may be due to the fact that the data contain zero scores which have the effect of lowering the rank sums (appendix M). The prototype compared favourably to write-on patient identification systems and the nurses were able read the standard items of patient information from it. One of the reasons that Brilliant performed better than the other wristbands is that standardised text such as printed or computer-generated text is generally much easier and quicker to read whereas hand written text is variable and difficult to read.

6.6.5 Further testing

Tests were carried out with nurses in a ward situation in order to assess how well nurses interacted with the intelligent hospital identity bracelet in a ward setting.

6.6.5.1 Test 2 method

Eight nurse participants were given a written scenario as follows:

> *The drug chart has been lost but you know that the patient is due another dose of an irregular drug but do not know whether they have been given it already. Find out what irregular drug they are taking and if it is due what the dosage is to be given and what regular drug they are due and the dosage to be given.*

The nurses were given the iButton prototype, and six bottles labelled A – F each with iButtons attached to the top. Their task was to use the iButton device to ascertain which of the drugs the patient was taking and whether or not it was due.

6.6.5.2 Test 2 Results

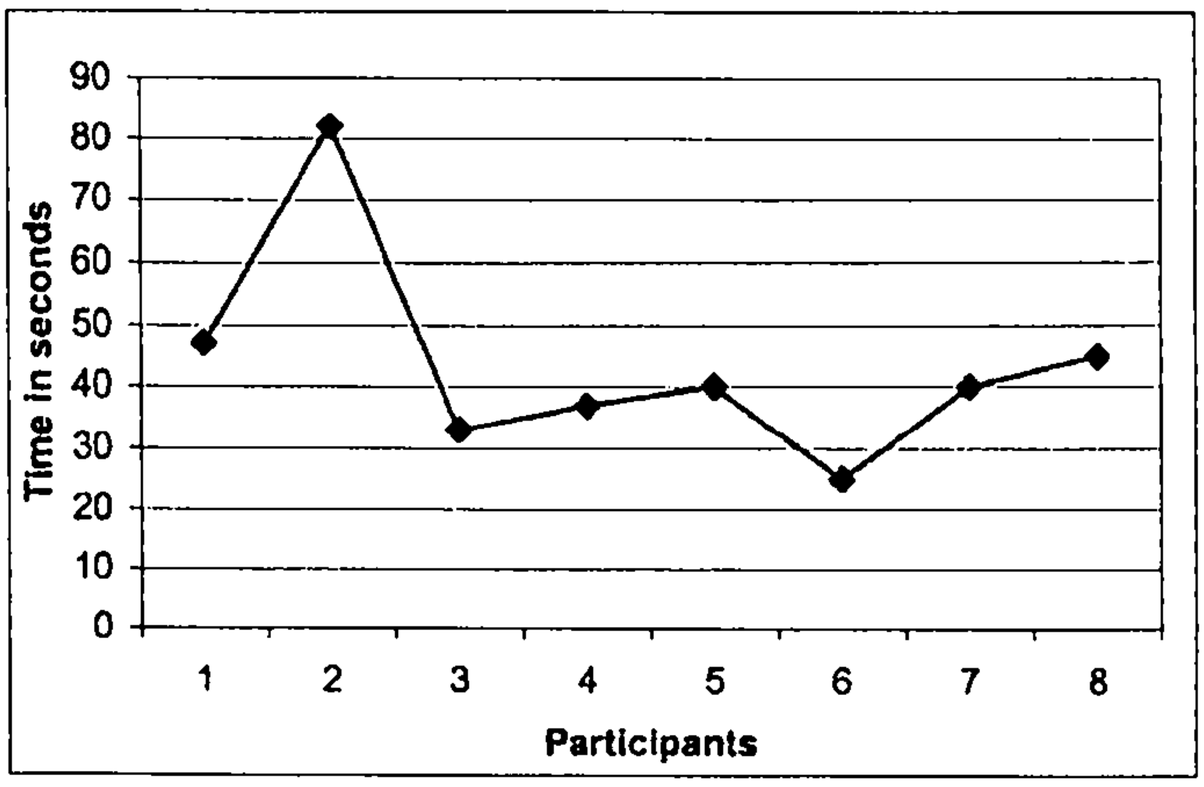


Figure 6.7: Time taken to determine which drug is due for administration

The nurses were able to use the Brilliant prototype to search for patient information and after a short period of familiarisation all were able to complete the required task. The results are shown in figure 6.7.

6.6.5.3 Test 3 method

Six nurse participants were given the following scenario:

> *You have three drug charts but two are out of date and incorrect. Find out which is the correct drug chart.*

Three drug charts were provided and six bottles labelled A-F. The nurse was required to touch the iButton on the bottle against the reader on the prototype device in order to determine which medications the patient was taking and match these to the current chart. In this way the obsolete charts would be identified.

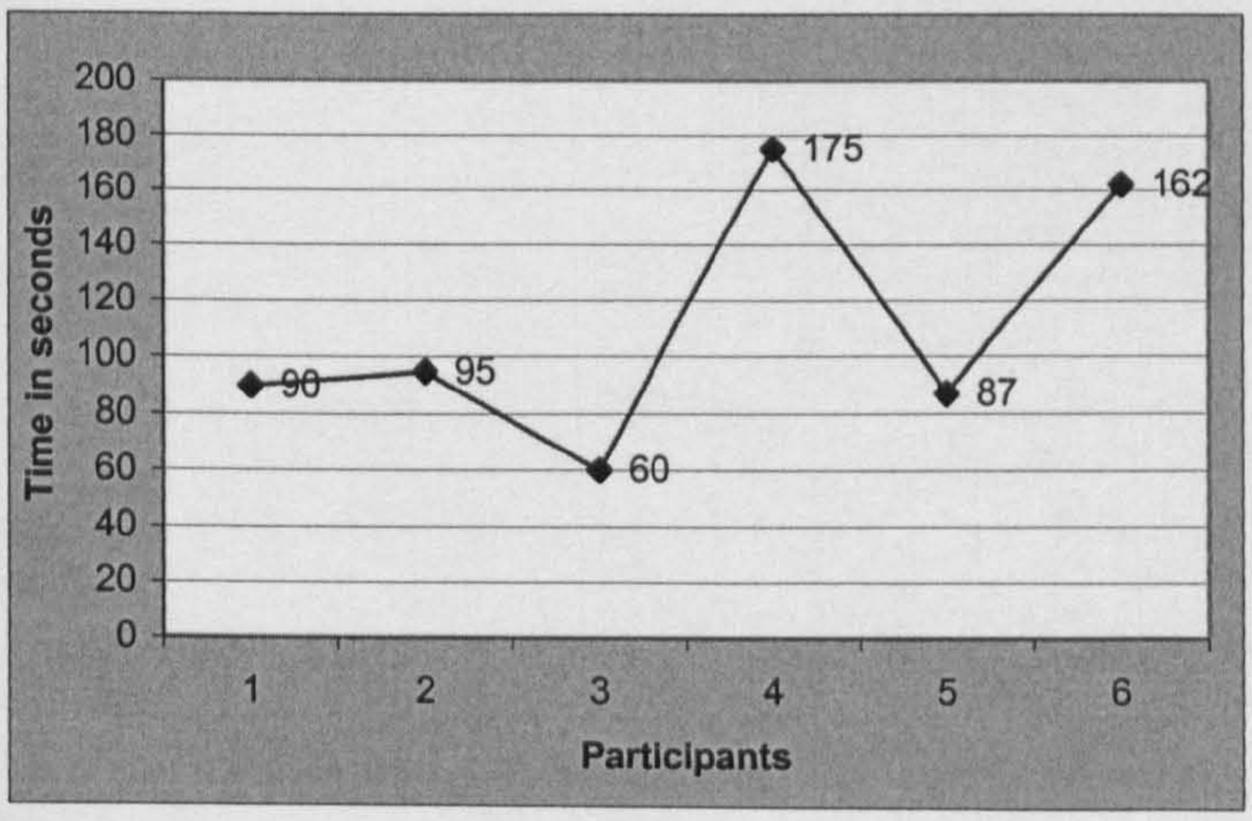


Figure 6.8: Time taken to determine which of three drug charts is current

The nurses were able to use the Brilliant prototype to identify the current drug chart and to reject the two that were not longer current. The results are shown in figure 6.8.

6.6.5.4 Combined test 2 and 3 discussion

The nurses were able to use the prototype to ascertain whether or not a medication was due for administration and to check for those medications that were no longer required. However some of the nurses did not correctly identify the drugs that were no longer needed. For these individuals the difficulty arose from the fact they experienced difficulty distinguishing the various dosages written in the chart when making comparisons with Brilliant's programmed information. This difficulty is marked by the peak in figures 6.9. This problem palpably highlights the difficulties of reading medication charts in a working environment as outlined in chapter 2 (p26).

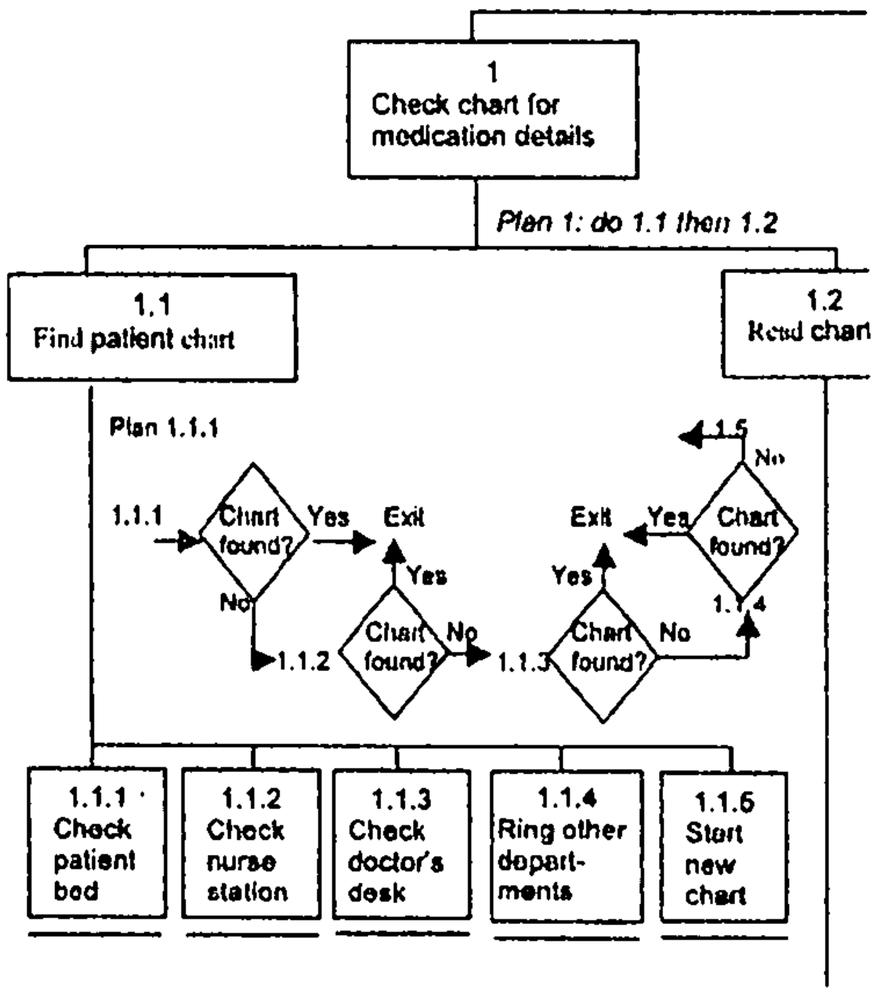


Figure 6.9: Extract from the drug administration HTA

Test 2 presents a lost chart scenario which participants resolved in less than 2 minutes by checking drugs against the iButton device. In a real-world situation a lost chart is likely to result in several drug doses being missed as nobody could be sure which drugs are due or if a colleague on a previous shift had given the patient the correct drugs. As illustrated in the extract from the drug administration HTA looking for the chart and organising a new one could take a few hours. In organising a new chart the drugs would have to be written up and signed by a doctor. The results from test 2 demonstrate how this process is reduced to a matter of minutes with the iButton device as the relevant information is in located within the patient's identification device.

Test 3 demonstrates that the nurses were able to be confident in their rejection of obsolete charts. Although time to complete the task was recorded this is irrelevant. In the event that an original chart reappears after a new one has been written can result in confusion. This is particularly the case where different members of staff do not know that more than one chart is being used for the same patient and continue to administer medication from an old one. Dates and times of administration may not offer much clue as to which is the most recent chart as they may overlap. Depending on the complexity of the drug regime, it might be possible to determine which of three charts for the same patient is current in less than three minutes. In test 3 the slowest participant recorded a time of 175 seconds. However in order to be confidant that the rejected charts are indeed obsolete it is likely to take a nurse much longer than this. The certainty that the iButton device brings is worth the possible extra time spent engaged in this task.

6.7 OVERALL DISCUSSION

Cullen et al (2000) cite the most common type of error as wrong dose which occurred more than three times as often as wrong choice errors which was the next most frequently occurring error type. With use of the iButton device these errors are completely eliminated. Transcription errors have been reported by Dean et al (2002) and Taxis et al (1999). Since the patients drugs are programmed into the device upon entry to hospital the need to transcribe medications is eliminated.

The strengths of the Brilliant design are that it can:

- reduce errors identified in the SHERPA analysis (summarised in table 6.2);
- it be added to a more complex automated drug delivery system that incorporates COPE and robot unit dose dispensing from the pharmacy;
- be used as a programmable standalone device in cases of limited financial resources;
- be used in organisations where it would not be desirable or appropriate to use a fully automated system.

There are very few standalone products that perform in this way. Most systems rely on a scanner and computer to read the patient's information from a bar coded label or RFID tag. This iButton device dispenses with these expensive items of equipment by making a direct link between the patient and the drug thus reducing expenditure.

Task Step	Error Mode	Description	Consequence	Recovery	P	Remedial measures
1.2.2	R2	Read drug dose incorrectly	Administration of overdose or dose of no therapeutic value	2.5.1.2	H	Only use standard abbreviations or write words in full. Computerised order entry.
1.2.3	R1	Fail to read pharmaceutical drug form	Administration of ineffective dose that could lead to an overdose	2.5.1.3	M	Computerised order entry
1.2.4	R1	Fail to read drug strength	Administer an overdose or dose of no therapeutic value	2.5.1.4	M	Computerised order entry coupled with barcodes and scanning
3.1.1	A7	Take wrong tablets to patient	Wrong drug given		H	Bar coding
	A6	Take tablets to wrong patient	Wrong drug given	3.1.2	L	Bar coding
3.1.2	C1	Fail to check chart	Wrong drug given	Immediate	L	Barcoding
3.1.3	C1	Fail to check patient ID	Wrong drug given	Immediate	H	Bar coding
3.1.4	A6	Present tablets to wrong patient	Wrong drug given		M	Bar coding

Table 6.2: Extract of the SHERPA analysis

Task Step	Error Mode	Description	Consequence	Design Solution	Error reduction potential
1.2.1	R2	Read drug name incorrectly	Selection of wrong drug for administration	Intelligent patient ID bracelet	100%
1.2.2	R2	Read drug dose incorrectly	Administration of overdose or dose of no therapeutic value	Intelligent patient ID bracelet	100%
1.2.4	R1	Fail to read drug strength	Administer an overdose or dose of no therapeutic value	Intelligent patient ID bracelet	100%
3.1.1	A7	Take wrong tablets to patient	Wrong drug given	Intelligent patient ID bracelet	100%
	A6	Take tablets to wrong patient	Wrong drug given	Intelligent patient ID bracelet	100%
3.1.2	C1	Fail to check chart	Wrong drug given	Intelligent patient ID bracelet	90%
3.1.3	C1	Fail to check patient ID	Wrong drug given	Intelligent patient ID bracelet	100%
2.5.2.1.1	A6	Take wrong bottle out of store	Give wrong drug	Colour label combined with tactile features	90%
2.5.2.1.2	R1	Fail to read label	Give wrong drug	Colour label combined with tactile features	90%

Table 6.3: Extract of the SHERPA analysis showing potential error reduction

Once programmed the device is simple to use, tamper proof and the data stored in its memory can be easily downloaded to a computer for analysis, billing or chart review. It goes further than some systems - rather than displaying an alert that the nurse is about to give an overdose in the event that the medication is not due, it has the ability to prevent administration of the drug. However in its present state it would not prevent malicious use and it should be pointed out that there is potential for errors to occur at the programming stage. Administering drugs using a computer can be a time-consuming process as nurses spend excess amounts of time scrolling through display screens to find the relevant one (Sublett, 2002). In the case of the iButton, as soon as the drug is presented to the reader the relevant information as to whether or not that drug is due is available.

There were some issues that needed to be resolved before this device could be rolled out on a larger scale. The first concerns partial accumulation of the required information. If, for example, a nurse scanned a drug using the device and read the name but did not read the drug strength and looked away to check the patient's chart the device would revert to default mode – showing the patient's name and hospital number. When the nurse looked at the device again she would no longer see the drug name or dose displayed and would be unable to access that information as the device assumes the drug has been given. This might be construed as a fault in the system but is more a reflection of how nurses routinely perform the checking aspect of medication administration. In this example it is by a series of matching small pieces of information. A small adjustment to the device that enabled the drug details to be displayed for a longer interval would resolve this issue. Alternatively

the nurse could spend a slightly longer time studying the medication requirements of the patient prior to commencing the administration sequence. However in the real world it is more likely that in a system such as this the patient's information would also be linked to a computerised physician order entry system that would perform the check automatically.

In its present form Brilliant does not prevent errors arising from missed doses. It could be programmed to signal when a dose has been missed. The Brilliant prototype demonstrated it has great potential for further development as a commercial product as it can be integrated into a large automated drug delivery system or used as a discrete arrangement to match the correct patient to the correct drugs.

Table 6.3 (p178) indicates that using the ibutton device has the potential to reduce 100% of medication administration errors. Using the example of errors arising from failure to read or of misreading the drug label (step 1.2.1), the ibutton device allows the nurse the opportunity to check the medication after initial selection by comparing it with the original patient chart. Presenting the drug to the patient offers the last opportunity for checking. Touching the drug to the reader in the bracelet enables the device to perform the necessary check and the nurse is simply required, at this final stage, to observe that the match has been made. If the wrong drug has been selected in error the nurse has the opportunity to recover.

Using the ibutton device to resolve failure to check the chart error (stage 3.1.2 in table 6.3) is likely to result in a 90% error reduction because without referring to the chart the nurse would have no way of ascertaining which medications were due, which were omitted and which had previously been administered as in its present form the device does not allow the nurse to register a digital 'signature' in the same way as she would on a chart. The feasibility of adding such a function is a good topic for future research. Further suggestions for research are discussed towards the end of the next chapter.

Chapter 7

Conclusions

7.1 SUMMARY

This thesis began by establishing that there is an issue concerning medical errors in the health care system and that these cause problems for both staff and patients. The prevalence and in some cases the severity of these problems have serious implications for the delivery of safe and effective health care. Several large studies have indicated that these errors are not only a major cause of death in the UK but in many countries around the world and in cases were patients are not killed, errors may lead to temporary or permanent disability or to an extended length of stay in hospital.

This Thesis contributes to knowledge by presenting a study of medication error at task level. Many studies have focussed on describing and categorising error types first and have considered causal factors such as the nature of nurses' tasks as a secondary issue. In presenting a task analysis of the hospital drug administration task this study is offering something that has not been done before. In systematically analysing medication errors using the SHERPA technique the study

applies a well- established human error identification technique to a novel domain. It then goes on to develop and test novel design products.

The misapplication of medications accounts for a large number of errors and there is a high level of similarity among the types of reported medication errors across the world despite the use of different systems of medicines management and administration. These errors include giving medication to the wrong patient, giving an incorrect dose, giving an incorrect drug, administering a drug by the incorrect route or in the wrong form. In many cases doses are omitted altogether.

Medication usage is complex and is dependent on the interaction of health professionals functioning within different disciplines. This means there are many opportunities for error during any one of the five major stages of prescription, documentation, dispensing, administration and monitoring. The responsibility for error is often placed on the nurse as she is often the last person in the drug administration chain. However there are many causes of medication errors and these often combine to cause the incident. Commonly reported reasons are workload, constant interruptions, shift patterns, communication failures, long working hours (Ferner, 1995; Fiesta, 1998, DoH, 2000). Factors associated with the individual include poor skill in calculating doses and compounding drugs. Reason' s (1990) model demonstrates how defence barriers can be penetrated by an accident. These might be a lack of computerised prescribing technology systems that have in-built alerts to highlight errors in prescribing, not following recommended practices, lack of communication between departments or when transferring from community care to hospital and vice versa.

Labelling and packaging are often poorly designed making it difficult for nurses to distinguish between different categories of drugs and routes of administration. The relevant information is often written in small lettering making it difficult to read. Similarity of drug names creates confusion and gives rise to selection errors which in turn have caused patient fatalities.

Attempts have been made to address this problem by adding visual cues to the packaging in order to help selection. Such as adding conspicuous labels, using upper case lettering at various salient positions in the letter string of the drug name.

Reporting systems have been set up in both this country and abroad in an effort to expose the underlying causes. One of the largest, the MedMarx system operated in collaboration with the US Pharmacopeia (USP) and Institute For Safe Medication Practices (ISMP) has monitored medication errors since 1991. A national non-punitive reporting system has recently been set up in the UK by the National Patient Safety Agency (NPSA) in an effort to garner lessons from these errors.

Failure mode and effects analysis (FMEA) has been applied to the problem of medication errors. It is a technique originally developed for use in the field of reliability engineering and is based on the assumption that errors will occur regardless of how knowledgeable or careful the individual is. A FMEA anticipates what errors can be made during medication usage and predicts what the results will be. The analyst then goes on to consider how best to prevent incorrect actions being completed or how to minimise their effects if they are completed.

Root cause analysis (RCA) is another method that has been applied to the problem. Using a single adverse incident a multidisciplinary team of practitioners use the technique to work backwards from the event though the sequence of actions and the events that led up to it. The strength of RCA is that it is a well-structured approach that focuses on processes and thus is a useful tool to address organisational and systems issues. Its major disadvantage is that it can be a labour intensive and time-consuming technique and whilst it can uncover the root causes of apparently separate incidents, these may result from hindsight bias.

Technological solutions have been implemented in an effort to counteract the limitations of human performance that arise when dealing with complex tasks that rely on high memory resources and most of these systems have been used in the US.

Many UK hospitals use a ward based pharmacy system however this is in a state of transition to a system that uses the patient's own drugs. In the ward system, a large proportion of the medications administered are held as ward stock. These drugs are the most frequently used and are kept in a locked trolley along with non-stock items. Nurses make a drug administration round four to six times daily depending on the ward during which the trolley is taken to each patient's bed. The patient's own drug system enables the patient to continue using medication they would normally use at home whilst in hospital. This is kept in a locked cabinet at the bedside.

Physicians use the patient's chart to indicate to the nurse which medications the patient is to receive. This is kept with the patient and used to record drug administration. Each dose administered is recorded on the medication chart, which usually allows 14 days of documentation. This allows the patient's most recent drug history to be viewed. If a drug is ordered that is not held as ward stock or is not in the patient's bedside drug cabinet, the ward pharmacist makes a note on the medication chart and a supply sufficient for several days is dispensed from the hospital pharmacy with the patient's name on the container. Dean and Barber (2000) have demonstrated the occurrence of similar rates of error between the two systems.

Many medication error studies have systematically analysed the context of drug administration. However there are very few published studies that have analysed the drug administration process at task level. A Human Factors approach offers a range of techniques that can be employed to address the issue of errors at task level. One such approach, task analysis, is a useful way of breaking a task down into its constituent parts and is a practical way of looking at how people interact with various aspects of their working environment. The technique has been used extensively in several domains to identify training needs but has been an underused technique in the health care domain.

Task analysis is defined as the study of what an operator is required to do in terms of observable physical actions or cognitive processes to achieve a system goal is a way of breaking the task down into its component parts. It is also a useful way of looking at how people interact with equipment and with various aspects of their

working environment and enables information to be collected in a systematic way to inform decisions. Implicit in the term Task Analysis is the notion of the task as a definitive entity whereas it might be described as a group of related discriminations, decisions and activities linked by temporal proximity, immediate purpose and common machine output (Miller et al (1953). A more useful overview of the elements that comprise a task is provided by Stammers and Shepherd (1995):

- The term 'task' generally applies to a unit of activity within work situations
- A task may be given to or imposed upon an individual or alternatively carried out on the individual's own initiative and volition
- It is a unit of activity, requiring more than one *simple* physical or mental operation for its completion
- It is often used with the connotation of an activity which is non-trivial, or even in some cases onerous in nature
- It has a defined objective.

Task analyses can be organised in a variety of ways and a commonly used format is to arrange information in a hierarchical form which models the goals of a system and enables the analyst to identify each feature that is pertinent to making design decisions. Using this technique the system goals are re-described in increasing detail until each aspect of the task is understood.

Hierarchical task analysis (HTA) has been applied to problems associated with issues of task design, training, documentation and human reliability analysis. HTA describes a task from its top-level goal down to individual operations. Each of the tasks must completely define how to achieve the top level goal. The HTA has three

structural components: the plan which determines when to move to the next part of the task, the stopping rule - the point at which further re-description will not add value to the process and a numbering system.

The top-level goal of the drug administration system is to deliver drugs to the patient. The task steps necessary to do this are listed as tasks on the subsequent lower levels of the hierarchy and are carried out in the order of the plans. The task analysis begins with activities related to acquiring the relevant drug information from the patient's chart, acquiring the medication and administering the medication. The operations that occupy the lower levels are the focus of the next stage in the process of human error identification.

The Systematic Human Error Reduction and Prediction Approach (SHERPA) is a human error identification technique that analyses tasks and opportunities for errors and was developed for use in the process industries. It identifies potential solutions in a structured way enabling the analyst to define the information that is useful for error reduction strategies. The approach has been validated against other human error identification approaches and has been used in various other domains. It performs well in terms of comprehensiveness, accuracy, consistency, validity, and auditability. It has also been used in health care to analyse the nature and incidence of errors enacted during keyhole surgery as a means of identifying training needs and informing prospective research areas.

SHERPA uses the bottom level outputs, (the actions or operations) of the HTA as its units of information. These were classified into one of a series error modes

using a taxonomy. The consequence of not performing that action or performing it in one of the error mode descriptors is considered and is all recorded in tabular form together with the stage at which the error might be recovered. The probability of the error occurring was also considered and remedial measures to reduce to opportunity for the error noted.

Several design features were suggested which included adding salient features to drug packaging in order to make them more conspicuous and utilising computerised systems such as bar coding technology to overcome errors associated with selecting the correct drug for administration and matching the right patient with the right drug.

Warnings have made extensive use of various visual and cognitive devices in an attempt to capture the attention of the individual, facilitate recognition and comprehension of the message with the intention of influencing their behaviour to bring about compliance. These devices include the use of shape, colour, borders, panels, graphics and text words that are semantically associated with levels of hazard such as the words "deadly", "warning", "caution" or "attention". In some instances these are written in different colours or various font sizes.

Graphics in the form of icons and pictograms have been demonstrated their ability to enhance the semantic meaning of warning messages and facilitated comprehension and memory. In cases of poorly understood pictorials, brief training can improve comprehensibility.

Noticeability is not solely influenced by these factors alone. People who are more familiar with a situation or with the use of a product tend to read, comply with and recall the warning less than those who are less familiar. However people who have had an accident or know someone who has been injured using a product are more likely to exercise caution when using that product. Similarly compliance is not merely a function of noticeability but is influenced by factors such as how much effort or time observance of the message will cost individual. Other issues include stress, perception of risk, training, age and culture.

Some of these factors have been taken into account when assessing the readability of prescription drug labels which should be designed in a way that captures attention. This can be achieved by increasing the overall surface area of the package, adding pictorials or legible print.

A designer was consulted and the issues surrounding medication errors that have appeared in the published literature were outlined. After a brief consideration of existing packages conceptual designs for new packaging were put forward. Colour is used extensively in both branded and generic drugs but its application is arbitrary and is more likely to emphasis insignificant aspects of the package rather than assist users in identifying the drug name or strength. A concept package was designed on which the key pieces of information were located in fixed positions on the package. This would aid users once familiarised with the package to become accustomed to locating relevant information in a precise position on the package.

The concept design was modified enabling it to be applied to medicine bottles in a more three dimensional representation of thc design using elements of the iconography to form tactile features. Comparisons of the two-dimensional design were made with existing packaging as part of a testing procedure. The results were not significant but this may have been due to the experimental design rather than the designs of the concept packages. .

Modelling the designs in a CAD package facilitated the construction of prototypes of the three dimensional design. These took the form of tactile shapes representing the three drug categories diuretics, analgesics and antibiotics constructed such that they fitted the neck of a standard medicine bottle. A blind touch test indicated that tactile features to medication bottles produced a good success rate and were demonstrably learnable.

One of the features of the design that caused participants difficulty was the design of the icons used on the labels. These were intended to facilitate recognition of the relevant drug category therefore a one-day design workshop was organised to generate further designs for icons. The selection of drug categories on which the icon representations would be based were made largely on the description of the various drug categories. The designers selected those categories they believed to be within their ability to represent graphically. For some drug categories this transpired not to be the case and even through a process of simplifying the description of the category there still remained difficulties in attempting to represent the pharmacological function of the medications in a concise way. Some drug categories lent themselves to different levels of description and a wide range of

different images were produced. Others drug categories such as vitamins seemed to possess simple descriptors that were more complex when attempts were made to represent them graphically. Whilst the designers recognised that abstract concepts were easier to depict in symbolic form and that symbols tend to be recalled more easily by users, the level of detail required for some categories was best captured pictorially.

Despite the challenge of producing representative icons in a short space of time the designers did generate several images that were standardised and then ranked for appropriateness. There were differences between the designers and the larger participant group as to which of the images were most representative of the drug categories. A selection of the icons was ranked by nurses and medical professionals for comprehension. It was noted that with the exception of the icons for sedatives, the images were not well understood which suggests the icons would need to be redesigned in an attempt to improve comprehension scores. Further investigation into how nurses view medications might yield useful findings that could be used to inform further designs of icons. The effects of training may need to be analysed in order to facilitate understanding of icons.

In the SHERPA analysis technological solutions in the form of barcoding and RFID tagging were suggested to address the problem of errors caused by failure to acquire the appropriate information from the medication chart, errors associated with selection of the wrong drug and errors related to patient identity. Such systems have been used for some time in the US and at the present time are undergoing trials in the UK. Chapter 6 assesses the design of a drug administration system that

links the patient information with the drug package by way of a device that uses an iButton. The patient's identity and drug requirements are programmed into the device upon admission and the patient wears the device as an identity bracelet on their wrist. Drug packages to which an iButton has been attached are held against the reader in the bracelet at the time of administration. If the drug is the correct one this is indicated on the identity bracelet. The device performed well against other types of identity bracelet. Nurses were able to use it to read patient information and to check for expired drugs. The effect of the design solutions is illustrated in figure 7.1.

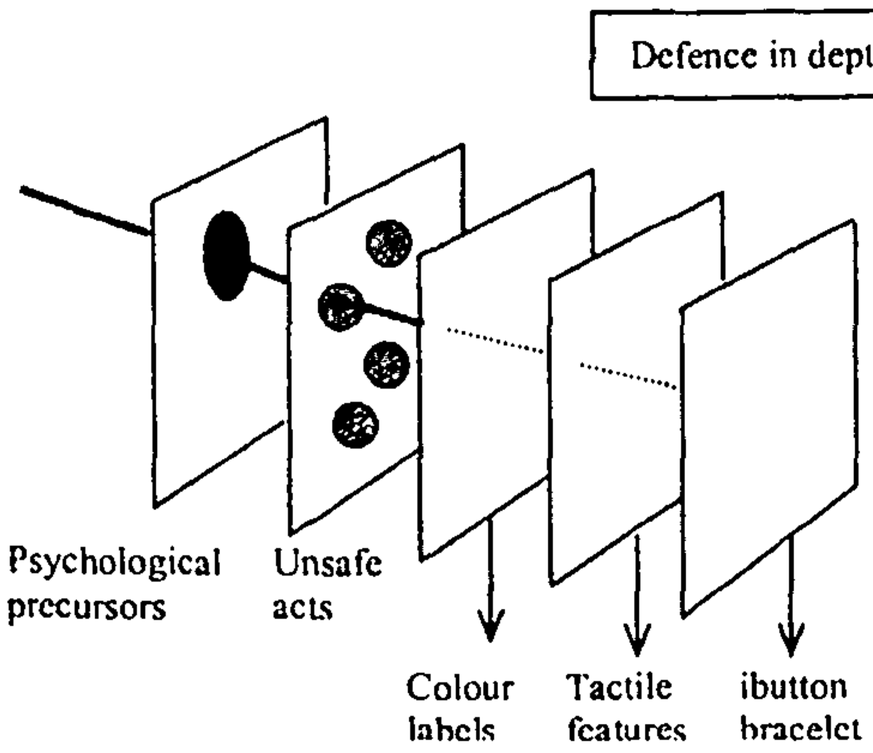


Figure 7.1: Model of how the design products reduce the accident trajectory

7.2 DIRECTIONS FOR FURTHER RESEARCH

7.2.1 Mental constructs of medication administration

When designing the labels it was assumed that using icons to signify the therapeutic categories into which medications are grouped would simplify the recognition of drug names. This was not the case. One reason for this finding may be that in reality people have more complex mental models of medications. A series of

further studies may uncover what these might be. Investigation into how nurses construct their working knowledge of drugs would give insight to the semantic elements of those models and would inform designers new systems.

7.2.2 Tactile features

Whilst carrying out this research the author was struck by how many observers remarked on how well the tactile features designed for the medication bottles would suit the needs of older people, who often take multiple medication preparations. Extending the range of tactile devices to include other drug categories would be beneficial as these features are likely to lead to easier identification. It is not uncommon for patients to refer to their 'heart tablets' or their 'water tablets'. The tactile feature makes it easier to differentiate between the categories of drug both as an aid to vision and by touch.

7.2.3 Expanded application

The limitation of this study is that it was based on a model of nurses' drug administration. Observations carried out to identify human error at the task level may reveal other types of errors. In Chapter 2 reference was made to the patient's own drug delivery system which is often used in preference to the ward pharmacy system. It might be beneficial to compare the types of errors that occur between the two systems using SHERPA.

This study has considered how packaging might be applied to tablets and medicines. However, it is injections that give much cause for concern as there are more opportunities for error during preparation since some of these have to be

reconstituted or diluted prior to administration. A detailed HTA of injections would yield an interesting examination of this process. Similarly the programming of infusion devices is an area that would greatly benefit from analysis using human error identification techniques. These devices have proved troublesome for nurses as it is often difficult to verify that the programme is correct due to lack of feedback systems. The interfaces of these devices have undergone redesign in the past few years, yet errors are still being reported. Error prevention becomes ever more critical with the increased use of patient controlled analgesic pumps. An HTA combined with a SHERPA analysis might reveal whether or not current interfaces are functioning as the designer intended.

Infusion pumps have palpably highlighted how much technology has altered the nurse's task and this is ever more so with the increased use of barcoding and RFID systems. However errors are still apparent within these systems. Whilst it is the case that there are fewer wrong dose, wrong drug, wrong time errors as there is less reliance on the nurse's memory with regard to these issues, computer systems still have to be programmed and backed up. Communication still has to be maintained between individuals on the same ward as well as between colleagues in other departments and whilst technology can facilitate this process, it also brings changes in the quality and salience of the information exchange. A cognitive task analysis may indicate the effects of the technology on communication and working practices and serve to inform second and third generation products of this type.

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APPENDIX A

General drug categories from which selections were made

CDER General Drug Categories

Analgesics: Drugs that relieve pain. There are two main types: non-narcotic analgesics for mild pain, and narcotic analgesics for severe pain.

Antacids: Drugs that relieve indigestion and heartburn by neutralizing stomach acid.

Antianxiety Drugs: Drugs that suppress anxiety and relax muscles (sometimes called anxiolytics, sedatives, or minor tranquilizers).

Antiarrhythmics: Drugs used to control irregularities of heartbeat.

Antibacterials: Drugs used to treat infections.

Antibiotics: Drugs made from naturally occurring and synthetic substances that combat bacterial infection. Some antibiotics are effective only against limited types of bacteria. Others, known as broad spectrum antibiotics, are effective against a wide range of bacteria.

Anticoagulants and Thrombolytics: Anticoagulants prevent blood from clotting. Thrombolytics help dissolve and disperse blood clots and may be prescribed for patients with recent arterial or venous thrombosis.

Anticonvulsants: Drugs that prevent epileptic seizures.

Antidepressants: There are two main groups of mood-lifting antidepressants: tricyclics and monoamine oxidase inhibitors.

Antidiarrheals: Drugs used for the relief of diarrhoea. Two main types of antidiarrheal preparations are simple adsorbent substances and drugs that slow down the contractions of the bowel muscles so that the contents are propelled more slowly.

Antiemetics: Drugs used to treat nausea and vomiting.

Antifungals: Drugs used to treat fungal infections, the most common of which affect the hair, skin, nails, or mucous membranes.

Antihistamines: Drugs used primarily to counteract the effects of histamine, one of the chemicals involved in allergic reactions.

Antihypertensives: Drugs that lower blood pressure. The types of antihypertensives currently marketed include diuretics, beta-blockers, calcium channel blocker, ACE (angiotensin- converting enzyme) inhibitors, centrally acting antihypertensives and sympatholytics.

Anti-Inflammatories: Drugs used to reduce inflammation - the redness, heat, swelling, and increased blood flow found in infections and in many chronic noninfective diseases such as rheumatoid arthritis and gout.

Antineoplastics: Drugs used to treat cancer.

Antipsychotics: Drugs used to treat symptoms of severe psychiatric disorders. These drugs are sometimes called major tranquilizers.

Antipyretics: Drugs that reduce fever.

Antivirals: Drugs used to treat viral infections or to provide temporary protection against infections such as influenza.

Barbiturates: See "sleeping drugs."

Beta-Blockers: Beta-adrenergic blocking agents, or beta-blockers for short, reduce the oxygen needs of the heart by reducing heartbeat rate.

Bronchodilators: Drugs that open up the bronchial tubes within the lungs when the tubes have become narrowed by muscle spasm. Bronchodilators ease breathing in diseases such as asthma.

Cold Cures: Although there is no drug that can cure a cold, the aches, pains, and fever that accompany a cold can be relieved by aspirin or acetaminophen often accompanied by a decongestant, antihistamine, and sometimes caffeine.

Corticosteroids: These hormonal preparations are used primarily as anti-inflammatories in arthritis or asthma or as immunosuppressives, but they are also useful for treating some malignancies or compensating for a deficiency of natural hormones in disorders such as Addison's disease.

Cough Suppressants: Simple cough medicines, which contain substances such as honey, glycerine, or menthol, soothe throat irritation but do not actually suppress coughing. They are most soothing when taken as lozenges and dissolved in the mouth. As liquids they are probably swallowed too quickly to be effective. A few drugs are actually cough suppressants. There are two groups of cough suppressants: those that alter the consistency or production of phlegm such as mucolytics and expectorants; and those that suppress the coughing reflex such as codeine (narcotic cough suppressants), antihistamines, dextromethorphan and isoproterenol (non-narcotic cough suppressants).

Cytotoxics: Drugs that kill or damage cells. Cytotoxics are used as antineoplastics (drugs used to treat cancer) and also as immunosuppressives.

Decongestants: Drugs that reduce swelling of the mucous membranes that line the nose by constricting blood vessels, thus relieving nasal stuffiness.

Diuretics: Drugs that increase the quantity of urine produced by the kidneys and passed out of the body, thus ridding the body of excess fluid. Diuretics reduce water logging of the tissues caused by fluid retention in disorders of the heart, kidneys, and liver. They are useful in treating mild cases of high blood pressure.

Expectorant: A drug that stimulates the flow of saliva and promotes coughing to eliminate phlegm from the respiratory tract.

Hormones: Chemicals produced naturally by the endocrine glands (thyroid, adrenal, ovary, testis, pancreas, parathyroid). In some disorders, for example, diabetes mellitus, in which too little of a particular hormone is produced, synthetic equivalents or natural hormone extracts are prescribed to restore the deficiency. Such treatment is known as hormone replacement therapy.

Hypoglycemics (Oral): Drugs that lower the level of glucose in the blood. Oral hypoglycemic drugs are used in diabetes mellitus if it cannot be controlled by diet alone, but does require treatment with injections of insulin.

Immunosuppressives: Drugs that prevent or reduce the body's normal reaction to invasion by disease or by foreign tissues. Immunosuppressives are used to treat autoimmune diseases (in which the body's defenses work abnormally and attack its own tissues) and to help prevent rejection of organ transplants.

Laxatives: Drugs that increase the frequency and ease of bowel movements, either by stimulating the bowel wall (stimulant laxative), by increasing the bulk of bowel contents (bulk laxative), or by lubricating them (stool-softeners, or bowel movement-softeners). Laxatives may be taken by mouth or directly into the lower bowel as suppositories or enemas. If laxatives are taken regularly, the bowels may ultimately become unable to work properly without them.

Muscle Relaxants: Drugs that relieve muscle spasm in disorders such as backache. Antianxiety drugs (minor tranquilizers) that also have a muscle-relaxant action are used most commonly.

Sedatives: Same as Antianxiety drugs.

Sex Hormones (Female): There are two groups of these hormones (estrogens and progesterone), which are responsible for development of female secondary sexual characteristics. Small quantities are also produced in males. As drugs, female sex hormones are used to treat menstrual and menopausal disorders and are also used as oral contraceptives. Estrogens may be used to treat cancer of the breast or prostate, progestins (synthetic progesterone to treat endometriossis).

Sex Hormones (Male): Androgenic hormones, of which the most powerful is testosterone, are responsible for development of male secondary sexual characteristics. Small quantities are also produced in females. As drugs, male sex hormones are given to compensate for hormonal deficiency in hypopituitarism or disorders of the testes. They may be used to treat breast cancer in women, but either synthetic derivatives called anabolic steroids, which have less marked side- effects, or specific anti-estrogens are often preferred. Anabolic steroids also have a "body building" effect that has led to their (usually nonsanctioned) use in competitive sports, for both men and women.

Sleeping Drugs: The two main groups of drugs that are used to induce sleep are benzodiazepines and barbiturates. All such drugs have a sedative effect in low doses and are effective sleeping medications in higher doses. Benzodiazepines drugs are used more widely than barbiturates because they are safer, the side-effects are less marked, and there is less risk of eventual physical dependence.

Tranquilizer: This is a term commonly used to describe any drug that has a calming or sedative effect. However, the drugs that are sometimes called minor tranquilizers should be called antianxiety drugs, and the drugs that are sometimes called major tranquilizers should be called antipsychotics.

Vitamins: Chemicals essential in small quantities for good health. Some vitamins are not manufactured by the body, but adequate quantities are present in a normal diet. People whose diets are inadequate or who have digestive tract or liver disorders may need to take supplementary vitamins.

http://www.fda.gov/cder/handbook/category.htm

APPENDIX B

Drawings for the 3D concept designs

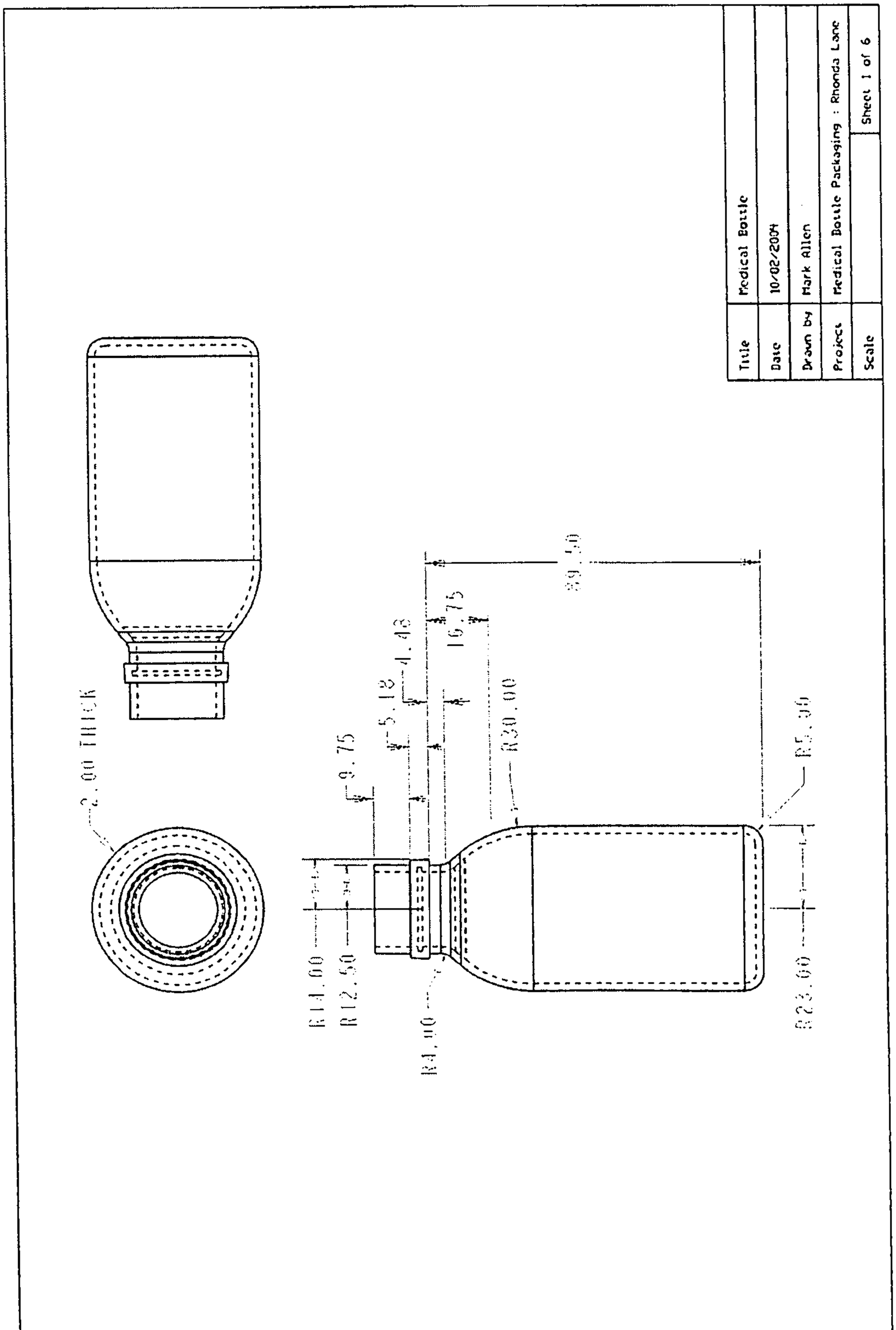


Figure B1: Pro- Engineer drawing of a standard 100ml glass medicine bottle

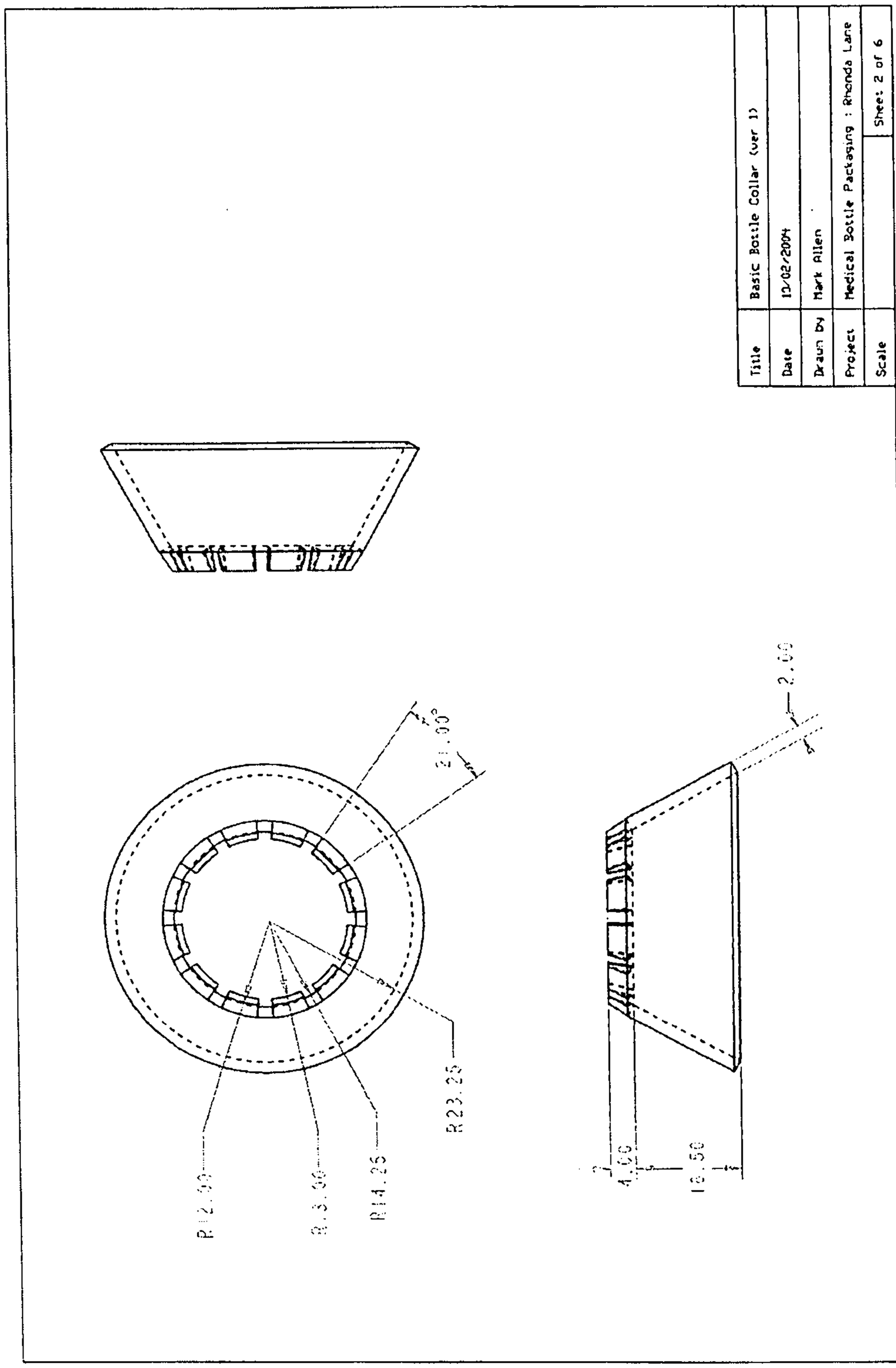


Figure B2: Pro- Engineer plan for construction of the drug identification bottle collar

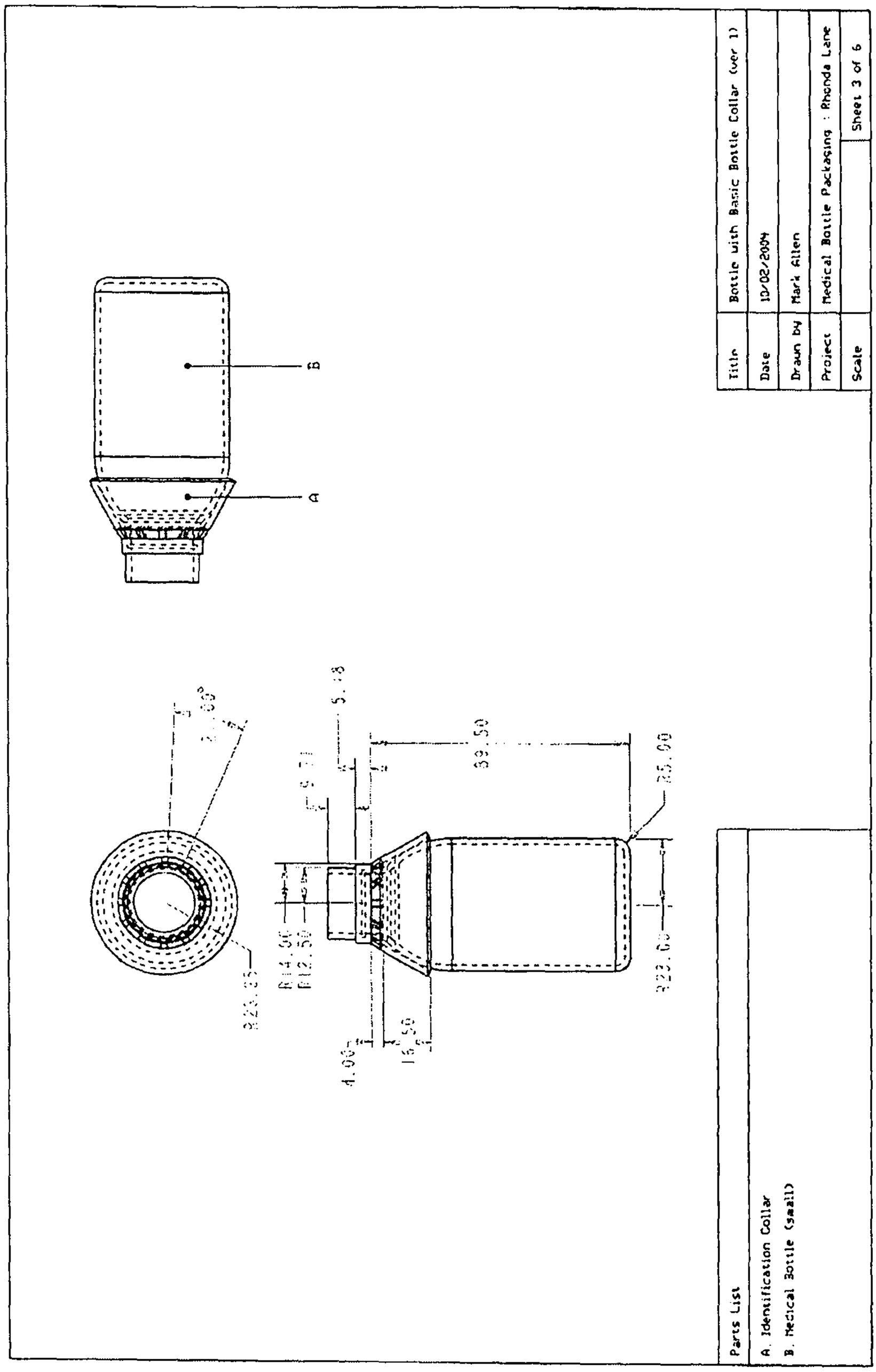


Figure B3: Pro- Engineer drawing of the basic drug identification collar

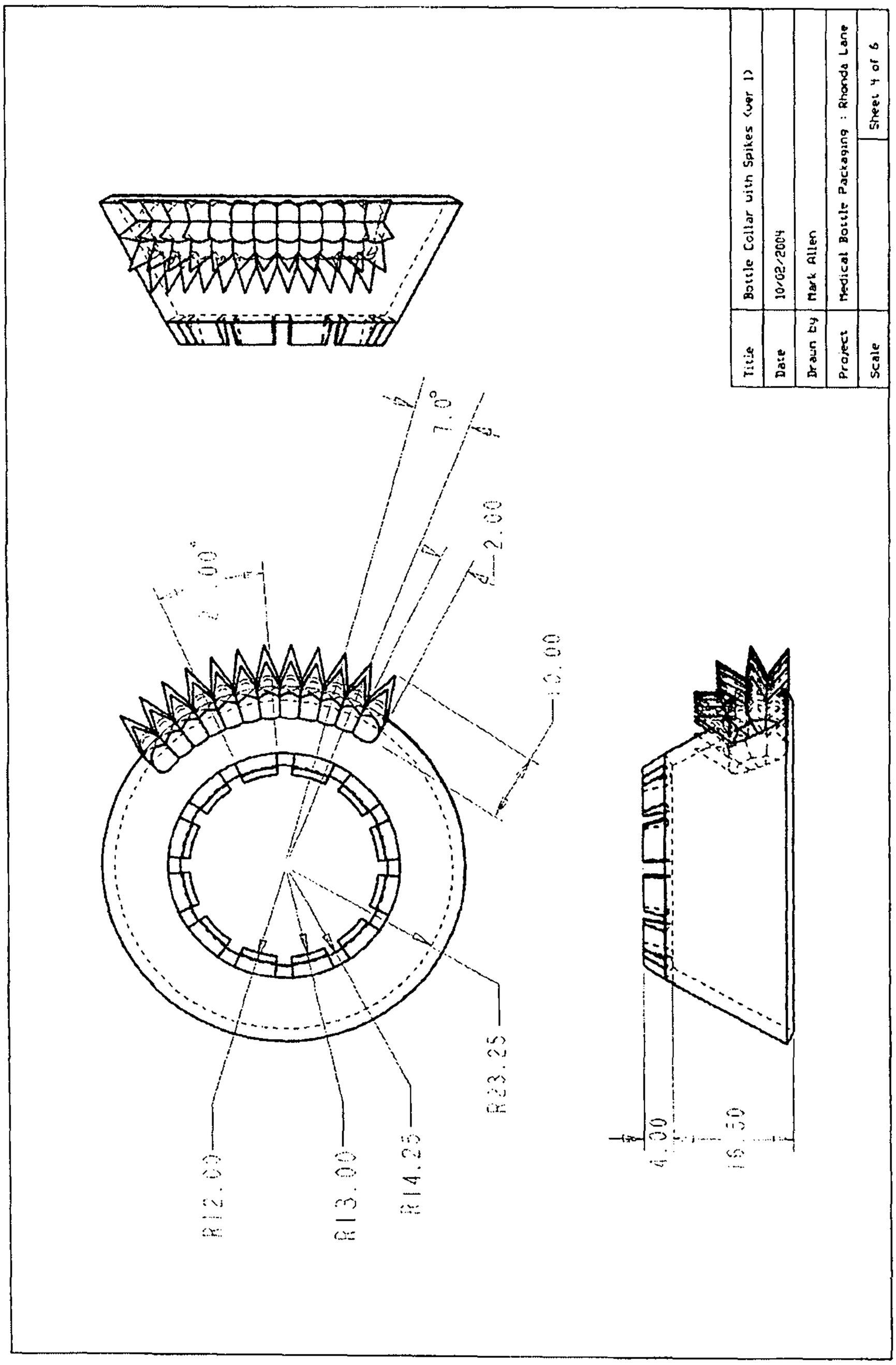


Figure B4: Pro- Engineer drawing of the drug identification collar with the haptic feature representing analgesic (pain relieving drugs)

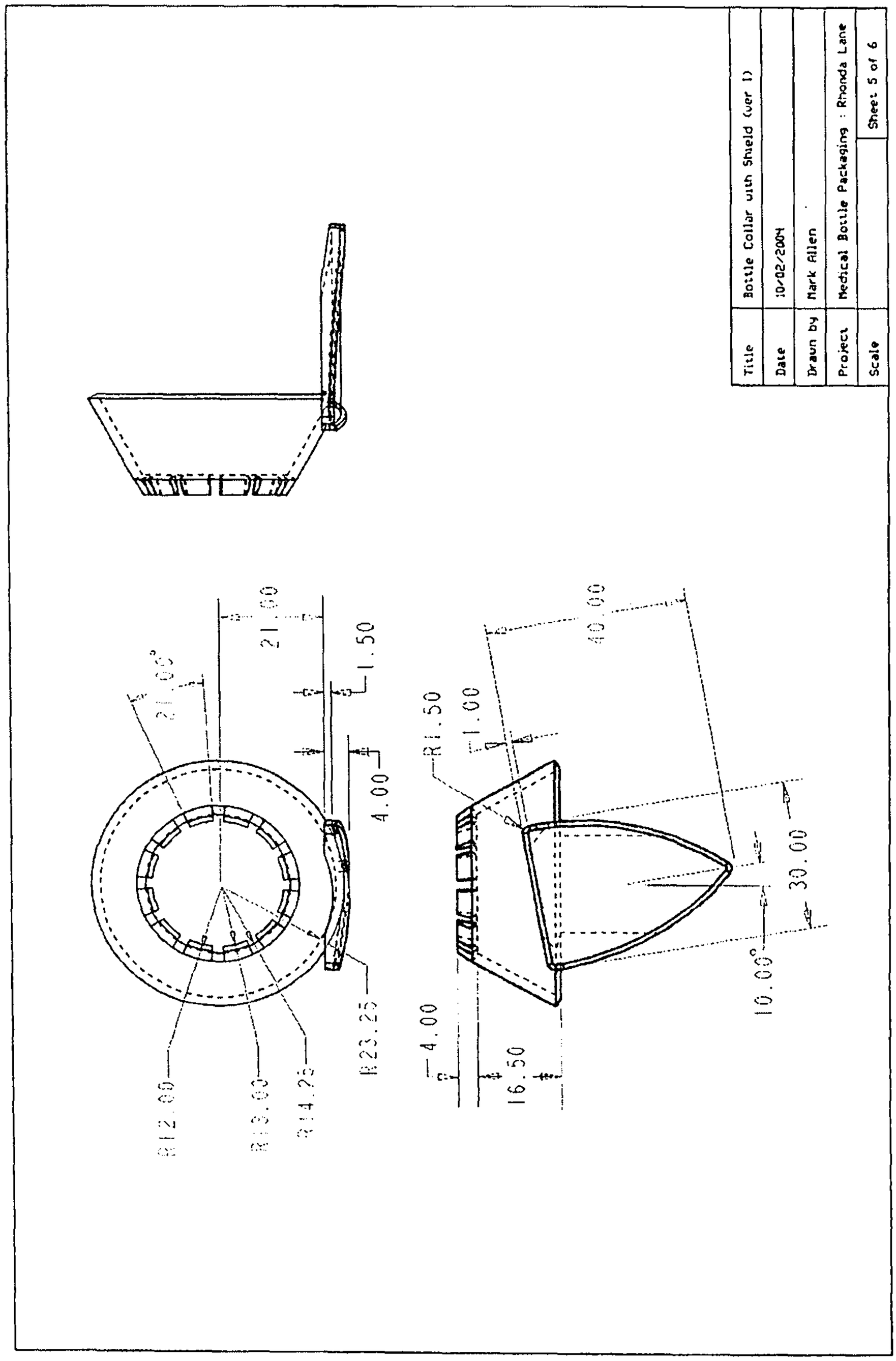


Figure B5 Pro- Engineer drawing of the drug identification collar with the haptic feature representing antibiotic drugs

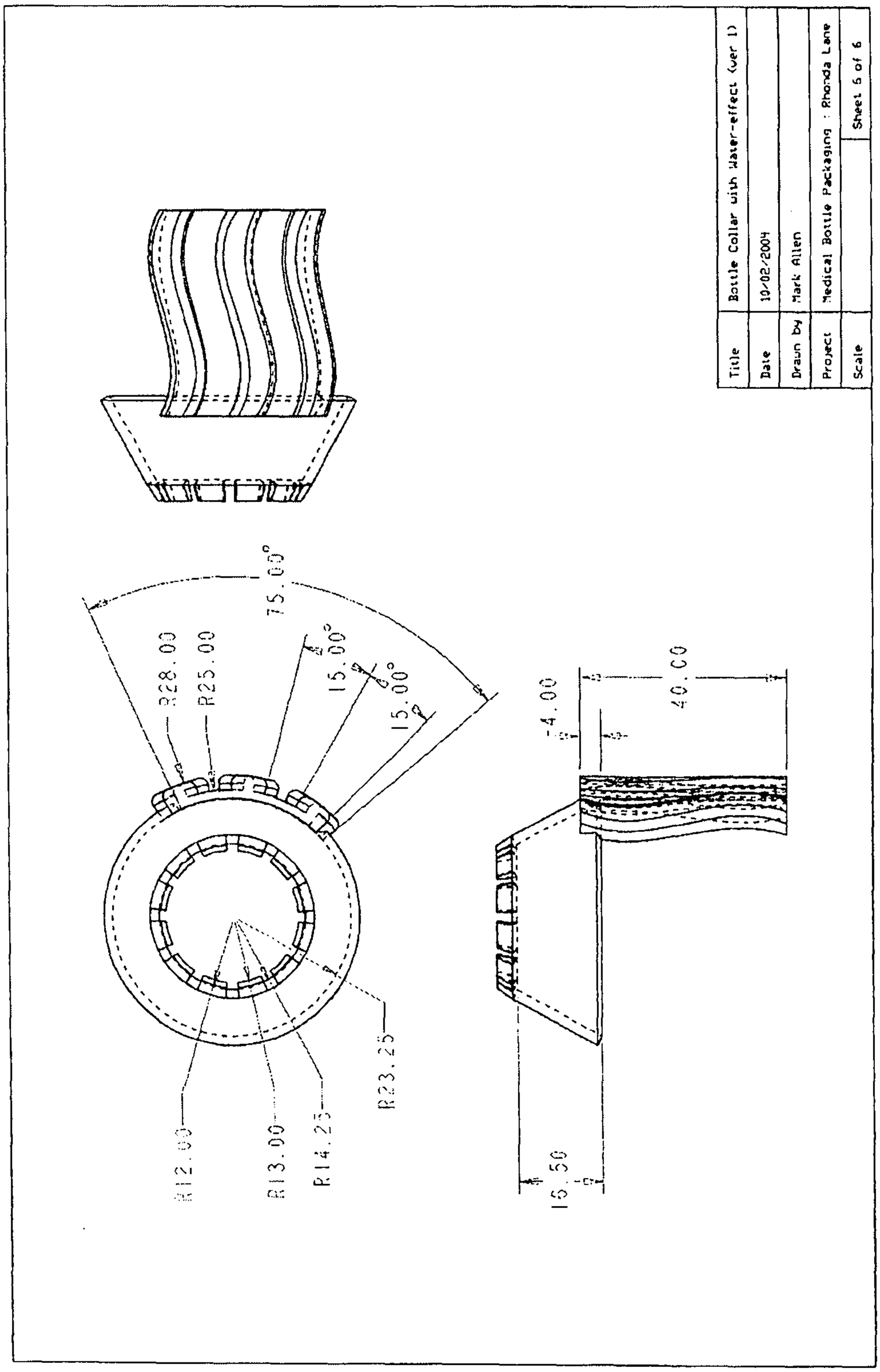
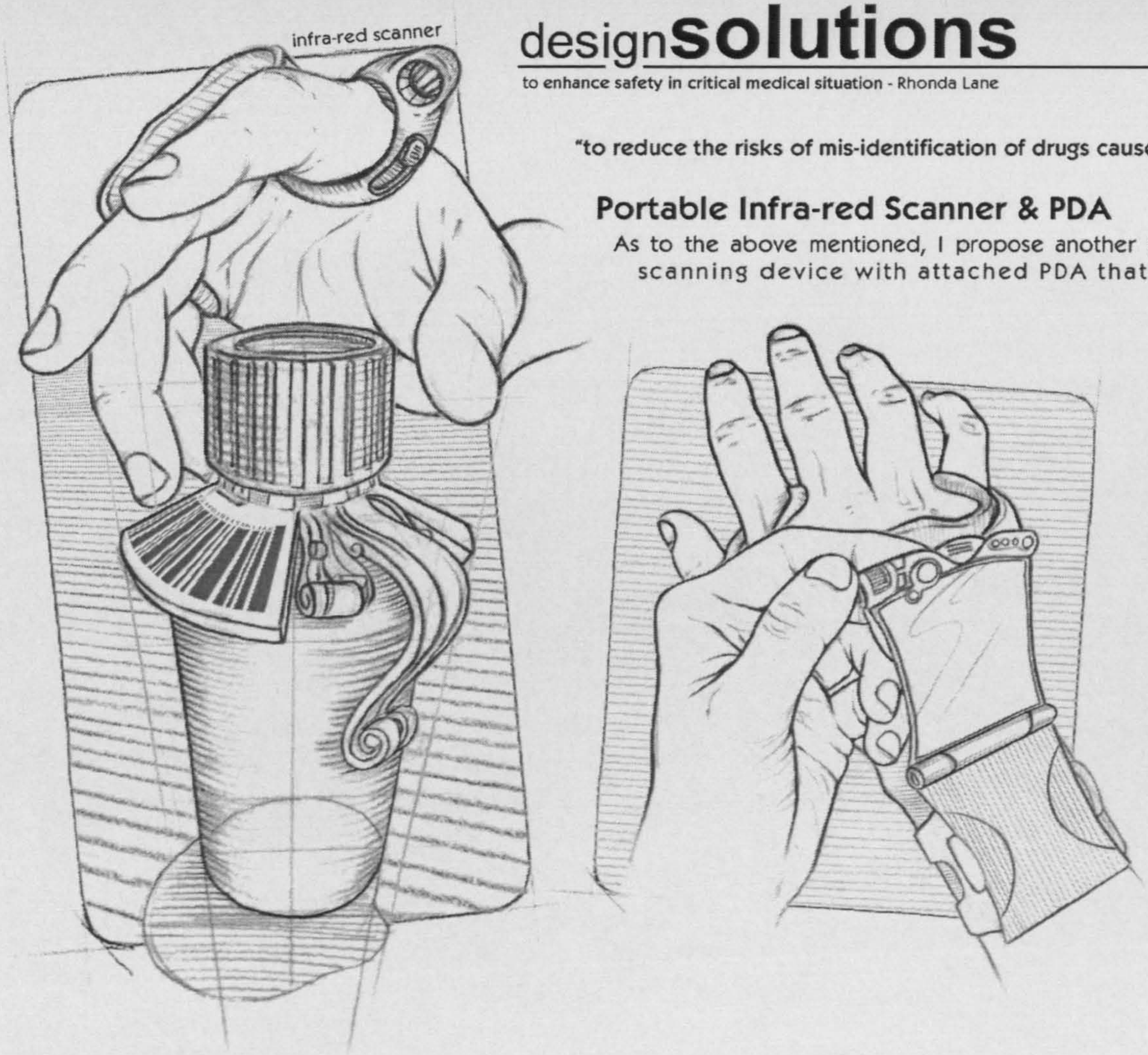


Figure C6: Pro- Engineer drawing of the drug identification collar with the haptic feature representing diuretic (fluid regulating) drugs

Appendix C

Concept designs for a scanner and PDA



designsolutions

part V

to enhance safety in critical medical situation - Rhonda Lane

"to reduce the risks of mis-identification of drugs caused by human errors."

Portable Infra-red Scanner & PDA

As to the above mentioned, I propose another possible solution - a portable scanning device with attached PDA that can enable medical staff to verify the drug:

1) uses "Smart Labels" and infra-red technology.
2) even with confusing packaging designs, the device will be able to identify the drug as long as there is a "Smart Label" on it.
3) the PDA can be customised with sound, graphics, or even animation to represent each drug.
4) has the ability to search for drugs too. As well as assist in stock-taking.
5) lightweight and small, it will be convenient to wear, even when the device is not in use.

Figure C1:Portable Scanner and PDA

designsolutions

part VI

to enhance safety in critical medical situation - Rhonda Lane

THE SCANNER

The scanner is designed with maximum comfort in mind, which is the reason why it is separated from the PDA. It communicates with the PDA using bluetooth technology.

1) made from thin, flexible ABS.
2) wraps around the 'folding lines' of the fingers so it hardly pose any restriction. The scanner is located at a hard to reach place, too posing little restriction.
3) the scanner houses the ON/OFF switch to accomodate for fast reaction. It is easily accessible by the thumb.
4) no worry of sweaty palms
5) very light weight.

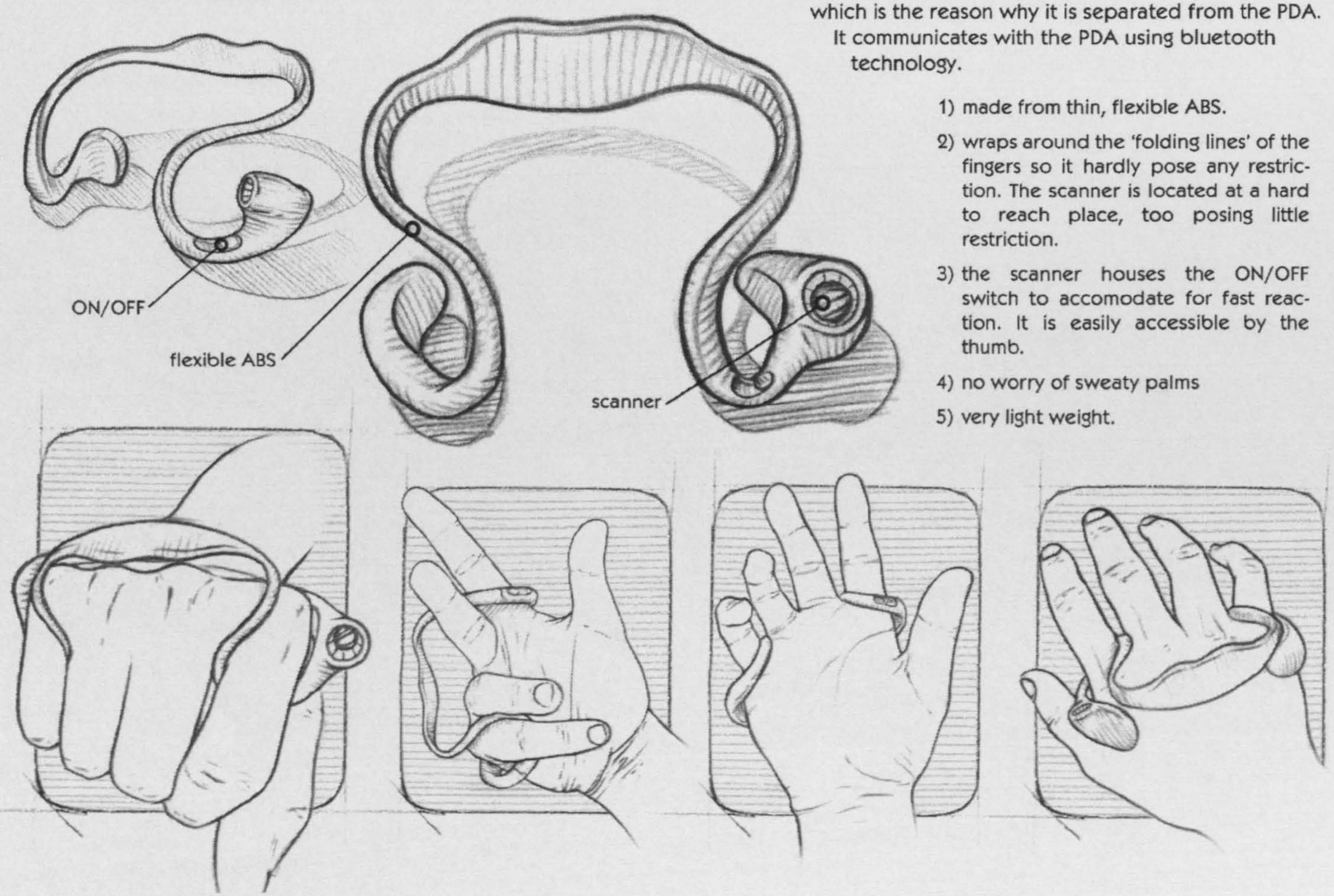


Figure C2: Scanner in detail

designsolutions

part VII

to enhance safety in critical medical situation - Rhonda Lane

The PDA

Considering the current advances in technology, the possibilites for the PDA is endless. The following is what I propose:

1) auto-identifies "smart tags" whenever in range.
2) options to display drugs names with accompanying sound, graphics or animation. This is only programmable by authorities who has to decide the set of iconography for the staff to familiarise with. Too many variations might lead to confusion.
3) has the capability to SEARCH for drugs from an existing data list. Users can assign hotkeys for the more commonly used drugs.
4) has the capability to do STOCKTAKING.
5) have individual user accounts for staff who shares the same set. Each can personalise their own preferences, such as hotkeys, etc.
6) SILENT/NORMAL mode so as not to disturb patients from resting.
7) ON/OFF control on scanner for quick reaction.
8) rotatable screen for maximum flexiblity.

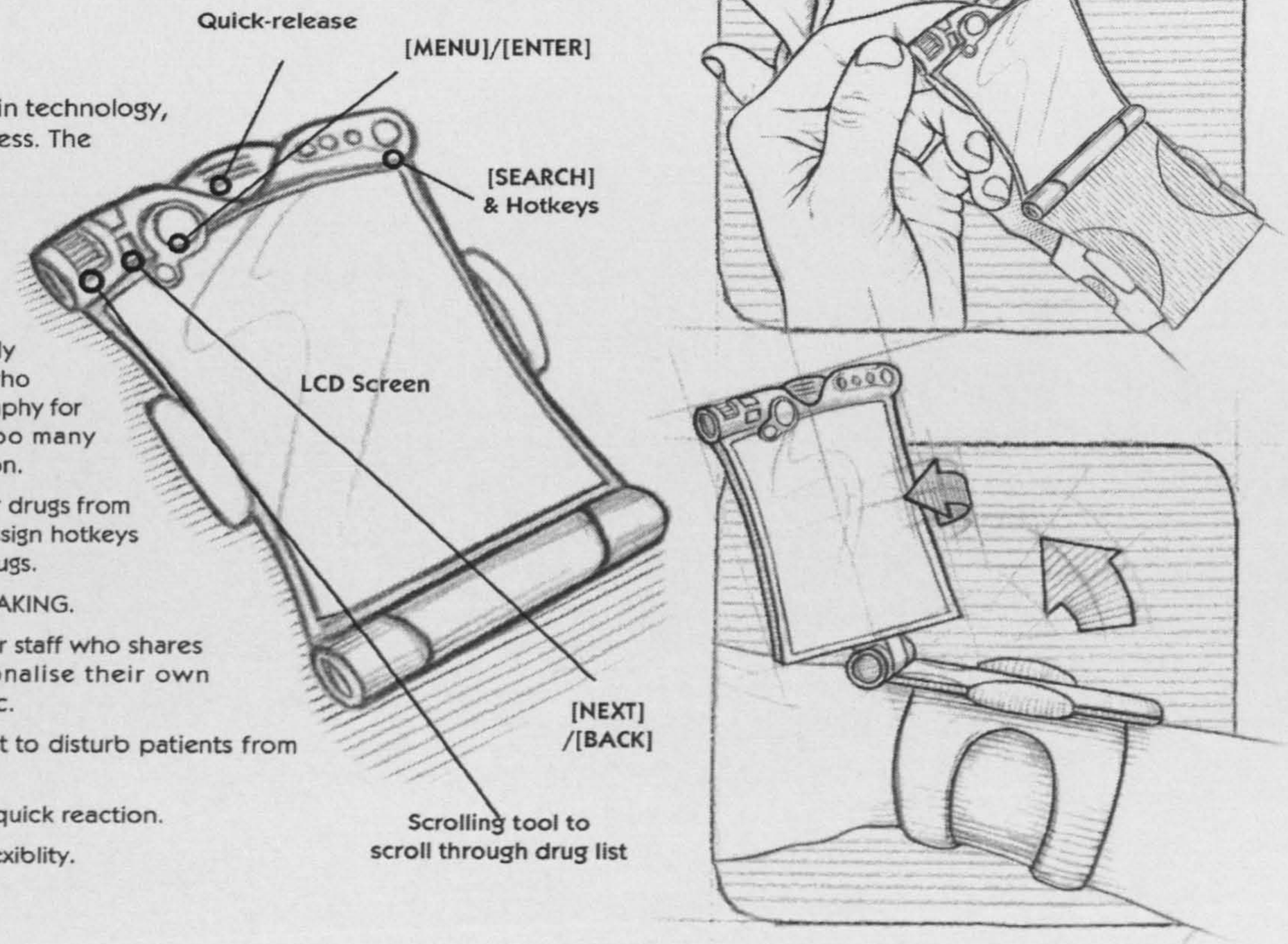
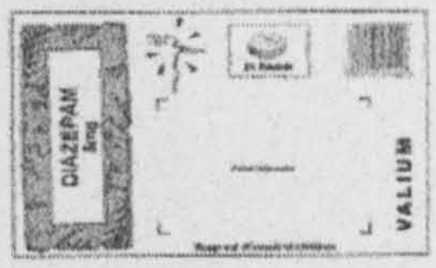
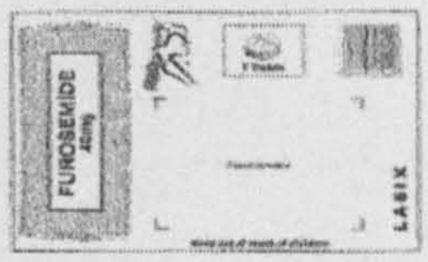


Figure C3:Wearable PDA

APPENDIX D

Presentation of the Slides





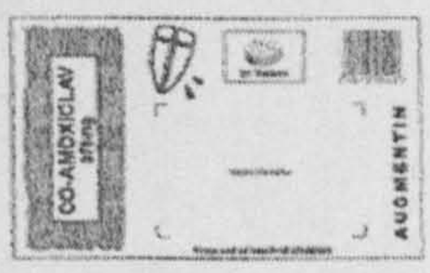
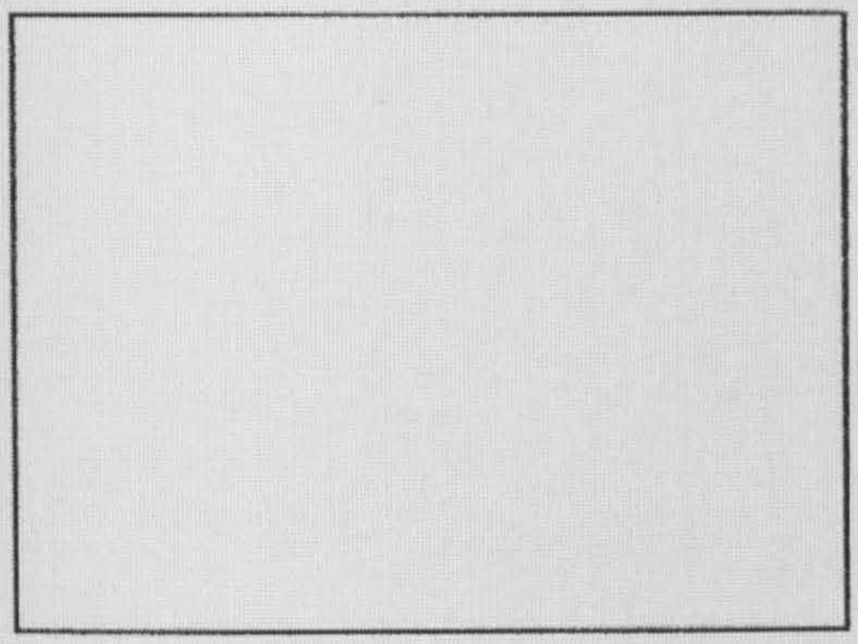
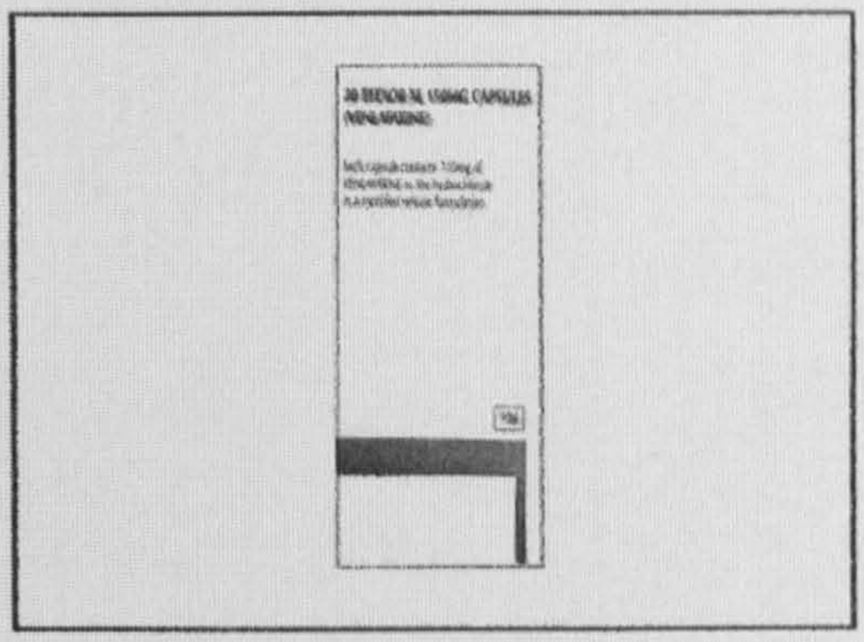
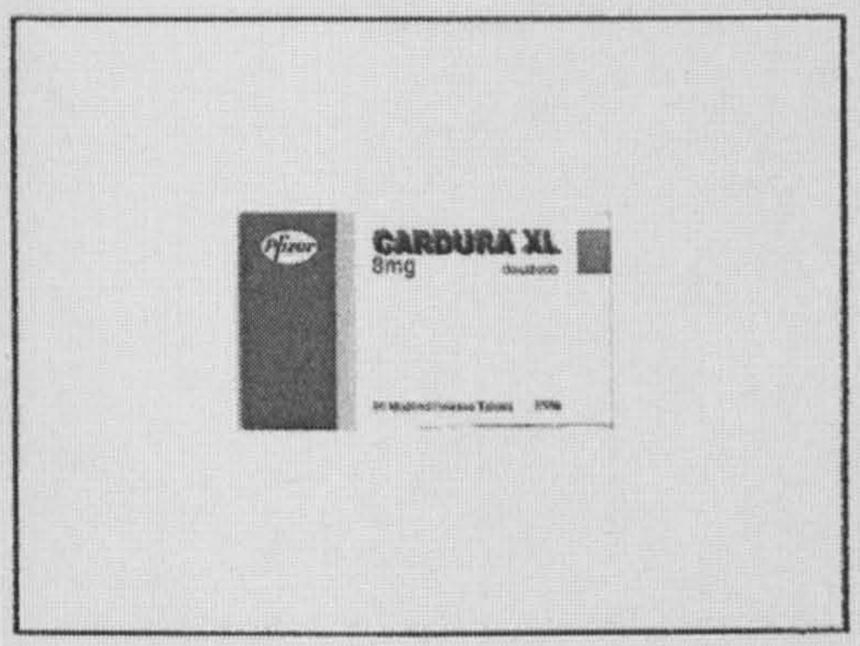
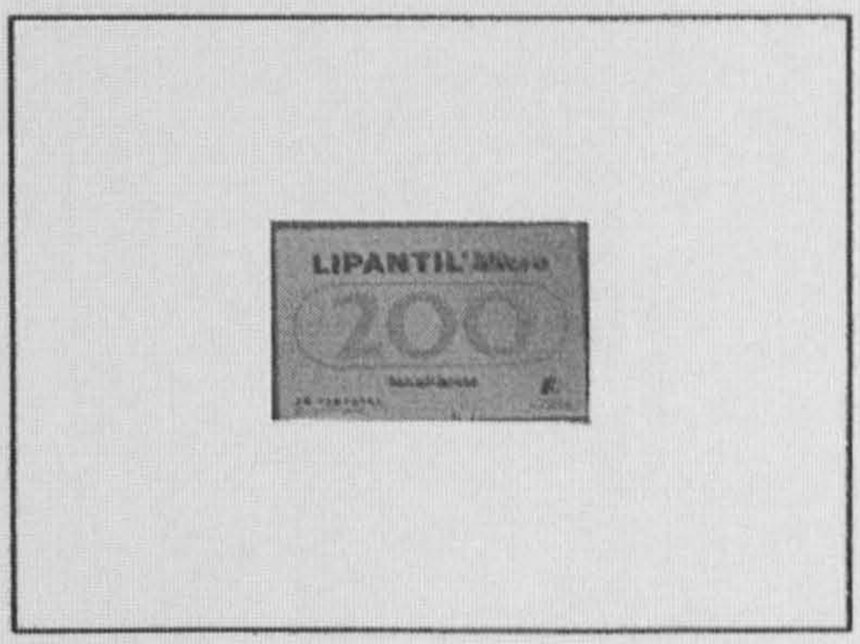


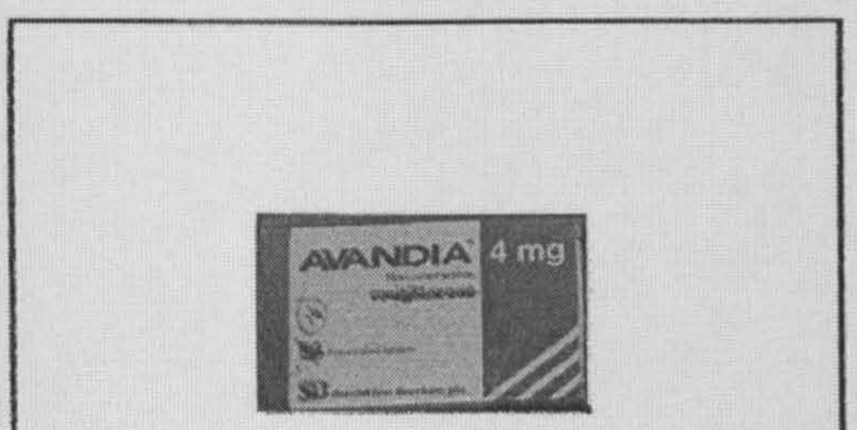
Figure D1: Plan of presentation of "new"slides - the order was of slide presentation was randomized for each trial and the order of presentation of 'old' and 'new' alternated











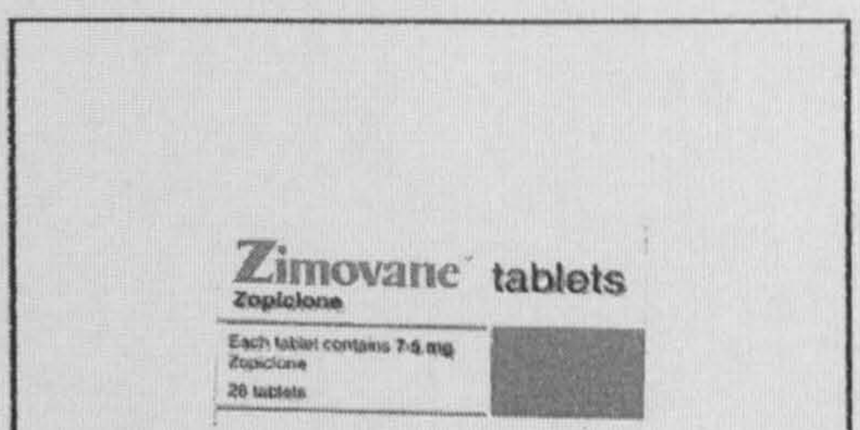


Figure D2: Plan of presentation of "Old"slides - the order was of slide presentation was randomized for each trial and the order of presentation of 'old' and 'new' alternated

APPENDIX E

Instructions to participants

Instructions to participants

Thank you for agreeing to participate in this study.

Your task will be to identify the names of drugs from a series of images displayed on the computer screen. Most drugs have two names – a brand name and generic name. You will be asked to give the **generic** name for each drug. A list of generic drug names is given on Sheets 1 and 2. Please take a moment to read the sheets now.

In each image a drug strength is also given and you will be required to state what that strength is. As soon as you are able to recognise the generic name and drug strength just say them out loud. Please state the generic drug name first followed by the strength.

If you have any questions please ask them now.

Thank you once again for your time and patience.

Rhonda Lane
PhD Researcher
Brunel University

Sheet 1

GENERIC DRUG NAMES

Warfarin

Diazepam

Co-Amoxiclav

Furosemide

Paracetamol

Sheet 2

GENERIC DRUG NAMES

Doxazosin

Fenofibrate

Rosiglitazone

Zopiclone

Venlafaxine

APPENDIX F

The 3D test

Student participation in a class memory test

As part of a PhD study we would like you to take part in a short memory test. This involves a short explanation of the test procedure and familiarisation of three types of collars fitted to medicine bottles. This should take no more than ten minutes during one lesson.

The second part of the memory test takes place during the lesson on the following day and will take each participant less than five minutes to identify the type of collar fitted to a bottle whilst doing a blind touch test.

There will be minimal disruption of the two lessons and the student's learning will not be affected.

If you are under 18 please ask a parent/guardian to give their consent to this test by signing below, and bring this with you to your next class.

.....

Thank you in anticipation, Rhonda Lane.

APPENDIX G

Original workshop drawings

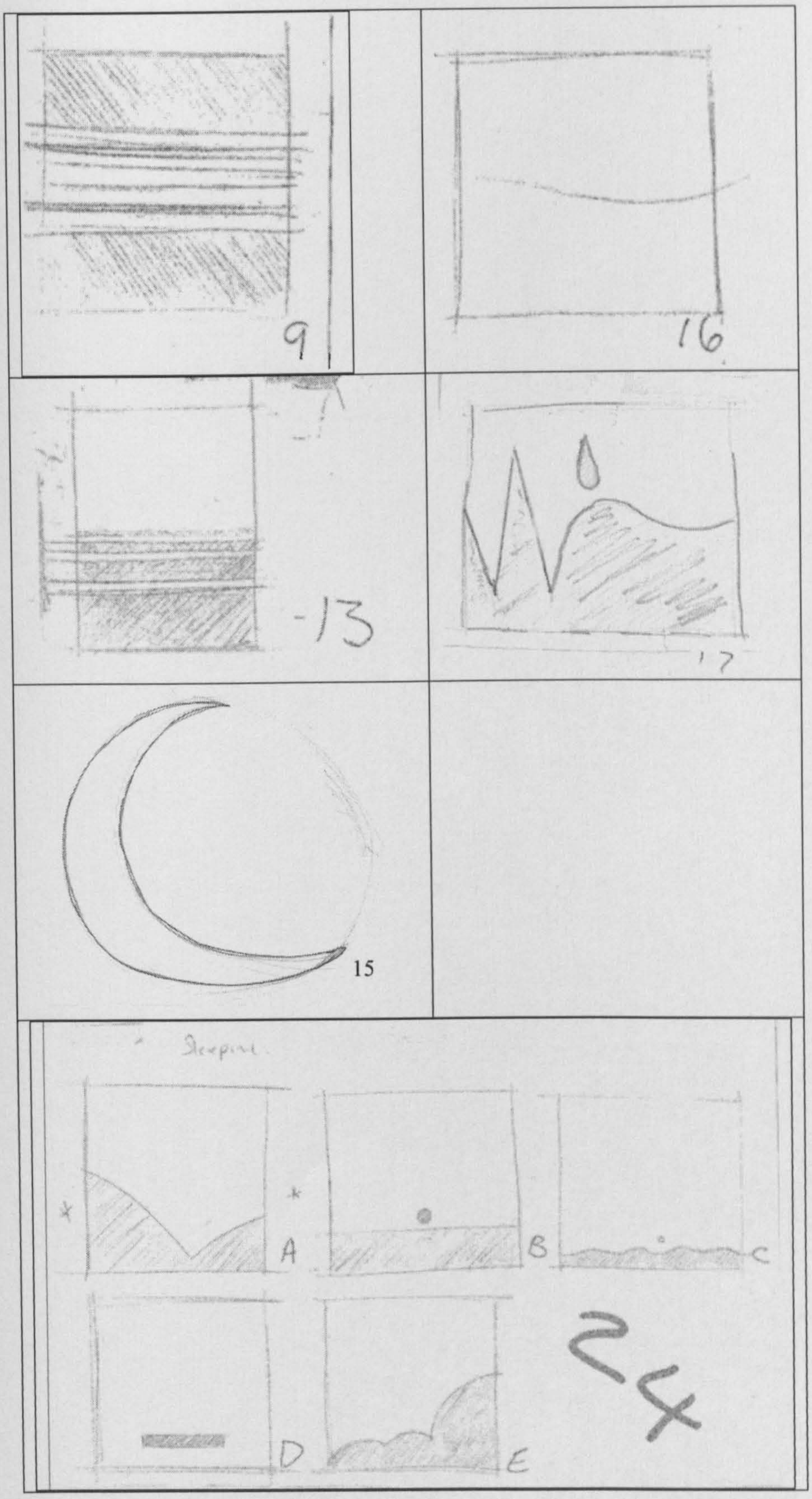


Figure G.1 Rejected images for sedatives

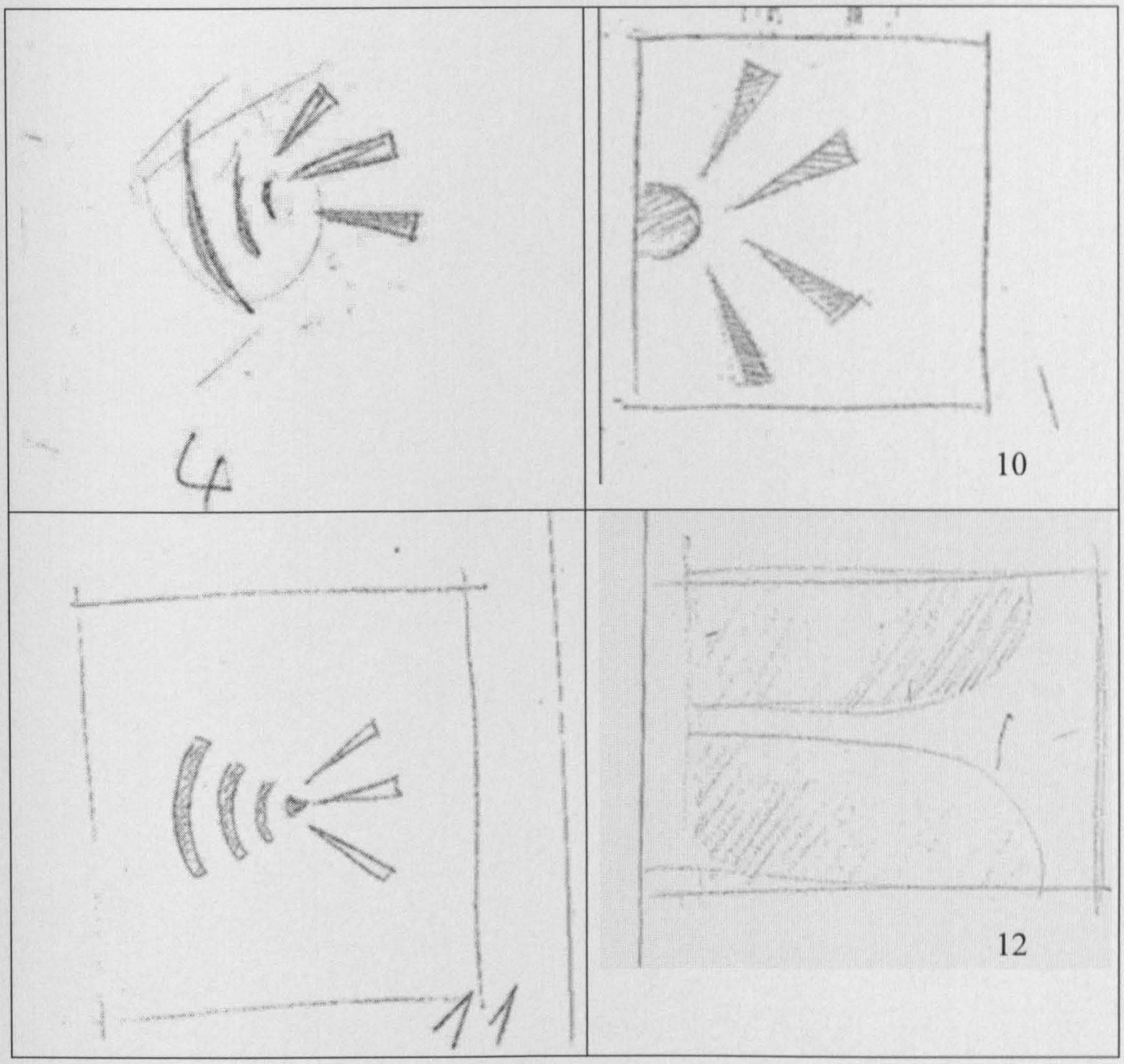


Figure G.2: Rejected drawings for expectorants

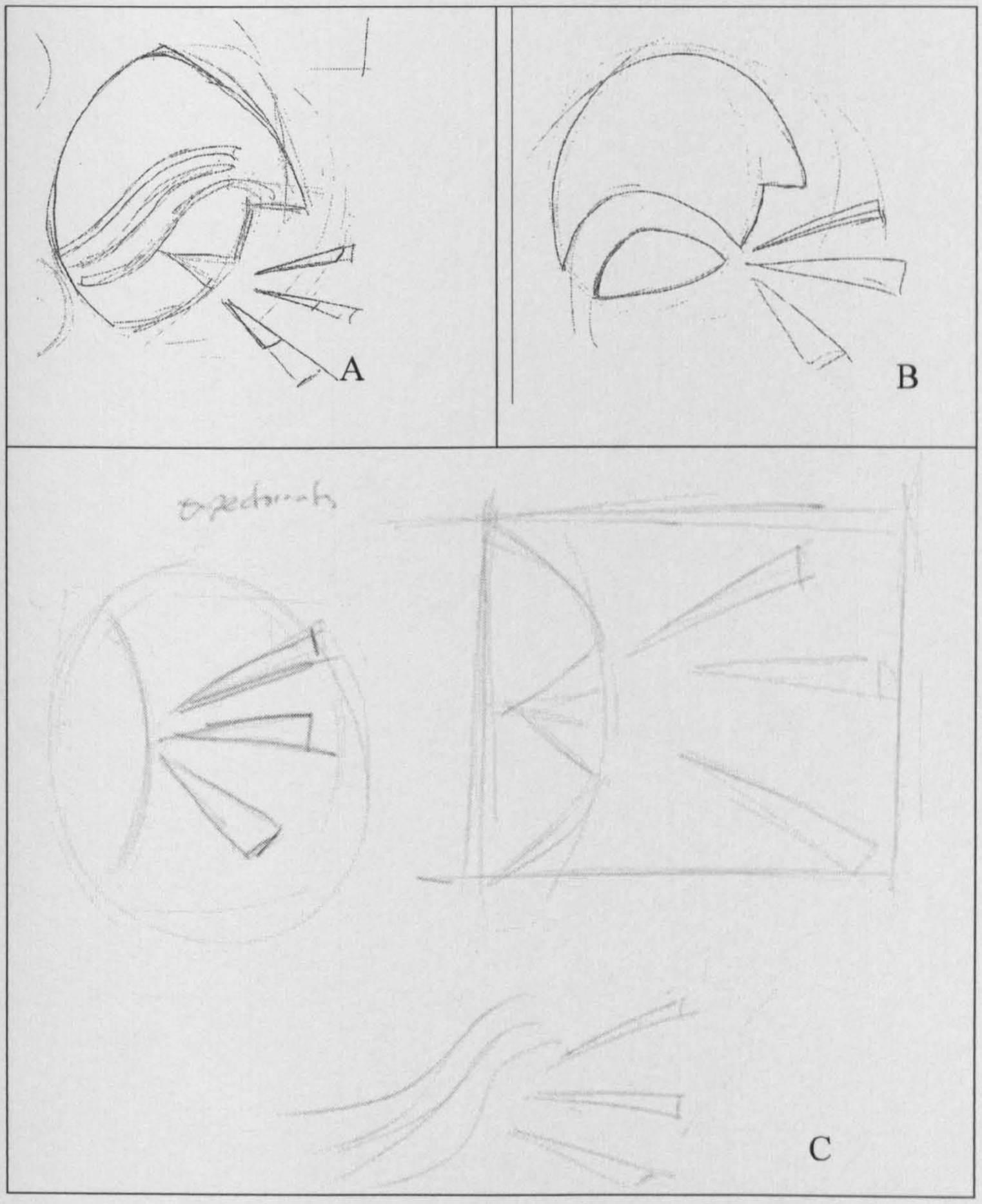


Figure G.3 Rough drawings for expectorants

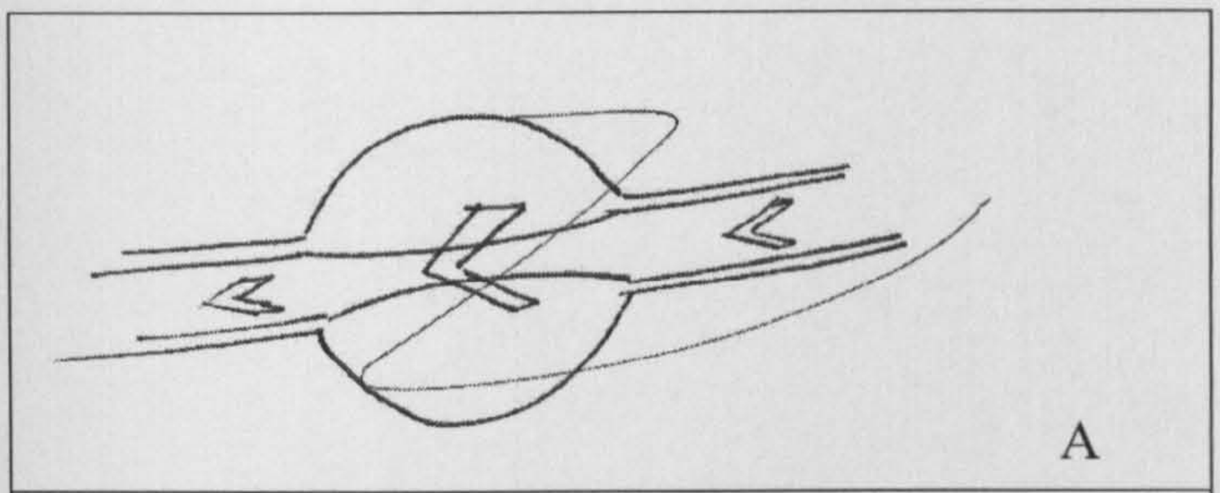


Figure G.3 Rough drawings for anticoagulants

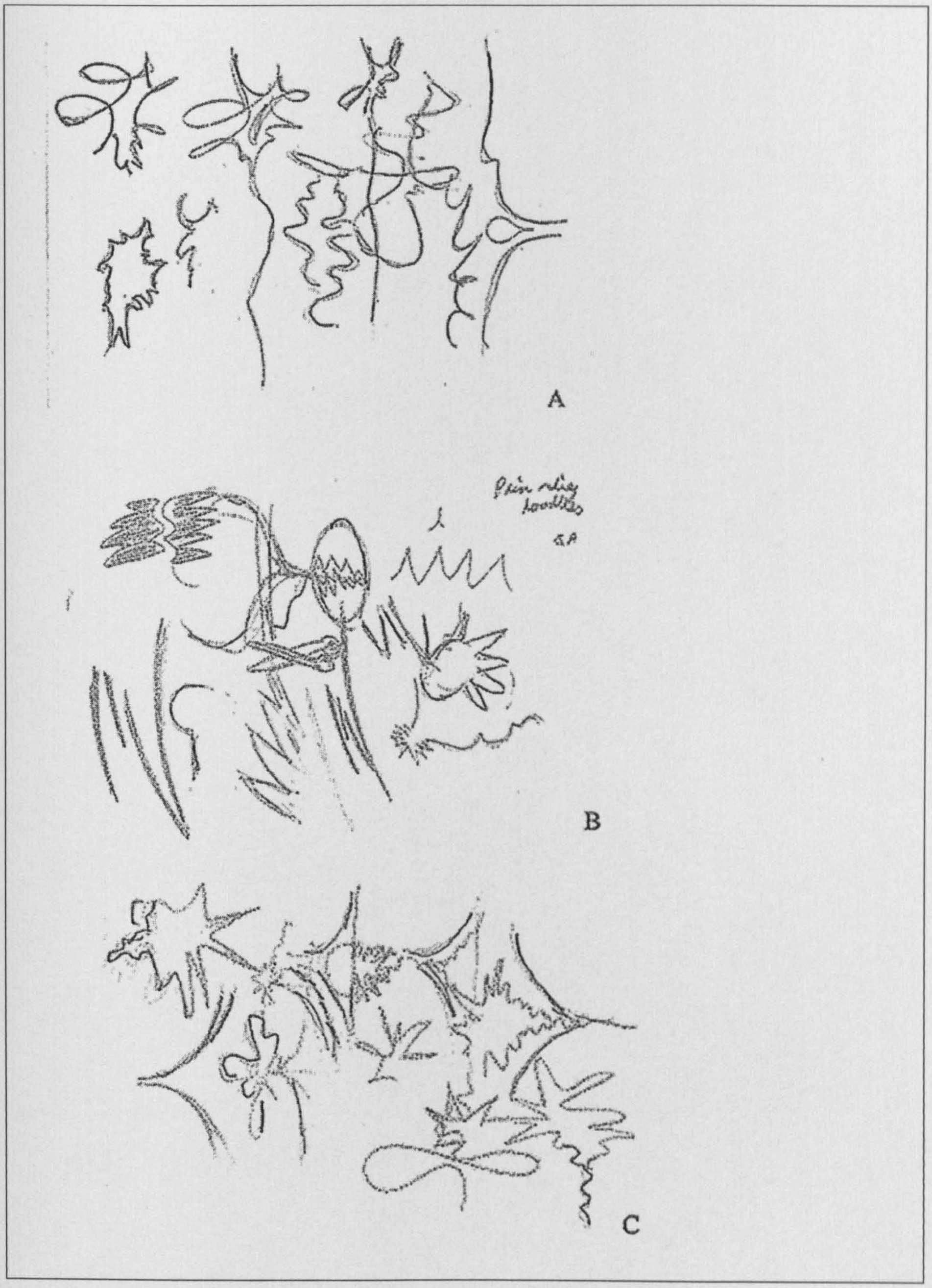


Figure G4. Rough drawings for painkillers

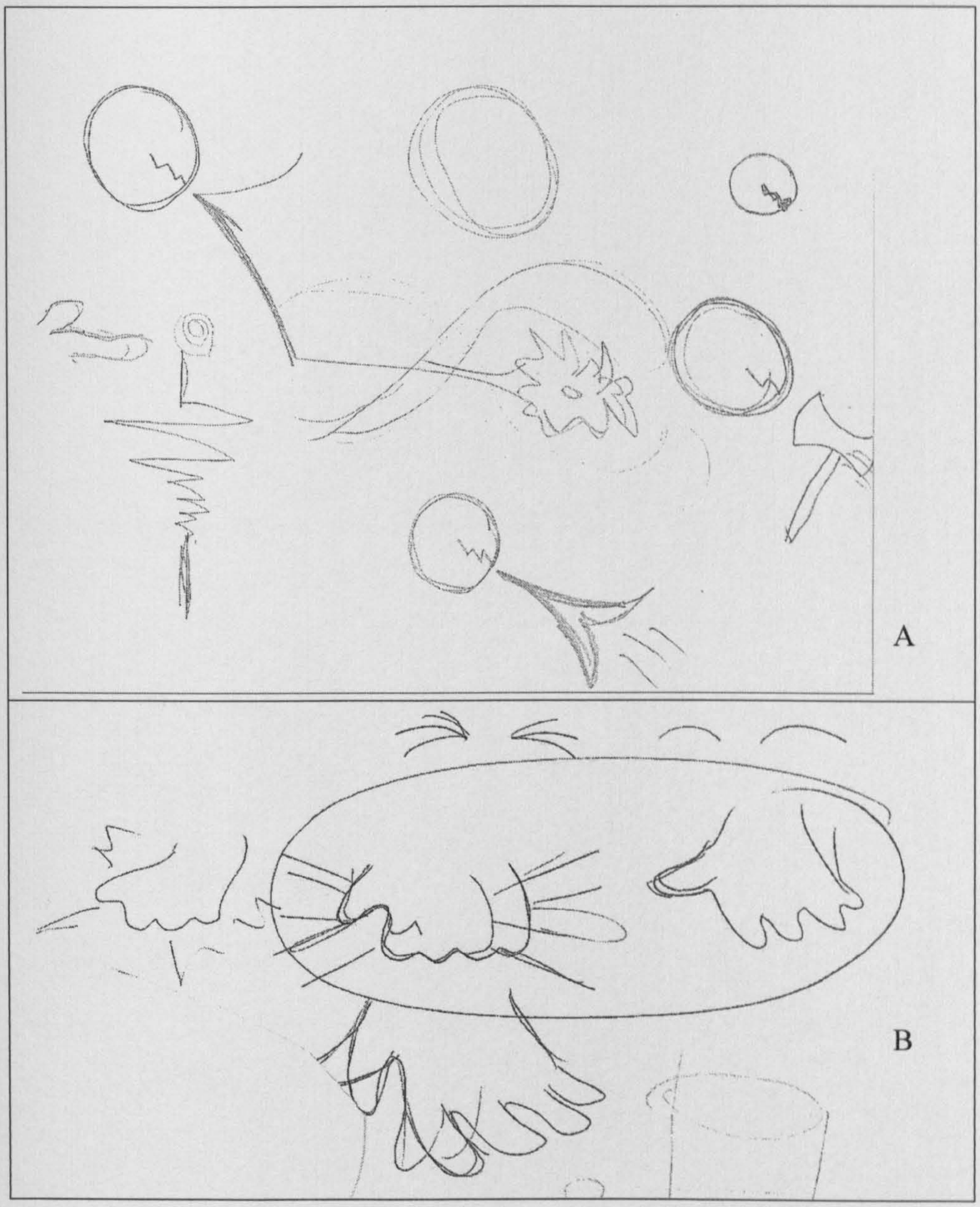
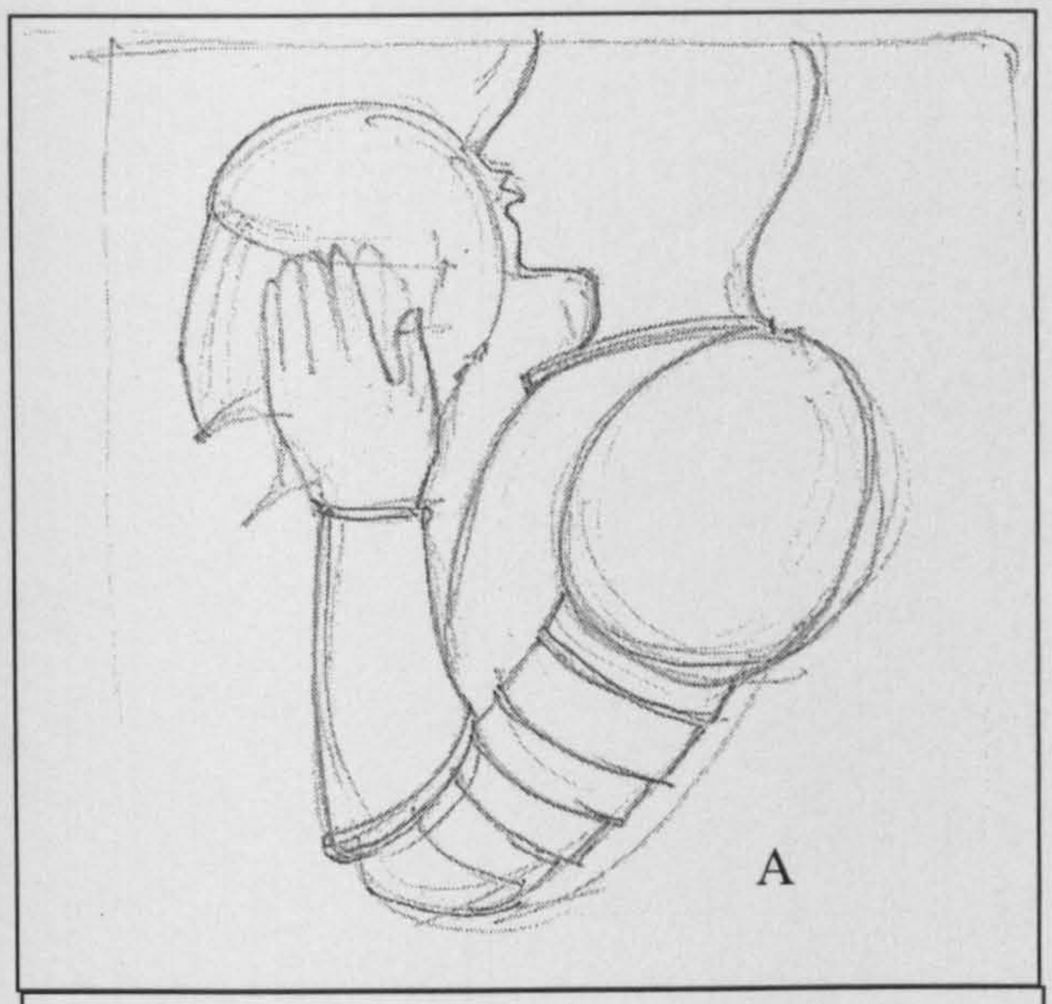
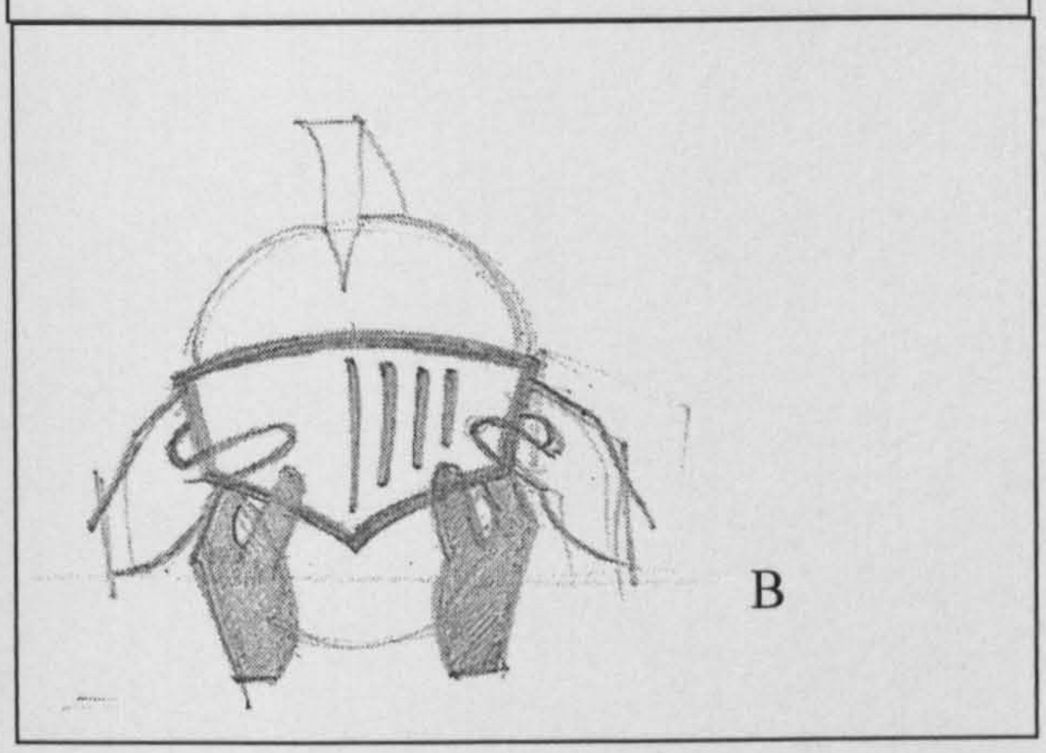


Figure G.5 Rough drawings for painkillers





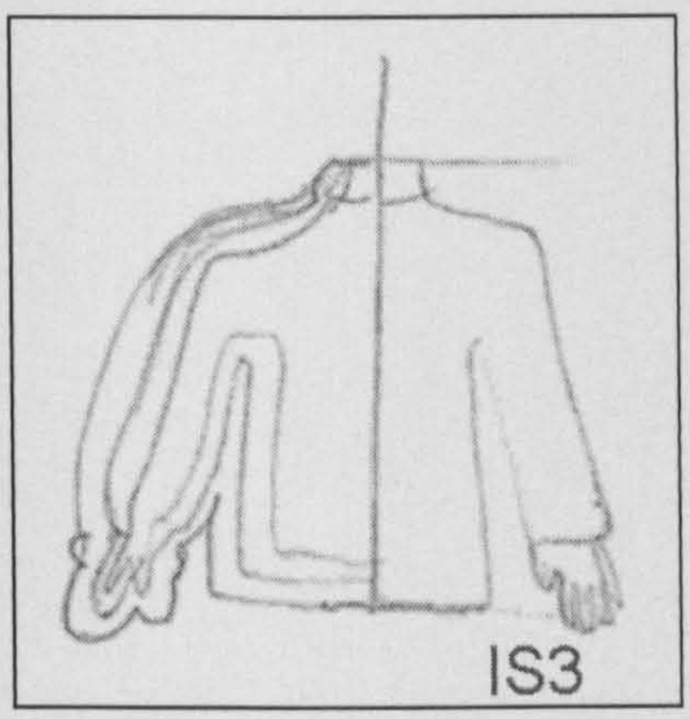


Figure G6 :Rough drawings for immunosuppressants

APPENDIX H

Appropriateness ranking test sheet

The purpose of this questionnaire is to measure how suitable the images presented on the next page are to help identify medication. Please read the description above the line of pictures and write the number 1 in the box below the picture that matches the description best. Then write number 2 in the box below the next best picture and so on until you have given all the pictures in that section a number. Then move on to the next section. An example is given below. There is no right or wrong answer.

Example

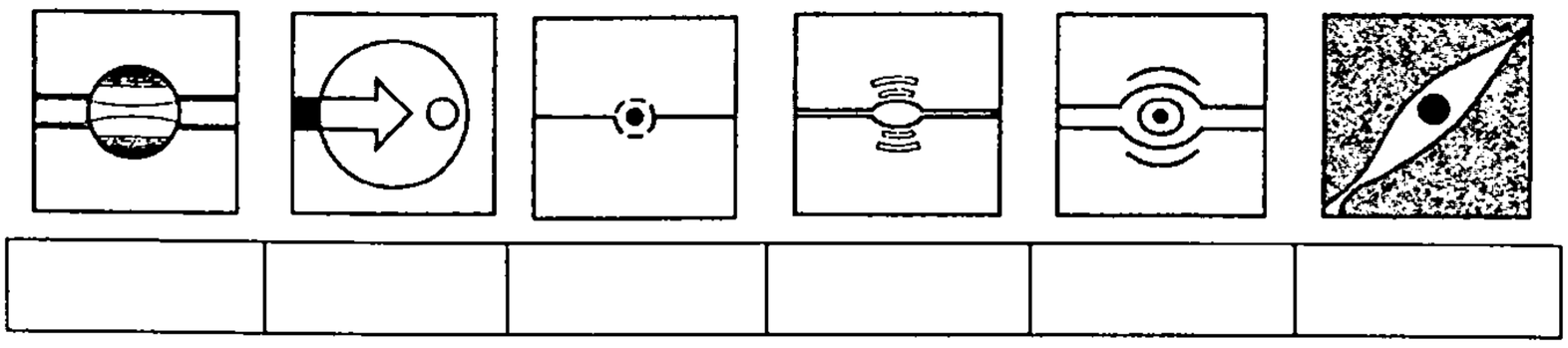
Diuretic – used to rid the body of excess fluids

			
3	1	2	4

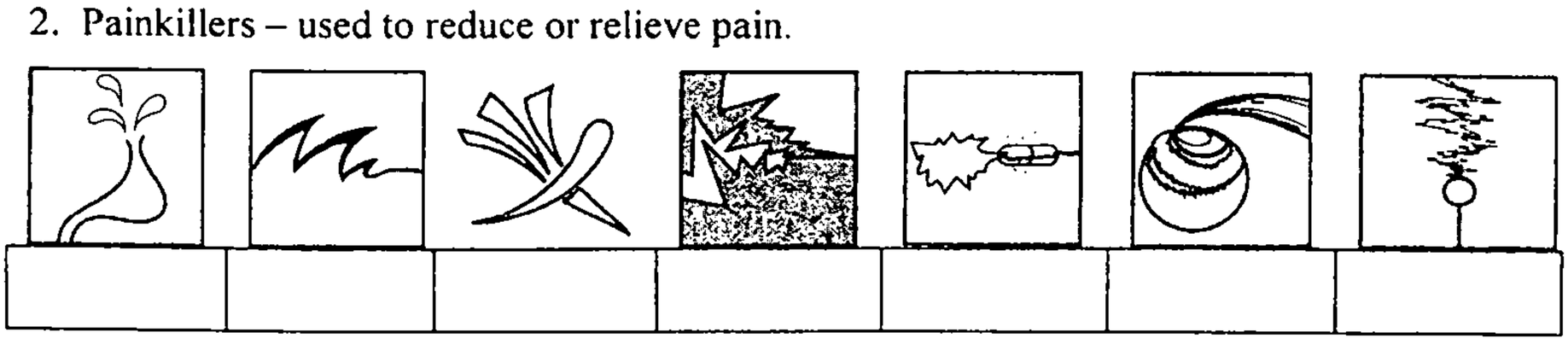
Many thanks for your help.

Rhonda Lane, PhD Student
Room 305, Howell Building
Department of Engineering and Design

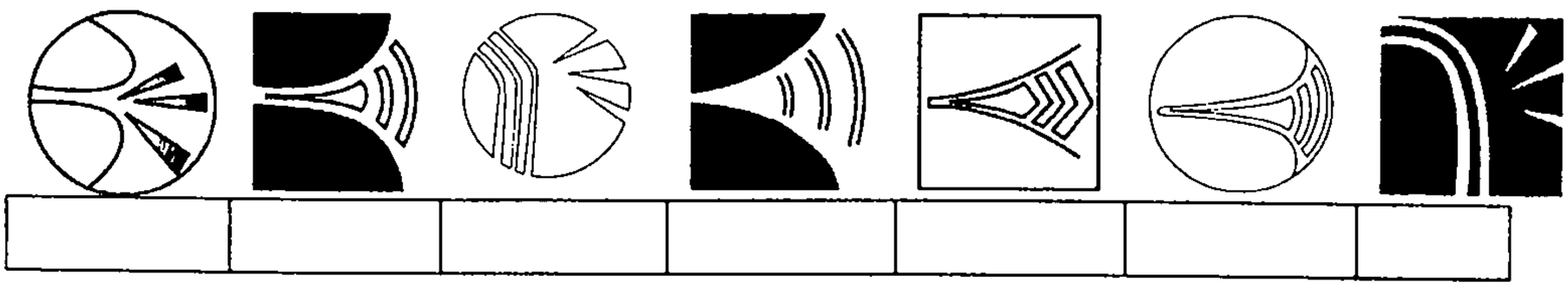
1. Anti-Coagulants and thrombolytics – used to stop blood clotting or to dissolve blood clots.



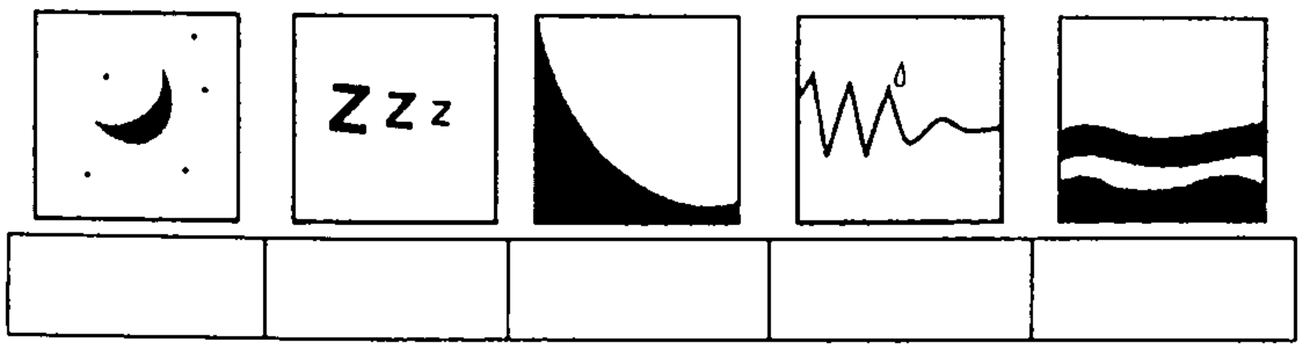
2. Painkillers – used to reduce or relieve pain.



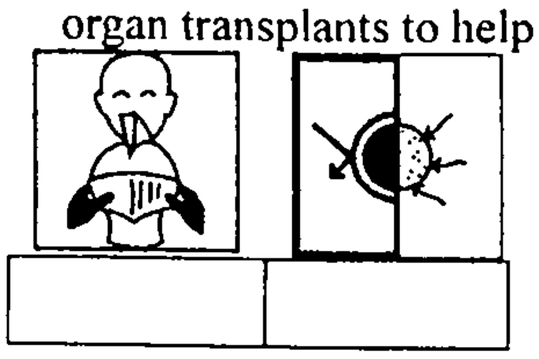
3. Expectorants – used to encourage the flow of saliva and promote coughing to eliminate mucous from the airway.



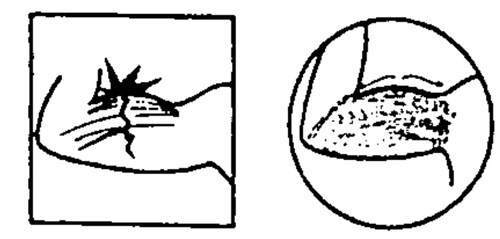
4. Narcotics or sedatives - used to cause sleep.



5. Immunosuppressant – used to reduce the body's normal reaction to attack by disease or by foreign tissues. Used in cancer treatments or after organ transplants to help prevent rejection of organ transplants.



6. Muscle relaxant – used to relieve muscle spasm in conditions such as backache.



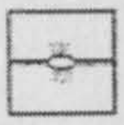
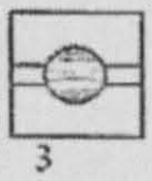
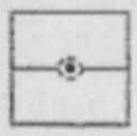
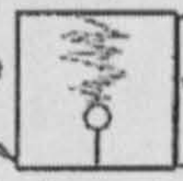
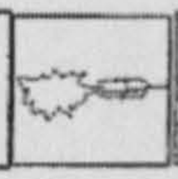
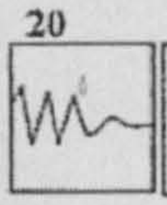
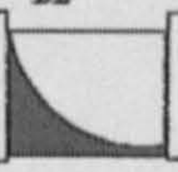
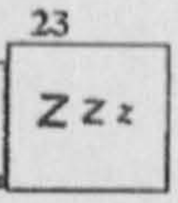
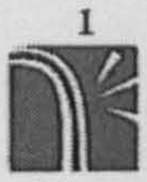
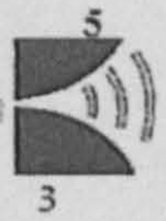
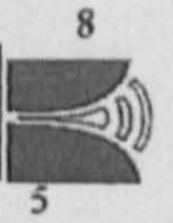
Are you: Male Female?

Please give your age

APPENDIX I

Results of appropriateness ranking

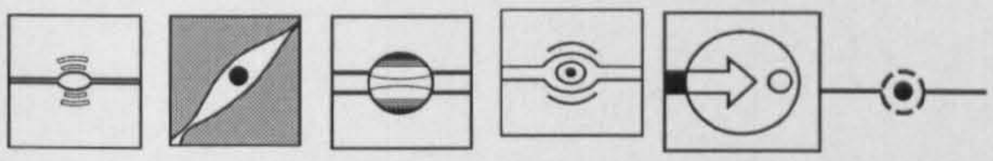
Table I1: The designers' rankings of their icons

Anticoagulants	*Item no*	25	26**	27	28	29	30	31
								
	D1	1	6	4	3	2	7	5
	D2	1	6	3	2	4	7	5
	D3	1	3	7	4	2	6	5
	D4	5	7	1	2	3	6	4
	D5*	2	6	4	5	1	7	3
	Totals	10	28	15	14	12	33	22
	Median	1.5	6	4	3.5	2.5	7	5
Painkillers	*Item no*	**32**	**33**	**34**	**35**	**36**	**37**	**38**
								
	D1	7	5	6	3	2	1	4
	D2	4	6	3	7	1	5	2
	JO	1	4	7	2	3	6	5
	D4	7	3	1	5	4	6	2
	D5*	5	6	3	2	4	7	1
	Totals	24	24	20	19	14	25	14
	Median	*6*	*5.5*	*4.5*	*4*	*3.5*	*6*	*3*
Sedatives	*Item no*	15**	17**	18	20	21	22	23
								
	D1	3	6	4	7	1	5	2
	D2	2	5	7	4	1	6	3
	D3	4	5	6	3	2	7	1
	D4	1	3	7	4	2	6	5
	D5*	1	6	7	4	3	5	2
	Totals	11	25	31	22	9	29	13
	Median	*2.5*	*5.5*	*7*	*4*	*2*	*6*	*2.5*
Expectorants	*Item no*	1	2	3	5	6	7	8
								
	D1	2	1	4	3	6	7	5
	D2	4	1	5	3	6	7	2
	D3	3	1	2	4	6	7	5
	D4	5	1	4	6	2	7	3
	D5*	6	1	7	2	5	4	3
	Totals	20	5	22	18	25	32	18
	Median	*4*	*1*	*4*	*3*	*6*	*7*	*3*

** These icons were not assessed by the experimental group

**D5 did not take part in the D5 workshop but agreed to assess the icons*

Table I2: Appropriateness ranking of anticoagulant icons by the exerpimental group



Subjects	25	27	28	29	30	31	
Q69	3	5	6	2	1	4	
Q80	6	1	3	4	5	2	
Q68	2	6	1	4	5	3	
Q07	4	1	3	2	3	5	
Q08	1	5	3	4	5	2	
Q09	1	2	5	2	5	4	
Q10	5	1	3	4	6	2	
Q11	5	2	1	4	3	6	
Q12	5	2	1	3	6	4	
Q13	3	1	2	5	6	4	
Q14	1	6	3	2	5	4	
Q15	4	2	6	1	5	3	
Q16	4	2	5	1	5	3	
Q20	6	1	3	2	5	4	
Q21	4	1	5	2	5	3	
Q22	1	4	5	3	5	2	
Q26	4	1	2	3	5	6	
Q27	4	3	5	1	6	2	
Q28	3	6	1	2	5	4	
Q30	3	6	1	5	4	2	
Q31	3	4	1	2	5	6	
Q32	5	1	2	4	6	3	
Q33	1	3	4	2	6	5	
Q34	4	1	6	3	5	2	
Q35	5	3	4	2	6	1	
Q36	2	4	5	1	3	6	
Q37	5	6	4	2	1	3	
Q38	1	6	4	2	5	3	
Q39	1	3	4	2	5	6	
Q40	2	6	4	1	3	5	
Q41	5	2	6	4	3	1	
Q42	2	5	1	3	4	6	
Q43	4	5	1	2	6	3	
Q44	2	1	5	3	6	4	
Q45	3	4	5	6	2	1	
Q46	3	4	1	2	5	6	
Q47	1	4	5	3	6	2	
Q48	4	2	5	3	6	1	
Q49	1	3	5	2	6	4	
Q50	3	4	1	2	6	5	
Q53	3	2	5	4	1	6	
Q55	1	5	2	3	6	4	
Q57	3	5	1	2	4	5	
Q58	2	5	1	3	6	4	
Q59	1	4	5	2	3	6	
Q60	2	5	4	3	1	6	
Q61	2	4	5	1	6	1	
Q70	4	1	2	3	6	4	
	144	160	162	128	223	178	995Sum of ranks
							166Mean rank total
	3.00	3.50	4.00	2	5.00	4.00	Median rank

Table I3: Appropriateness ranking of painkiller icons by experimental group

Subjects	32	33	34	35	36	37	38		
Q69	6	7	5	3	1	2	4		
Q80	4	6	5	7	2	1	3		
Q68	3	5	7	6	4	1	2		
Q07	3	5	7	4	2	1	5		
Q08	5	6	1	7	3	2	4		
Q09	7	5	3	1	2	4	6		
Q10	5	7	2	1	3	4	6		
Q11	7	5	4	3	2	2	6		
Q12	6	5	7	4	2	1	3		
Q13	2	5	3	4	7	1	6		
Q14	2	7	5	1	6	3	4		
Q15	5	2	6	7	3	1	4		
Q16	5	5	2	4	3	7	1		
Q20	4	5	7	2	1	3	6		
Q21	6	4	5	7	3	1	2		
Q22	7	3	6	4	1	2	5		
Q26	6	4	5	7	1	2	3		
Q27	5	6	2	7	3	1	4		
Q28	7	5	6	4	3	2	1		
Q30	5	7	3	1	4	6	2		
Q31	5	3	4	1	7	2	6		
Q32	7	3	6	5	2	1	4		
Q33	7	3	6	4	2	1	5		
Q34	5	6	3	4	1	2	7		
Q35	5	6	7	4	2	1	3		
Q36	5	3	4	6	6	1	2		
Q37	6	3	7	5	2	1	4		
Q38	5	6	7	1	3	2	4		
Q39	6	7	4	2	5	1	3		
Q40	7	5	6	4	1	2	3		
Q41	5	7	4	2	3	2	1		
Q42	2	4	5	7	3	1	6		
Q43	7	2	4	6	5	3	1		
Q44	6	3	5	7	4	2	1		
Q45	7	6	5	3	4	2	1		
Q46	5	6	7	2	1	4	3		
Q47	1	4	2	3	5	6	5		
Q48	7	5	3	5	2	1	4		
Q49	6	2	7	3	5	1	4		
Q50	7	6	3	4	2	1	4		
Q53	6	7	2	3	1	4	5		
Q55	7	4	1	6	2	5	3		
Q57	7	3	4	6	1	1	5		
Q58	6	7	1	3	5	4	2		
Q59	3	7	6	4	1	1	3		
Q60	3	7	3	6	1	1	5		
Q61	3	2	5	1	7	4	6		
Q70	6	7	1	3	4	5	2		
	252	238	213	194	143	109	179	1328	Sum of ranks
								190	Mean rank total
	5.5	5	5	4	3	2	4		Median rank

Table I4: Appropriateness ranking of sedative icons by the experimental group

Subjects	18	20	21	22	23	
Q69	3	5	2	3	1	
Q80	4	5	2	3	1	
Q68	2	5	4	3	1	
Q07	5	4	2	3	1	
Q08	3	4	2	5	1	
Q09	5	2	3	2	4	
Q10	3	5	2	4	1	
Q11	5	3	2	4	1	
Q12	4	5	2	3	1	
Q13	5	3	2	4	2	
Q14	4	5	2	3	1	
Q15	4	3	2	5	1	
Q16	3	4	2	5	1	
Q20	4	5	1	3	2	
Q21	4	5	1	3	2	
Q22	5	4	1	3	2	
Q26	3	5	2	4	1	
Q27	5	3	2	4	1	
Q28	5	4	2	3	1	
Q30	5	4	1	3	2	
Q31	3	5	2	4	1	
Q32	4	3	2	5	1	
Q33	4	3	2	5	1	
Q34	4	5	2	3	1	
Q35	5	3	2	4	1	
Q36	5	2	4	3	1	
Q37	4	3	2	5	1	
Q38	3	5	2	4	1	
Q39	3	3	2	4	1	
Q40	5	2	3	4	1	
Q41	5	4	2	3	1	
Q42	4	5	2	3	1	
Q43	5	3	2	4	1	
Q44	5	4	3	2	1	
Q45	5	3	2	4	1	
Q46	4	3	1	5	2	
Q47	5	4	2	3	1	
Q48	3	5	2	4	1	
Q49	3	4	2	5	1	
Q50	3	4	2	5	1	
Q53	3	5	2	4	1	
Q55	3	5	2	4	1	
Q57	4	5	1	3	2	
Q58	4	5	2	3	1	
Q59	2	4	5	1	3	
Q60	3	5	2	4	1	
Q61	4	3	2	5	1	
Q70	3	5	2	4	1	
	189	193	100	177	60	719Sum or ranks
						143Mean rank total
	4	4	2	4	1	Median rank

Table I5:Appropriateness ranking of expectorant icons by the experimental group

Subjects	1	2	3	5	6	7	8	
Q69	4	5	7	1	6	2	7	
Q80	5	6	4	1	3	6	2	
Q68	7	4	6	2	5	3	1	
Q07	6	3	7	1	5	7	2	
Q08	5	2	7	3	4	6	1	
Q09	5	1	7	2	6	7	4	
Q10	6	2	7	3	5	4	1	
Q11	1	2	7	5	6	3	4	
Q12	5	2	7	4	6	3	1	
Q13	7	5	6	3	1	2	4	
Q14	5	3	6	1	4	7	2	
Q15	7	1	6	3	5	4	2	
Q16	7	3	6	1	5	4	2	
Q20	4	7	6	2	5	3	1	
Q21	7	1	6	3	4	5	2	
Q22	6	1	7	3	4	5	2	
Q26	7	5	6	2	3	4	1	
Q27	7	1	6	5	2	3	4	
Q28	4	3	7	2	6	5	1	
Q30	6	4	7	1	5	3	2	
Q31	4	6	5	2	1	7	3	
Q32	3	4	7	1	6	5	2	
Q33	4	5	7	1	6	3	2	
Q34	4	1	7	3	6	7	2	
Q35	2	1	7	5	3	6	4	
Q36	5	7	4	2	3	1	6	
Q37	4	1	7	2	6	5	3	
Q38	6	5	7	3	4	2	1	
Q39	6	3	7	2	5	7	1	
Q40	6	1	7	1	4	5	2	
Q41	7	4	6	1	5	3	2	
Q42	6	4	6	2	7	3	1	
Q43	1	3	7	4	6	5	2	
Q44	4	2	5	6	7	1	4	
Q45	3	4	7	1	5	6	2	
Q46	7	1	6	4	3	2	5	
Q47	6	4	5	3	7	2	1	
Q48	7	6	5	1	4	3	2	
Q49	6	1	7	3	4	5	2	
Q50	7	5	6	3	4	1	2	
Q53	5	3	6	2	6	4	1	
Q55	5	3	7	2	7	4	1	
Q57	7	1	6	2	5	4	3	
Q58	4	7	5	2	6	3	1	
Q59	3	5	4	2	7	1	5	
Q60	4	1	7	6	2	5	3	
Q61	6	1	7	3	4	5	2	
Q70	4	1	6	2	5	7	3	
	247	151	301	119	228	198	114	1358Sum of ranks
								194Mean rank total
	5	3	6.5	2	5	4	2	Median rank

Experimental group rankings for immunosuppressants and muscle relaxants




Subjects	Gender	Age	41		40		42		43	
		Rank	A	B	A	B	A	B	A	B
Q69	M	52		1	1			1	1	
Q80	F	37		1	1			1	1	
Q68	F	45		1	1			1	1	
Q07	M	23		1	1			1	1	
Q08	M	22		1	1		1			1
Q09	M	19		1	1		1			1
Q10	M	19		1	1			1	1	
Q11	M	19		1	1			1	1	
Q12	M	20		1	1			1	1	
Q13	F	20		1	1			1	1	
Q14	M	19		1	1			1	1	
Q15	M	22		1	1			1	1	
Q16	M	23	1			1		1	1	
Q20	M	33		1	1			1	1	
Q21	M	22	1			1		1	1	
Q22	M	22		1	1		1			1
Q26	F	20		1	1			1	1	
Q27	M	19	1			1		1	1	
Q28	M	23		1	1			1	1	
Q30	F	23		1	1			1	1	
Q31	F	20		1	1			1	1	
Q32	F	21		1	1			1	1	
Q33	F	22		1	1		1			1
Q34	M	22		1	1			1	1	
Q35	M	18		1	1			1	1	
Q36	M	21	1			1	1			1
Q37	M	19		1	1		1			1
Q38	M	21		1	1			1	1	
Q39	F	21		1	1		1			1
Q40	M	21		1	1		1			1
Q41	M	20		1	1			1	1	
Q42	M	19		1	1			1	1	
Q43	M	23		1	1			1	1	
Q44	F	30	1			1	1			1
Q45	M	22		1	1			1	1	
Q46	M	22		1	1		1			1
Q47	M	21		1	1			1	1	
Q48	M	20		1	1			1	1	
Q49	M	32		1	1		1			1
Q50	M	22		1	1			1	1	
Q53	F	45		1	1			1	1	
Q55	F	51		1	1			1	1	
Q57	F	47		1	1		1			1
Q58	F	36		1	1			1	1	
Q59	M	34		1	1			1	1	
Q60	F	-		1	1			1	1	
Q61	M	46	1			1		1	1	
Q70	F	45		1	1			1	1	
		Total	6	42	42	6	12	36	36	12

Summary results of appropriateness ranking test

			Rank												
Referent		**1**		**2**		**3**		**4**		**5**		**6**		**7**	
			%		%		%		%		%		%		%
Expectorants	**1**	2	4.17	1	2.08	3	6.25	10	20.8	8	16.7	12	25	12	25
	2	15	31.3	5	10.4	8	16.7	7	14.6	7	14.6	3	6.25	3	6.25
	3	0	0	0	0	0	0	3	6.25	5	10.4	16	33.3	24	50
	5	13	27.1	15	21.3	12	25	3	6.25	3	6.25	2	4.17	0	0
	6	2	4.17	2	4.17	5	10.4	10	20.8	13	27.1	11	22.9	5	10.4
	7	4	8.33	5	10.4	11	22.9	7	16.7	9	18.8	4	8.33	7	14.6
	8	13	27.1	20	41.7	5	10.4	6	12.5	2	4.17	1	2.08	1	2.08
Painkillers	**32**	1	2.08	3	6.25	5	10.4	2	4.17	13	27.1	11	22.9	13	27.1
	33	0	0	4	8.33	8	16.7	5	10.4	11	22.9	9	18.8	11	22.9
	34	4	8.33	5	10.4	7	14.6	7	14.6	9	18.8	7	14.6	9	18.8
	35	7	14.6	4	8.33	8	16.7	11	22.9	3	6.25	6	12.5	9	18.8
	36	11	22.9	12	25	10	20.6	5	10.4	5	10.4	2	4.17	3	6.25
	37	21	43.9	13	27.1	3	6.25	6	12.5	2	4.17	2	4.17	1	2.08
	38	6	12.5	6	12.5	9	18.8	11	22.9	7	14.6	8	16.7	1	2.08
Sedatives	**18**	0	0	2	4.17	15	31.3	15	31.3	15	31.3				
	20	0	0	3	6.38	12	25	11	22.9	20	41.7				
	21	6	12.5	36	75	2	4.17	2	4.17	1	2.08				
	22	1	2.08	2	4.17	17	35.4	17	35.4	10	20.8				
	23	39	81.3	7	14.6	1	2.08	1	2.08	0	0				
Anticoagulants	**25**	11	22.9	8	16.7	9	18.8	11	22.9	6	12.8	2	4.17		
	27	11	22.9	7	14.6	6	12.5	9	18.8	8	16.7	6	12.5		
	28	11	22.9	5	10.4	6	12.5	7	14.6	14	29.2	4	8.33		
	29	6	12.5	18	37.5	12	25	8	16.7	2	4.17	1	2.08		
	30	4	8.33	1	2.08	6	12.5	3	6.25	16	33.3	17	35.4		
	31	5	10.4	8	16.7	8	16.7	11	22.9	4	8.33	11	22.9		
Immuno	**40**	42	87.5	6	12.5										
	41	6	12.5	42	87.5										
Relaxant	**42**	12	25.5	36	75										
	43	36	75	12	25.5										

APPENDIX J

Calculation of Kendall's coefficient of concordance

Calculating Kendall's coefficient of concordance expectorants

R represents the rank sum of the jth individual. The sum of squares for k individuals is given as:

$$S = \sum \left(R_j - \frac{\sum R_j}{k} \right)^2$$

The coefficient of concordance W defined as the ratio of S to the maximum possible value of S is:

$$W = \frac{12S}{N^2\left(k^3 - k\right)}$$

The sum of the ranks for expectorants is 1358

$$S = (249 - 194)^2 + (151\text{-}194)^2 + (301 - 194)^2 + (118 - 194)^2 + (227 - 194)^2 + (197 - 194)^2 + (115 = 194) = 29438$$

$$W = \frac{12 \times 29438}{48^2\left(7^3 - 7\right)} = 0.456$$

Converting to Spearman's rho:

$$\bar{\rho} = \frac{NW - 1}{N - 1}$$

$$\bar{\rho} = \frac{(48 \times 0.456) - 1}{47 - 1} = 0.454$$

Calculating Kendall's coefficient of concordance for sedatives

R represents the rank sum of the jth image. The sum of squares for k images is given as:

$$S = \sum \left(R_j - \frac{\sum R_j}{k} \right)^2$$

The coefficient of concordance W defined as the ratio of S to the maximum possible value of S is:

$$W = \frac{12S}{N^2\left(k^3 - k\right)}$$

The sum of the ranks for sedatives is 719

R represents the rank sum of the jth image. The sum of squares for k images is given as:

$$S = \sum \left(R_j - \frac{\sum R_j}{k} \right)^2$$

$$S = (46-143)^2 + (50-143)^2 + (43-143)^2 + (34-143)^2 + (83-143)^2 + = 14510$$

$$W = \frac{12 \times 14510}{48^2\left(5^3 - 5\right)} = 0.630$$

Converting to Spearman's *rho*

$$\bar{\rho} = \frac{NW - 1}{N - 1}$$

$$\bar{\rho} = \frac{\left(48 \times 0.63\right) - 1}{47 - 1} = 0.635$$

Calculating Kendall's coefficient of concordance for anticoagulants

R represents the rank sum of the jth image. The sum of squares for k images is given as:

$$S = \sum \left(R_j - \frac{\sum R_j}{k} \right)^2$$

The coefficient of concordance W defined as the ratio of S to the maximum possible value of S is:

$$W = \frac{12S}{N^2\left(k^3 - k\right)}$$

The sum of the ranks for anticoagulants is 994

$$S = (143 - 166)^2 + (160\text{-}166)^2 + (162\text{-}166)^2 + (128 - 166)^2 + (223 - 166)^2 + (178 - 166)^2 = 5418$$

$$W = \frac{12 \times 5418}{48^2\left(6^3 - 6\right)} = 0.134$$

converting to spearmans *rho*

$$\bar{\rho} = \frac{NW - 1}{N - 1}$$

$$\bar{\rho} = \frac{\left(48 \times 0.134\right) - 1}{47 - 1} = 0.118$$

Calculating Kendall's coefficient of concordance for painkillers

R represents the rank sum of the jth image. The sum of squares for k images is given as:

$$S = \sum \left(R_j - \frac{\sum R_j}{k} \right)^2$$

The coefficient of concordance W defined as the ratio of S to the maximum possible value of S is:

$$W = \frac{12S}{N^2\left(k^3 - k\right)}$$

The sum of the ranks for painkillers is 1328.

$$S = (252 - 190)^2 + (238 - 190)^2 + (213 - 190)^2 + (194 - 190)^2 + (143 - 190)^2 + (109 - 190) + (179 - 190) = 15584$$

$$W = \frac{12 \times 15584}{48^2\left(7^3 - 7\right)} = 0.241$$

Converting to Spearman's *rho:*

$$\bar{\rho} = \frac{NW - 1}{N - 1}$$

$$\bar{\rho} = \frac{\left(48 \times 0.241\right) - 1}{47 - 1} = 0.23$$

Appendix K

The Comprehension test

The images presented here are symbols that might be used on drug packaging in the future. The aim of this presentation is to match each symbol with one of the column descriptions. Please put a tick in the column with the description you think most closely matches thesymbol. Please do this for each symbol in turn. If you cannot find a description to match the symbol, then please leave the column blank.

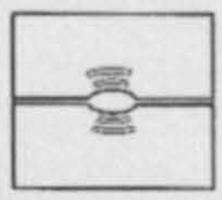
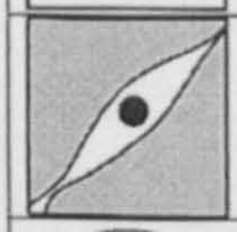
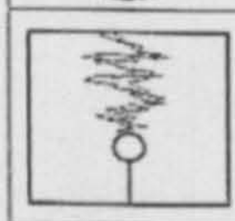
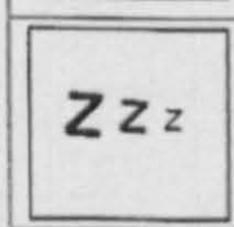
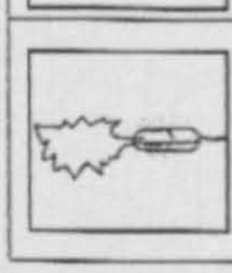
Symbol	Muscle relaxant	Expectorant	Pain reliever	Anti-coagulant	Immuno-suppressant	Sedative
						
						
						
						
						
						
						
						
						
						

Figure K1: Comprehension test sheet

23 Lea Springs
Fleet
GU51 5AR

The attached sheet is an assessment for icons that might be used on drug packaging. It forms part of my PhD research which is looking at ways of reducing medication administration errors in hospitals.

Although there are many factors involved in medication administration errors, one major source of confusion is the design of packaging and labelling. Using simple pictures or icons might have a major impact in reducing these errors.

Please look at the icons and follow the instructions on the sheet. I would be grateful if you would write on the sheet the number of years you have been practising.

Thank your valuable contribution to my research.

Rhonda Lane
PhD Student
Brunel University

Figure K2: Letter accompanying the comprehension test

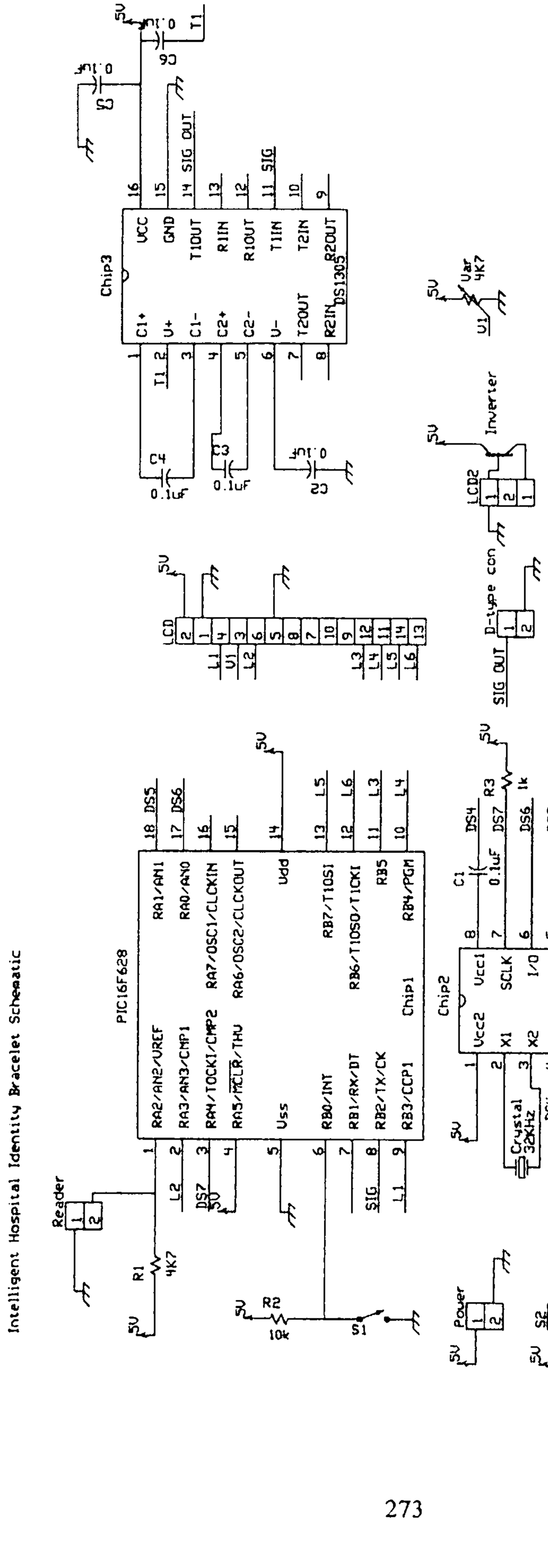
	Images									
Subjects	**2**	**8**	**21**	**23**	**25**	**27**	**36**	**37**	**40**	**42**
S1	1	1	1	1	-	-	1	1	1	-
S2	-	-	1	1	-	1	-	-	1	1
S3	1	1	1	1	1	-	1	1	1	1
S4	1	-	1	1	-	-	-	-	1	-
S5	1	-	1	1	-	-	-	-	1	-
S6	-	-	1	1	-	-	1	-	1	1
S7	-	-	1	1	-	-	-	-	-	1
S8	-	-	1	1	-	-	-	-	-	-
S9	-	-	1	1	-	-	-	-	-	-
S10	-	-	1	1	-	-	-	-	-	1
S11	-	-	1	1	-	-	-	-	-	1
S12	-	-	1	1	1	-	-	-	1	-
S13	-	1	1	1	-	-	1	1	1	1
S14	-	1	1	1	-	-	-	1	1	1
S15	-	-	1	1	-	-	1	-	1	-
S16	-	-	1	1	-	-	-	1	1	-
S17	-	-	1	1	-	-	-	-	-	1
S18	-	-	1	1	-	-	-	-	1	1
S19	-	-	-	1	-	-	1	-	-	-
S20	1	1	1	1	-	-	1	1	1	1
S21	1	1	1	1	-	-	-	-	-	-
S22	1	-	-	1	-	-	1	-	-	-
S23	-	-	1	1	-	-	-	-	1	-
S24	-	-	1	1	-	-	1	-	-	-
S25	1	-	-	1	-	-	-	-	-	1
S26	-	-	1	1	-	-	-	-	-	-
S27	-	-	1	1	-	-	-	-	-	1
S28	1	-	1	1	-	-	-	-	1	-
S29	-	1	1	1	-	-	1	1	-	1
S30	-	-	-	1	-	-	-	-	-	-
S31	-	-	1	1	-	-	1	1	-	1
S32	1	1	1	1	1	-	-	-	-	-
S33	1	-	-	1	-	1	1	-	-	1
	11	8	29	33	3	2	12	8	15	16
	33%	24%	88%	#####	9%	6%	36%	24%	45%	48%

1= correct identification of symbol
- = no response or error
-= 100%

Figure K3: Results of comprehension test

Appendix L

Schematic of intelligent hospital identity bracelet


Intelligent Hospital Identity Bracelet Schematic
Designer
Reader
L2
DS7
SIG
L1
R1
4K7
5V
R2
10k
S1
Power
S2
Chip2
DS1302
Vcc2
X1
X2
Gnd
Vcc1
SCLK
I/O
RST
Crystal
32KHz
C1
0.1uF
DS4
DS7
DS6
DS5
R3
1k
PIC16F628
RA2/AN2/VREF
RA3/AN3/CMP1
RA4/T0CKI/CMP2
RA5/MCLR/THV
Vss
RB0/INT
RB1/RX/DT
RB2/TX/CK
RB3/CCP1
Chip1
RA1/AN1
RA0/AN0
RA7/OSC1/CLCKIN
RA6/OSC2/CLCKOUT
Vdd
RB7/T1OSI
RB6/T1OSO/T1CKI
RB5
RB4/PGM
L5
L6
L3
L4
LCD
L1
V1
L2
L3
L4
L5
L6
LCD2
Inverter
Var
4K7
U1
D-type con
SIG OUT
Chip3
DS1305
VCC
GND
T1OUT
R1IN
R1OUT
T1IN
T2IN
R2OUT
C1+
V+
C1-
C2+
C2-
V-
T2OUT
R2IN
T1
T1_2
C4
0.1uF
C3
0.1uF
C2
0.1uF
C5
0.1uF
C6
0.1uF

Appendix M

Summary results of Test 1

Responses for test 1

Test 1 Results

Bracelet	Seconds	Questions 1	Correct	Questions 2	Correct	Questions 3	Correct	Questions 4	Correct	Questions 5	Correct
Write on	1	Surname	1	Last 2 digits	0	Date born	0	Month born	1	Year born	1
Write on	2	Year born	0	Date born	1	Surname	0	First 2 digits	0	Last 2 digits	1
Write on	3	Last 2 digits	1	Surname	1	Month born	0	First name	1	Month born	0
Write on	4	First 2 digits	0	Year born	0	Last 2 digits	0	Date born	1	Date born	0
Insert	1	Month born	1	Surname	0	First name	1	Last 2 digits	0	Surname	0
Insert	2	First 2 digits	0	First 2 digits	1	Year born	1	Year born	1	Date born	0
Insert	3	Date born	1	Month born	1	Last 2 digits	0	Surname	1	First 2 digits	1
Insert	4	Surname	1	Date born	1	Month born	0	Date born	0	Year born	0
RFID	1	Last 2 digits	0	Year born	0	Surname	1	First 2 digits	0	Year born	0
RFID	2	First name	1	Last 2 digits	0	Date born	1	Surname	0	First name	1
RFID	3	Surname	1	First name	0	First 2 digits	1	Year born	1	First 2 digits	1
RFID	4	Month born	1	Month born	0	Last 2 digits	1	Month born	0	Surname	1
iButton	1	First 2 digits	0	Firstname	1	Year born	1	First name	1	Month born	0
iButton	2	Date born	0	Month born	1	First 2 digits	0	Last 2 digits	0	Surname	1
iButton	3	Month born	1	Last 2 digits	0	Surname	1	Date born	1	Year born	1
iButton	4	First name	1	Surname	1	Date born	0	First 2 digits	1	Last 2 digits	1

Legend: correct 1, Incorrect 0

Amount of time reversed

Bracelet	Seconds	Questions 6	Correct	Questions 7	Correct	Questions 8	Correct	Questions 9	Correct	Questions 10	Correct
Write on	4	First 2 digits	0	Year born	1	Last 2 digits	0	Date born	0	Date born	1
Write on	3	Last 2 digits	1	Surname	1	Month born	0	First name	1	Month born	1
Write on	2	Year born	1	Date born	0	Surname	1	First 2 digits	0	Last 2 digits	1
Write on	1	Surname	1	Last 2 digits	0	Date born	1	Month born	0	Year born	1
Insert	4	Surname	1	Date born	0	Month born	0	Date born	0	Year born	1
Insert	3	Date born	1	Month born	1	Last 2 digits	1	Surname	1	Last 2 digits	1
Insert	2	First 2 digits	0	First 2 digits	0	Year born	1	Year born	0	Date born	1
Insert	1	Month born	0	Surname	1	First name	1	Last 2 digits	0	Surname	1
RFID	4	Month born	1	Month born	0	Last 2 digits	0	Month born	1	Surname	1
RFID	3	Surname	1	First name	1	First 2 digits	1	Year born	0	First 2 digits	0
RFID	2	First name	1	Last 2 digits	1	Date born	1	Surname	1	First name	1
RFID	1	Last 2 digits	1	Year born	0	Surname	1	First 2 digits	1	Year born	0
iButton	4	First name	1	Surname	1	Date born	1	First 2 digits	0	Last 2 digits	0
iButton	3	Month born	0	Last 2 digits	0	Surname	1	Date born	1	Year born	1
iButton	2	Date born	1	Month born	1	First 2 digits	1	Last 2 digits	0	Surname	1
iButton	1	First 2 digits	1	Firstname	1	Year born	1	First name	1	Month born	1

Legend: correct 1, Incorrect 0

(Source:Dunne, 2005)

Summary results

Subject	Write-on	Insert	RFID	iButton
1	2	3	3	2
2	2	3	0	3
3	0	2	4	2
4	3	2	1	3
5	2	1	2	3
6	3	2	4	3
7	2	2	2	3
8	2	3	3	4
9	1	1	3	2
10	2	2	2	3
Total	**19**	**21**	**24**	**27**
Percentage	**47.50%**	**52.50%**	**60%**	**67.50%**

Total items of information recalled from 4 hospital identity bracelets

Appendix N

Published work