UNIVERSITY OF SOUTHAMPTON

INFORMING PATIENTS ABOUT MEDICINES: AN EVALUATION OF PRESCRIPTION INFORMATION LEAFLETS IN GENERAL PRACTICE

by

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ABSTRACT

FACULTY OF MEDICINE
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INFORMING PATIENTS ABOUT MEDICINES: AN EVALUATION OF PRESCRIPTION INFORMATION LEAFLETS IN GENERAL PRACTICE

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Despite the widespread prescription of medicines, patients' knowledge about the drugs they take is limited. Many people feel that not enough is explained by doctors and pharmacists, but even when information is given verbally it is often forgotten or misunderstood. One solution might be to provide information leaflets with prescribed medicines. Although patients would welcome additional written information, well designed patient-oriented leaflets have not been available in the UK until recently. Moreover, there have been few systematic studies which have examined the effects of leaflets in this country. This thesis describes the development of Prescription Information Leaflets (PILs) and an evaluation of their effects in general practice.

A two-sided "details plus summary" PIL format was developed, which conferred advantages in terms of improved knowledge and satisfaction over a one-sided "details only" version. A series of generic PILs were produced for six commonly prescribed groups of medicines: non-steroidal anti-inflammatory drugs (NSAIDs), penicillins, ß-adrenoceptor antagonists, inhaled bronchodilators, diuretics and benzodiazepines. The leaflets were constructed according to guidelines for the design of technical information and contained information on how to take the medicine, its common side-effects and advice about safe storage and disposal.

The PILs were evaluated in six small Hampshire towns. Leaflets were given to 671 patients in four of the towns by either a pharmacist or a general practitioner. A further 547 patients in the two control towns received no leaflets. Those who received leaflets knew more about their medicines, particularly the side-effects. However, this knowledge was not associated with spurious side-effects, except in the case of benzodiazepines. Although some were worried at the prospect of side-effects, almost all patients thought that these leaflets were a good idea. An important finding was that patients who received leaflets were significantly more satisfied with the information they received about their medicine. In addition, initial improvements in knowledge and satisfaction were apparent 12 months after the original prescription.

It is concluded that the benefits of PILs outweigh the disadvantages and justify the use of leaflets on a routine basis. However, since general practitioners and pharmacists had difficulty remembering to issue the leaflets, it is suggested that they should be incorporated in original packs by the pharmaceutical manufacturer.

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Finally, I would especially like to thank my husband, Ian, for his kindness, patience and continual encouragement.

For Ian

CONTENTS

LIST OF TABLES

LIST OF FIGURES

The author's contribution to the work presented in this thesis

The Prescription Information Leaflet (PIL) initiative was a large scale series of studies conducted at Southampton University, with advice from a national Steering Group[1]. The author made a major contribution to the stages of the work which are presented in this thesis. Research carried out by the author alone or by staff working under her supervision, included the following:

- **Leaflet design** : Development, design and piloting testing Prescription Information Leaflets, including a detailed literature review on leaflet design. The contents of the leaflets were initially discussed within a Steering Group.

- **Review of the literature** : Review and critical appraisal of the multidisciplinary literature. Discussion with interested bodies. Establishment of the aims of the study.

- **Questionnaire design** : Development and design of an interview schedule and postal questionnaires. Pilot work and revision of questionnaires.

- **Study design** : The design of the study was discussed within a Steering Group. The author was responsible for protocol development and modifications to the original design in the light of pilot work.

- **Coordination of the study** : Liaison with GPs and Pharmacists; coordination of the data collection; overseeing the smooth running of the surveys.

- **Data collection** : Interviewing patients in their homes. The author conducted around 700 patient interviews (all of those included in the preliminary studies and approximately half of the main study data collection). Training and supervision of an interviewer.

- **Data analysis** : Organisation of data coding and transfer to University of Southampton mainframe computer. Data checking. The author was responsible for the statistical analysis of the data. Statistical advice was obtained from the Department of Medical Statistics, Southampton University.

- **Presentation of results** : Assembling of the results. Discussion of the findings and their implications. Preparation of papers for publication.

Finally, the author contributed throughout this research by approaching these studies from the patients' perspective.

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[1] *Steering Group members included: Professor D.R.Laurence (University College Hospital, London), Professor C.Fletcher (London), Dr.F.O.Wells (Association of the British Pharmaceutical Industry), Mr.D.N.Sharpe (Royal Pharmaceutical Society of Great Britain), Mr.B.H.Hartley, Mr.P.E.Green (Department of Health), Mr.J.Wyatt (Disabled Living Foundation), Dr.C.F.Donovan (Royal College of General Practitioners), Dr.M.Goodman (British Medical Association), Mr.S.Steele (Sir Jules Thorn Institute, London).*

"They don't tell you nothing about the tablets - I mean what's going to happen and what to look out for, and that. Now me, I'd like to know more....."

Mr W.
(one of the patients)

CHAPTER 1

GENERAL INTRODUCTION AND LITERATURE REVIEW

CHAPTER 1

In this chapter the literature is reviewed in three parts. In part one, the case is made for the provision of information with prescribed medicines; part two considers the problems associated with verbal communication, and in part three, the studies which have examined the effects of leaflets on patients are discussed. The review is limited to articles published before the commencement of the main study in 1987. Articles published subsequently are discussed in chapter 8.

1.1 THE NEED FOR INFORMATION ABOUT PRESCRIBED MEDICINES

1.11 Medicine taking

"Man has an inborn craving for medicine.... The desire to take medicine is one feature that distinguishes man the animal from his fellow creatures." Sir William Osler (1894)

Historical perspective

Medicine taking has been a feature common to human civilizations throughout the ages (Dunlop 1973). Documentary evidence of medicine use dating back to 1550 BC is provided in the Ebers papyrus, which lists over 900 medical recipes used by the ancient Egyptians. An impressive variety of animals, plants and mineral substances were employed medicinally including "Lizards' blood, crocodile dung, the teeth of swine, the hooves of an ass, putrid meat and fly specs" (Holmes and Kitterman 1914; Findley 1953). Medicinal uses for "Vipers' flesh, the spermatic fluid of frogs, the horns of deer, animal excreta and holy oil" were found by the physicians of ancient Greece (Leslie 1954). The salts of lead and copper were popular Roman treatments (Wootton 1910); benzoin, camphor, myrrh, musk, naptha and senna were introduced by the Arabic culture (Guthrie 1945) and Galen's treatments incorporating many of herbal substances in one

prescription were favoured in the middle ages (Chamberlain 1981).

Until the twentieth century, the success of therapy depended almost entirely upon the placebo effect (Shapiro 1960; Benson and Epstein 1975). In many instances, magic, ritual and superstition appear to have been as important for the healing process as the medicinal substances imbibed. Although several specific treatments, namely quinine, mercury, ipecacuanha, opium and digitalis had been introduced by the end of the 18th century, it has only been during the "therapeutic explosion" of the last 60 years that pharmacologically effective therapy has become widely available for many common diseases (George 1974).

Medicines prescribed

More than 6,500 preparations are presently available for prescribing in the UK (Medawar 1984). In 1984, 321 million items were prescribed by the 23,640 general practitioners in England (Department of Health and Social Security 1985) and the number of items prescribed has more than doubled over the last 30 years (Mapes 1980). Rates of prescribing vary from country to country. It has been estimated that an average Frenchman is prescribed 2.3 times more drugs than a Swiss, and about 4.6 times more than a Briton (Szuba 1986). The rate of prescribing varies also between different groups within the UK population. The elderly, for example, received 39% of the prescription items dispensed despite making up only 18% of the population in 1985 (Anderson and Cartwright 1986).

Over 90% of NHS prescriptions are written by general practitioners working in the community. General practitioners in England prescribe from around 90 therapeutic classes, eight of which account for almost half of the prescriptions written. The most popular therapeutic classes are sedatives and tranquillisers, which made up 7.2% of the prescriptions, followed by minor analgesics, which accounted for 6.4% and diuretics, which made up 6% (Department of Health and Social Security 1978). Preparations acting on the heart, penicillins,

hypnotics, asthma preparations and non-steroidal anti-inflammatory drugs (NSAIDs) were also commonly prescribed. In 1986, there were around 20 million prescriptions written for NSAIDs (Committee on Safety of Medicines 1986).

Analyses of prescription rate data clearly indicate that for general practitioners working in the community, prescribing is a common activity. However, the lack and inaccessibility of national prescription rate statistics, combined with uncertainties about the representativeness of data derived from small samples of prescriptions, limit the usefulness of the data[1]. In addition, information obtained from prescriptions reflects the number of drugs prescribed but not necessarily those consumed. For these reasons, a detailed picture of medicine taking in the community has been built up largely from ad hoc, small scale, community based surveys.

Community surveys of medicine consumption

Community surveys have confirmed that general practitioner prescribing is a common activity. In a survey of 1,980 people chosen at random from 14 parliamentary constituencies in Britain, the respondents said they received a prescription at two-thirds of their consultations with general practitioners (Dunnell and Cartwright 1972). Moreover, many doctors claimed this was an underestimate of their prescribing. Studies suggest a similar situation in the USA (Stolley and Lasagna 1969; Rabin and Bush 1975). Three-quarters of British patients consult their doctors on average at least once a year (Brotherston and Chave 1956; Cartwright and Anderson 1981) and 90% of patients will obtain a prescription in a 5 year period (Fowler 1985). Since the majority of consultations end with the issuing of a prescription, sooner or later almost everyone will receive a prescribed medicine.

Forty-percent of adults in Dunnell and Cartwrights' study had taken a prescribed medicine in the 2 week period prior to interview (Dunnell and Cartwright 1972). Very similar results were obtained more recently in a postal survey of

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[1]*The situation has been greatly improved by the introduction of analysis of prescribing in general practice (PACT) by the Department of Health.*

Southampton residents (Ridout et al 1986). Of the 443 adults systematically drawn from the electoral register, 42% said they had taken a prescribed medicine within the previous month. Other estimates of consumption, based on smaller, less representative samples, have been slightly lower (Jefferys et al 1960; Wadsworth et al 1971). The most commonly consumed prescribed drugs in Dunnell and Cartwrights' study were preparations acting on the central nervous system, which were taken by 18.6% of their sample; preparations affecting metabolism, nutrition and blood, consumed by 17.4% of respondents; preparations acting on the skin, used by 10.2%; preparations acting on the digestive system, taken by 8.4% of the sample; others acting on the respiratory system, used by 7.8% and preparations acting on the cardio-vascular and genito-urinary systems, taken by 7.2% (Dunnell and Cartwright 1972). Similar findings were reported following a two-day American survey (Rabin and Bush 1975).

Surveys have revealed that women and the elderly consult doctors more often (Cartwright and Anderson 1981; Vebrugge 1985) and take more medicine that men and the young (Jefferys et al 1960). Although the excess medicine consumption amongst women cannot be accounted for by sex specific factors alone (Vebrugge 1985; Waldron 1983), women are more likely than men to be taking psychotropic drugs and analgesics (Anderson 1980). The difference in medicine consumption between the sexes declines or disappears among older people, who as a group report higher levels of consumption of prescribed medicine than younger people (Wadsworth et al 1971; Skegg et al 1977; Anderson 1980; Law and Chalmers 1976; Knox 1980; Parish et al 1983; Royal College of Physicians 1984). Diuretics, ß-adrenoceptor antagonists, respiratory drugs and non-steroidal anti-inflammatory drugs (NSAIDs) are used particularly often by elderly people (Anderson and Cartwright 1986). Other groups whose utilisation of medicines has been found in surveys to be high are the disabled (Peach and Charlton 1986), and children under 2 years old (Dunnell and Cartwright 1972). Despite these marked differences in the prescription and

utilisation of medicines, prescription rate data and surveys of medicine consumption confirm the widespread use of medicines throughout the population.

1.12 Patients' knowledge about their medicines

The majority of the surveys which have investigated patients' knowledge about their medicines have been carried out in the USA and Canada. Surveys conducted amongst hospital patients (Fox 1969; Cyr and McLean 1978; Crichton et al 1978) and patients in the community (McKenny et al 1973; Joubert and Lasagna 1975a; German et al 1982; Ascione et al 1986) have revealed a widespread ignorance of all but basic information about medicines. Patients' awareness of the potential side-effects of their treatment has been found to be particularly poor. Ascione et al (1986) investigated the drug knowledge of 187 patients taking cardiovascular medicines in a USA family practice setting. Ninety-percent of the respondents knew of no side-effects which might accompany their treatment.

Although there have been few systematic investigations conducted in the UK, a similar lack of knowledge has been reported in this country (Busson and Dunn 1986; Ridout et al 1986). In a national pharmacy survey, 27,400 questionnaires were distributed to 1,096 Boots pharmacies throughout the UK (Busson and Dunn 1986). Pharmacists issued questionnaires to patients presenting a prescription at the pharmacy during the last week of July 1985. Patients were selected in a "random manner", unless it was obvious the patient would not be able to cooperate. Over half of the respondents claimed they did not know precisely how, when or with what to take their medicines. Seventy-three percent claimed to know nothing about side-effects of their medicine; 43% felt they would not know what action to take if side-effects occurred.

Despite the considerable potential for sample selection bias, the measurement of perceived knowledge rather than recall and a very low response rate (under one third returned a questionnaire), the level of ignorance uncovered by Busson and

Dunn was consistent with that reported in the Southampton community by Ridout et al (1986). They dispatched a postal questionnaire to a 1 in 200 sample of adults systematically selected from the electoral register. Of the 740 adults surveyed, 443 (60%) returned completed questionnaires, 188 of whom had taken a prescribed medicine in the month prior to the survey. Whilst most of these patients could name their medicine and were aware of its purpose, other items of knowledge were less well known. Almost three-quarters of the respondents knew of no side-effects which could result from their treatment (Ridout et al 1986).

Side-effects of treatment

Any drug may produce unwanted effects. For a drug to be a useful medicine, it must produce more benefit than harm (Laurence and Black 1978). Thus, widespread public ignorance about the possibility of side-effects is a cause for concern. With the increasing consumption of prescribed medicines, particularly those used over a long period to treat chronic conditions (Mapes 1980), a growing number of people will be exposed to the risks as well as the benefits of modern drug therapy.

Adverse reactions to medicines are a common problem producing significant morbidity and mortality. In the USA, studies indicate that adverse drug reactions may be responsible for between 1.7% and 4.5% of hospital admissions, and may result in as many as 140,000 deaths annually (Caranosos et al 1974; Silverman and Lee 1974). Iatrogenic disease is frequently diagnosed as a cause of hospital admission in this country (Williamson and Chopin 1980) and it makes a significant contribution to morbidity in general practice (Martys 1979). For example, gastro-intestinal reactions after taking non-steroidal anti-inflammatory drugs (NSAIDs) are common; they account for a quarter of all suspected adverse reactions reported to the Committee on Safety of Medicines (Committee on Safety of Medicines 1986). The elderly as a group have been found to be particularly susceptible to adverse drug reactions (Seidl et al

1965; Hurwiz and Wade 1969; Knox 1980; Parish et al 1983; Royal College of Physicians 1984).

Storage and disposal of medicines

Patients do not always store their medicines in a safe place. When 151 elderly patients were visited at home, one third were found to have left their drugs in exposed places (Law and Chalmers 1976). Furthermore, unused medicines are often not disposed of safely. In a survey in which 361 house-holders in Leeds were questioned about unused or out of date prescribed medicines, each household had, on average, 80 tablets or capsules (Hindmarch 1981). An earlier survey of 192 homes, broadly representative of households in England and Wales, revealed that each home had on average 3.2 prescribed medicines, 44% of which were classified as "hardly ever used" (Leach and White 1978). This figure is in agreement with the 45% of prescribed medicines which had not been used in the month before interview in a large nationwide survey (Dunnell and Cartwright 1972). Twenty-two percent of the medicines uncovered by Dunnell and Cartwright had been in peoples' homes for a year or more. The success of amnesties for unused prescribed medicines gives further insight into the degree of hoarding of medicines in the community. One collection of "unwanted" drugs from 500 households in Hartlepool resulted in the return of 43,554 unwanted pills or capsules during the collection week (Nicholson 1967). DUMP campaigns run by community pharmacies repeatedly have received large responses from the public (Anonymous 1978a).

Poor storage and disposal of medicines presents several problems. Firstly, accidental poisoning by drugs is a common cause of admission of children to hospital. In 1985, there were 77 admissions to the paediatric wards in Southampton for accidental poisoning; 44 of these children were under 5 years old (George 1986). Although the circumstances leading up to these incidents were not documented, it is possible that casual storage of drugs at home may have been a contributory factor, despite the advent of child proof containers

(Lane et al 1971). Secondly, the consumption of old medicines may endanger the patient if the drug has deteriorated with age. Thirdly, patients who hoard prescribed medicines may confuse bottles of newly prescribed drugs with older ones, or be tempted to supply them to other members of the family or friends. Around 5% of the Southampton residents who responded to a postal questionnaire admitted to having taken a medicine prescribed for someone else or had allowed someone else to take their medicine in the year prior to the study (Ridout et al 1986).

Whilst no recent publications were found in which awareness of the need to store medicines out of reach of children was assessed, 37% of the respondents in the postal survey conducted by Ridout et al were unaware of safe methods of disposal of medicines (Ridout et al 1986).

How to take the medicine correctly

In order to obtain maximum benefit from medicines, patients need to take them correctly. It is clear from the extensive literature on patient compliance that patients do not always do this (for reviews of this research see Ley and Spelman 1967; Marston 1970; Sackett and Haynes 1976; Cohen 1979; Haynes et al 1979; Garrity 1981; DiMatteo and DiNicola 1982; Koltun and Stone 1986). Non-compliance has been defined in these studies as anything from minor alterations to the prescribed dosage regimen to stopping the medicine prematurely or not getting the prescription cashed in the first place (Rashid 1982; Begg 1984). In a review of 185 original articles investigating patient compliance with various medical regimens, rates of compliance varied between 18%-89%, with an average of just over half the patients defined as compliant (Sackett and Haynes 1976; Haynes et al 1979). The authors estimate that about a third of patients took almost all of their medicine, a third took none, and the remainder were within the above range.

Poor compliance can have effects on the patient and the course of his disease,

some of which may be potentially serious. The therapeutic effect of metered inhalers, for example, is diminished by inadequate administration technique (Roberts et al 1982). Orehek et al (1976) reported that three-quarters of inhaler users fail to obtain the desired dose. At the other extreme, the overuse of isoprenaline in asthma has been linked to fatalities (Inman and Adelstein 1969). In a survey of 66 asthma patients, all of whom were using inhaled $\beta_2$agonists, almost half said they would take between 8 and 12 puffs in a 24 hour period. A further 12% said they would take more than twelve puffs, with one claiming that 30 was his maximum dose (Partridge 1986).

Discontinuation of drugs can also lead to problems: the consequences of premature discontinuation of penicillins include the possibility of recurrence of a bacterial infection, whereas abrupt withdrawal of β-adrenoceptor antagonists can cause ventricular arrhythmias, infarction and death (Kendall 1978). Success of treatment may depend also on whether a medicine is taken on a full or empty stomach, with food, fluid or in combination with other medicines (Hermann et al 1978; Anonymous 1981a).

It has been estimated that up to a third of patients' medication errors could pose a serious threat to their health (Stewart and Cluff 1972; MacDonald et al 1977). Two studies have suggested that between a tenth and a quarter of admissions to hospital may be the result of non-compliance with a medication regimen (McKenney and Harrison 1976; Ausburn 1981). Patients most at risk are those on drugs with a narrow therapeutic index and those in whom loss of control of the disease is serious (Royal College of Physicians 1984). However, for others the dosage may be less critical. Gordis et al (1979) note that adults with hypertension needed to take only 80% of their medication to bring their blood pressure under control, whereas approximately 60% of patients who took their medicines correctly did not achieve target blood pressure levels in studies reported by Sackett (1979). Despite the lack of exact data on the dose required to achieve a therapeutic response, most doctors are in agreement that patient

compliance is desirable. Finally, the economic consequences of non-compliance are considerable, including as they do the direct costs of drugs and the indirect costs of wasted time on the part of the patient and the doctor.

In order to comply, patients need to know the correct dosage instructions. Several studies have suggested that a significant minority of patients are unsure of even this basic information. Of the 417 out-patients prescribed medicines on either a twice, thrice or four times a day schedule, Hermann (1973) found around a third were confused about the dosage regimen. In 15% of cases patients were unable to specify any schedule at all. In another American study, only just over half of the 187 respondents knew the correct regimen for their cardiovascular drugs (Ascione et al 1986). Other estimates vary between 5% to 53% of patients who have inadequate knowledge of medication regimens (Boyd et al 1974; Hulka et al 1975; Parkin et al 1976; Ellis et al 1979; German et al 1982; Wartman et al 1983). Awareness that medicines need to be swallowed with food or fluid has also been found to be poor. Sixty-percent of the patients responding to a national pharmacy postal survey did not know whether or not to take their medicine with a fluid (Busson and Dunn 1986). In the Southampton postal survey, 11% of those taking tablets and 24% of those receiving capsules said they took them without fluid (Ridout et al 1986).

Ignorance of the dosage instructions is clearly not the only factor contributing to non-compliance. The idea that patients sometimes do not take medicines as prescribed (and often conceal their actions from doctors) has been recognised since Hippocrates. "The physician should keep aware of the fact that patients often lie when they say they have taken certain medicines" (Jones 1967). Despite extensive research, the demographic characteristics which can predict a "non-complier" have not been identified. Compliance has not been associated with the characteristics of the disease, including its seriousness. A detailed discussion of the factors which have been found to influence compliance is outside the scope of this review. However, the list includes poor communication

between doctors and patients (Ley and Spelman 1967; Hulka et al 1976; Eraker et al 1984; Pederson et al 1984; Fincham and Wertheimer 1985; Calnan and Rutter 1986); satisfaction with the treatment (Korsch et al 1968; Kincey et al 1975); continuity of care (Ettlinger and Freeman 1981); the level of control patients feel over the situation (Hayes-Bautista 1976; Conrad 1985); the complexity of the drug regimen (Drummond 1975; Hulka et al 1976), the patients' health beliefs (Becker 1974; Inui et al 1976) and explanatory models (Roth et al 1962; Snow 1974; Stimson and Webb 1975; Kleinman 1978; Blumhagen 1980; Helman 1981a) and the way these factors influence "illness behaviour" (Mechanic 1978).

1.13 The demand for information

Surveys conducted over the past 30 years have consistently found that the majority of patients want to be informed about their prescribed medicines (for example Cartwright 1964; Duff and Hollingshead 1968; Ley and Spelman 1967; Fletcher 1973; Waitzkin and Stoekle 1976; Locker and Dunt 1978; Cartwright and Anderson 1981; Patrick et al 1982; Ley and Morris 1984; Ridout et al 1986).

In summary, patients need and want to be informed about their prescribed medicines. The demand for information has been accompanied by an increasing emphasis on the patients' right to be informed about the medicines they are prescribed (Loftus and Fries 1979; Kaufman 1983). Consumerism, championed by the consumer rights movement in the USA, proposes that people have a right[1] to receive accurate and adequate information about all products they purchase. Prescription drugs are seen within this framework as a special class of consumer product. More recently, consumer organisations in the UK, and their representatives, have put forward this argument to encourage information to be provided about medicines (Anonymous 1981a; Medawar 1984).

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[1] *Entitlement (non-statutory)*

1.2 THE PROVISION OF INFORMATION

1.21 Information provided during the consultation

Several investigations conducted over the past 20 years have examined communication between doctors and patients during general practitioner consultations. The studies conducted fall into three categories:
(1) studies in which patients have been asked about the information they received during the consultation,
(2) studies where doctors have been asked about the information they gave during the consultation,
(3) direct observation of the consultation itself.

Patients were asked about the information they received during the consultation in the studies conducted by Cartwright (Cartwright 1964; Cartwright and Anderson 1981). Patients were asked if they thought they had received more than or less than "enough" information, and whether or not explanation was "adequate". The respondents themselves were left to decide what was enough information. Eighty Australian women were asked about the information they had received during their consultations by Boreham and Gibson (1978). Between one fifth and one third of these patients said that doctors provided information on a drugs name, purpose and effects and gave instructions for treatment during the initial consultation. Information on the side-effects of treatment was provided to 15% of patients. During follow up consultations, about half of the patients were told the drugs name, but other information was infrequently provided. In a telephone survey of 1,223 Americans, about half of the respondents said that they had received information from their doctor about the purpose and directions for use of their most recent prescription (Morris 1982). Eleven-percent claimed they had been informed about the drugs side-effects, but 19% said they had been told nothing about their medicine. Just under 30% of the 522 Norwegian hypertensives interviewed by Bakaas and Helgeland claimed to have received any information about their drug treatment

from their physician (Bakaas and Helgeland 1980).

All of these studies suffer from a major drawback: they rely on the patients memory for medical information. Since it is well established that patients are unable to recall a great deal of what they are told in a consultation (Ley 1979), they may underestimate the amount and type of information actually provided. Attempts to ascertain the information content of a consultation from doctors' memories of what they said (Hulka et al 1976; Ley et al 1976b) are subject to a similar recall bias.

Observation of consultations by using either a tape or video recorder, or by direct observation, avoids this problem. Studies utilising these techniques have confirmed patients' reports that doctors in America (Waitzkin and Stoekle 1976; Roter 1977; Stiles et al 1979; Ascione et al 1986) and in the UK (Bain 1976; Pendelton and Bochner 1980; Tuckett et al 1985) often do not offer full information about the drugs they prescribe. In a study of 187 American patients with cardiovascular problems, patients visits to their doctor were tape recorded (Ascione et al 1986). The recordings revealed that "general information" about the medicine was provided in 86% of the consultations and the drug regimen was discussed during 68 percent. Side-effects were mentioned in only 26% of the consultations. An earlier study of 80 patients which used direct observational found that doctors in a New York clinic informed patients about the length of their therapy 10% of the time, and dosage frequency 17% of the time. Very few of the doctors attempted to give rationales for their treatment decisions (Svarstad 1976). Even basic instructions are not always provided. Cyr and McLean (1978) found that over half of their sample of 78 patients were not given any instructions on how to administer their medication. Moreover, Webb (1976) reported that in the opinion of a qualified observer, none of the 28 patients observed in her study received adequate information about treatment during their consultations. What was said to the patients was limited to giving instructions about dosage and making reassuring statements about the medicines

proposed efficacy such as "this should put you right". Sometimes the doctor would refer back to the diagnosis, "this is for the rheumatics", as a way of explaining the treatment prescribed. In none of the consultations did the doctor name the drug he was prescribing to the patient. The possibility of side-effects was mentioned in only one consultation (Webb 1976).

The results of these observational studies must however be treated with caution for several reasons. First, the presence of observers might affect the doctors' behaviour during consultations. Second, different methods of measuring the amount and type of communication in a consultation make it difficult to compare results of different studies. Third, researchers may not be explicit about what they have considered sufficiently important to be counted as an item of information (eg Ley 1979). Despite these reservations it remains clear that doctors often fail to give adequate information about drug treatment.

Why information is not provided

One reason why doctors may fail to provide information is the shortage of time (Fletcher 1980). Formerly, general practitioner consultations lasted an average of 6 minutes (Cartwright and Anderson 1981), and not surprisingly, doctors often do not have time to discuss treatment fully (Fletcher 1973). However, since then the average consultation times have increased towards 10 minutes.

Secondly, doctors themselves may not be fully informed about the risks associated with drug therapy (Morris 1978a). There is evidence that doctors find it hard to keep up with the facts about prescribed medicines (Taylor 1977; Price et al 1986).

A third reason why information may not be provided is that patients do not ask about their treatment. Indeed, it is frequently assumed by doctors that patients do not want information about their medicines because they are reluctant to ask questions. However, evidence suggests this is not always the case. For example,

Korsch et al (1968) found that although 10% of the 800 mothers in their sample asked paediatricians no questions, and 27% asked only one or two such as "how do I find the bathroom?", around a quarter of the mothers later said they would have liked to have asked the doctor more questions. Carstairs (1970) reported that over half of her random sample of 432 Scottish patients who wanted more information failed to ask for it. Finally, of patients the 80 patients studied by Ley et al (1976c) 27% reported that although they usually wanted more information they never asked questions. This behaviour has been interpreted by Pratt et al (1957) as waiting for the doctor to take the initiative in explanations.

Patients may not ask for further explanation if they misunderstand something because they do not want to bother the doctor with "silly" questions (Ley and Spelman 1967); because the doctor and his staff give the impression of being too busy to answer (Rosenberg 1971; Mathews 1983); because questioning implies a lack of respect and confidence in the doctors judgement (Boreham and Gibson 1978; Fletcher 1980) or because they are anxious about the outcome of their illness. "You get hot and bothered when they are there and think afterwards "I wish I had asked them that"" (Cartwright 1964). In spite of the reluctance to ask, the majority of patients do want information (Ridout et al 1986). Moreover, Joubert and Lasagna (1975a) found that patients felt physicians should provide drug information with each prescription.

Assumptions about the inevitable competency gap between patients and doctors (Parsons 1951) have been suggested to be a fourth reason why information may not be provided. Hippocrates stated that, "Lacking in professional training, the client is too ignorant to be able to comprehend what information he gets" (Friedson 1970). This traditional perception of the patients' inability to comprehend and cope with medical matters persists today. For example the level of word comprehension of lower working class women attending an ante-natal clinic was consistently underestimated by the doctors (McKinlay 1973).
The fear that patients will not be able cope with negative information about

possible adverse drug effects is one manifestation of this belief (Drury 1984).

It has been suggested that traditional views of the doctor-patient relationship, where patients are seen as passive and dependent, underpin much of the reluctance about providing information (Parsons 1951; Szasz and Hollender 1956; Freidson 1970). How much information to give to patients (and how much to withhold) has been debated throughout the history of medicine. Hippocrates set the tone for the debate by arguing that doctors have the subtle responsibility of deciding how much information is in the patients' best interest (Waitzkin 1985). However, by controlling the amount of information a patient receives, the doctor may be also maintaining uncertainty to preserve power (Tuckett and Williams 1984; Waitzkin and Stoekle 1972).

A final reason why full information about treatment may not be provided is that it might interfere with the placebo response (Shapiro 1960). Patients have traditionally been denied knowledge about medicines because they had to believe in them if they were to work. Although the use made of placebo treatment has been likened to the practice of magic (Dunlop 1973), and there remains a symbolic element in drug prescribing (Joyce 1962; Claridge 1972), the effects of drugs no longer rely entirely on the placebo effect.

Problems associated with communication

It is clear that patients do not always receive information about their prescribed medicines during general practitioner consultations. However, even when information is provided there are barriers to the effective transfer of that information (Ley and Spelman 1967; Pendelton and Bochsler 1980). Firstly, technical jargon may confuse patients. Thus, Korsch et al (1968) found that when an American mother was told that her sick child would have to be "admitted for a work-up" the mother did not realise that the child would need to be hospitalised. Terms that are frequently used and have specific meaning to doctors, such as piles, jaundice, constipation and medicine are often defined

differently by the layman (Boyle 1970). Mazzullo et al (1974) found that tablets prescribed for "fluid retention" were often interpreted as causing fluid retention. Similar misunderstandings have been reported by Samora et al (1961); Cole (1979); Dunkelman (1979); Spiro and Heidrich (1983); Tuckett et al (1985).

Secondly, many doctors are middle class white males who are, by definition, highly educated in a very specialised discipline with its own concepts, language, and ethics. Because of this, a "cultural gap" between doctors and patients has been described (Kleinman 1978; Pendelton and Bochsler 1980). Communication with patients who do not share middle class values has been found to be less successful than when the patient is from a middle class background (Duff and Hollingshead 1968; Bain 1976; Pendelton and Bochner 1980).

Thirdly, even when communication appears to have been successful, verbal advice given during a consultation is often forgotten (Ley and Spelman 1967; Ley et al 1973; Bradshaw et al 1975). Several factors contribute to recall problems. Ley and Spelman (1965; 1967) found that patients with low or high levels of anxiety were able to recall a smaller proportion of presented information than patients reporting moderate levels of anxiety. Anxiety about the medical encounter may result in the patient not paying attention to the instructions of the physician (Fletcher 1980). In addition, patients remember the information which they perceive to be important. It is often the diagnosis rather than instructions about therapy which is seen as being the most important. Ley and Spelman (1965) found that only 44% of advice and instruction statements were recalled, whereas diagnostic statements were recalled by 86% of patients (Ley and Spelman 1965).

There is evidence that doctors do not structure the information they provide in a way that facilitates recall. Medical information is often delivered in a series of disjointed remarks (Morris 1978a) but Ley et al (1973) found that improved organisation of information could significantly improve recall. In general,

patients tend to remember what they are told first. Diagnostic information is recalled better because there is a strong primacy effect, whereas instructions on therapy are usually given toward the end of an interview whilst the patient is still processing the diagnostic information (Ley and Spelman 1967; Morris 1978a). The inclusion of a summary at the end of consultations has been found to increase patient satisfaction and recall of information (Bertakis 1977).

The amount of information presented has also been found to affect recall (Ley and Spelman 1965; Ley 1979). The more statements made to a patient, the greater the percentage forgotten. Ley found that patients remembered only about half of what they were told about their treatment (Ley and Spelman 1965; Ley 1979). This has led some to suggest that doctors should limit their advice to one or two statements (Walton et al 1980). However, the findings of Ley are not supported by Tuckett et al (1985), who found that only 10% of the 328 patients they interviewed were unable to remember key points mentioned during the consultation. Whilst these differences may in part be explained by the different methods used to assess recall (Tuckett et al used probed recall, whereas Ley employed free recall), they do suggest that the content, as well as the amount of information presented, will determine whether it will be remembered.

Research has shown that many of the ingredients for successful communication between doctors and their patients can be taught (see for example Pendelton and Hasler 1983). Whilst increasing emphasis is being placed on the training of doctors in communication skills, the situation is clearly less than optimal at present. This is reflected by the extent of patients' dissatisfaction with communications.

1.22 Patients' satisfaction with communications

Surveys of patients attitudes to health care in Britain and in the United States generally report high levels of patient satisfaction. Hospital patients (Cartwright

1964) and patients in general practice (Varlaam et al 1972; Cartwright and Anderson 1981) claim to be very satisfied with their care when asked to give an overall assessment (Locker and Dunt 1978). An important source of patients' views of primary care in England and Wales is the survey by Cartwright and Anderson (Cartwright and Anderson 1981). In their study, 90% of people described themselves as satisfied or very satisfied with the care they received from their family doctor. Similarly, Kincey et al (1975) found that answers to a question about general satisfaction with communications showed 82% of their sample to be satisfied. However, when patients are asked specifically about the adequacy of the information provided, a different picture emerges. Patients tend to be more dissatisfied about the information they receive about their illnesses and treatment than other aspects of their health care (Cartwright 1964; Ley and Spelman 1967; Fletcher 1973; Ley et al 1976; Locker and Dunt 1978; Cartwright and Anderson 1981). In a survey conducted in the USA, over half of the patients recently discharged from hospital were not satisfied with the type of information made available to them (Cyr and McLean 1978). Communication problems were the most common source of dissatisfaction expressed in a community based study of patient satisfaction in Lambeth (Patrick et al 1982), and 23% of the patients interviewed by Cartwright and Anderson (1981) described their general practitioner as "not so good" about explaining things fully. Closer questioning of the respondents in the study conducted by Kincey et al (1975) revealed that only just over half felt that they had been fully informed.

In these studies, patients express more dissatisfaction with the information provided on the cause of illness than with details about the nature of treatment (Kincey et al 1975; Fitzpatrick et al 1984; Partridge 1986). Nevertheless, considerable dissatisfaction with the information provided about medicines has been reported. In a systematic postal survey of the Southampton electorate, 62% of the 443 respondents felt that not enough was explained about medicines by doctors and pharmacists (Ridout et al 1986). Similar proportions of American patients taking antibiotic therapy (Gotsch and Ligouri 1982) and

Norwegian patients taking anti-hypertensives (Bakaas and Helgeland 1980) felt a need for more information about their drugs. In summary, patients would like more information about prescribed medicines than they feel they currently receive (Joubert and Lasagna 1975; Ley and Morris 1984).

Other sources of information

The desire for information leads many patients to supplement the advice they receive from doctors with information from a variety of alternative sources. In an American survey, around half of the respondents mentioned the pharmacist as being an important source of information about medicines (Joubert and Lasagna 1975a). Similarly, Fitton and Acheson (1979) reported that some of their British respondents were in the habit of asking their chemist for more information. However, other studies suggest that pharmacists are only a minor source of information in the UK (Gray 1985). Friends and family networks provide a rich exchange of ideas and information about drugs, and about health matters in general (Friedson 1960; Mckinlay 1973; Stimson and Webb 1975; Calnan 1983). In the studies conducted in one general practice by Elliot-Binns (1973; 1986), advice from friends was often sought and seen as good. Women were the chief source of informal advice on medical matters and this did not change much over the 15 year interval between his two studies. Self-help groups, alternative practitioners (Bakaas and Helgeland 1980; Gray 1985), pre-recorded telephone tapes and the media are other popular sources of information about medicines, the latter having a tendency to dwell on the "bad" news (Best et al 1977). Radio phone-ins on the subject of medicines are also popular. One such phone in had an overwhelming response when a community pharmacist answered enquiries about prescribed medicines. Most of the queries were about the side-effects and long term effects of drugs (Faunch 1980). Finally, pharmacopoeias written for the layman have become best sellers: The Swedish lay pharmacopiea (FASS) was second only to the Bible in terms of its popularity.

Patients welcome written information

Surveys conducted in the USA indicate that a substantial number of patients are interested in receiving written information with all prescribed drugs (Joubert and Lasagna 1975a; 1975b; Fleckenstein 1977a; Morris and Groft 1982). Morris et al (1977) report a broad-based support amongst patients for the introduction of patient information leaflets. Bannister et al (1980) found in a study of 40 out-patients that the majority liked to have some written information on their medicines. Furthermore, in Norway about 80% of hypertensives who expressed a desire to know more about their drugs wanted written information (Baksaas and Helgeland 1980). Finally, two British studies suggest that information leaflets would be welcomed in this country. Eighty-three percent of the respondents to a postal survey of the Southampton electorate (Ridout et al 1986) and 90% of the patients who returned questionnaires in a national pharmacy survey (Busson and Dunn 1986) thought an information leaflet would be helpful.

To summarise, lack of information has been found to be a major cause of patient dissatisfaction. Many patients feel not enough is explained by doctors and pharmacists, and even when information is given verbally it is often forgotten or misunderstood. Since many patients would welcome additional written information, one way to deal with this problem might be to provide information leaflets with prescribed medicines.

1.3 THE EFFECTS OF INFORMATION LEAFLETS

1.31 Provision of leaflets

Prescription drugs have traditionally been exempt from patient labelling requirements. Historically, whilst the law has prevented deceptive statements, such as Cuforhedake Brane-Fude (a headache mixture) or Spotty Days Invigorator (a "male-weakness" remedy) from appearing on medicine labels

(Young 1970), there has been no requirement to offer any helpful information. It is only recently that the name of a prescribed medicine has been required on the medicine container (Malahy 1966; Dunlop 1973).

Today, the strength of the medicine, the prescribed dose and the total quantity of the product dispensed in the container are included on the label as well as the name of the preparation (British National Formulary 1986). Additional cautionary and advisory labels, such as "avoid alcohol" and "take with or after food" are also provided by pharmacists. "For external use only" is a legal requirement on external liquid preparations, while "Keep out of reach of children" is a legal requirement on all dispensed medicines. Since the label is what the patient will see when taking each dose it is in some ways the ideal place for information about the medicine. However, the space available on a label to provide information is limited. In many cases, the only way to give more written information is to provide a leaflet with the medicine.

Until recently, few patient-oriented information leaflets have been available for prescribed medicines. There has, however, been a trend towards their development over the past 15 years. In America a considerable amount of printed information is available from pharmacists, including multipage brochures and pamphlets (Morris 1978b; Morris 1982). Furthermore, the American Medical Association has produced Patient Medication Instruction Sheets, which give information about 81 prescribed drugs, and these are available for distribution by physicians. The United States Pharmacopoeia, the American Academy of Family Physicians and the American Association of Retired Persons have also introduced written medication education programmes (Kelly and West 1980).

Several European countries have developed similar programmes (Committee of Inquiry 1986). Kelly and West found that in 1980 a "small but significant number" of British pharmacies provided some form of written information (Kelly

and West 1980). But by comparison with the United States, British patients have few potential sources of information leaflets about drugs. Booklets, sheets and warning cards are available from drug manufacturers (Smith 1980; Sloan 1984) and other bodies such as the British Diabetic Association and the British Epileptic Association (Anonymous 1978b).

Package inserts

Recently the package insert, traditionally provided for the health professional only, has been considered as a vehicle to inform patients about their drugs. In America, the Food and Drugs Administration has required manufacturers of certain products, including isoprenaline inhalers, oral contraceptives, intrauterine contraceptives, diethylstilbestrol (DES) and progestational products to produce package inserts for patients (Institute of Medicine 1979). Moves to extend the FDA programme to all prescribed drugs were cancelled in 1982 (Anonymous 1981b). Since then calls to make patient package inserts a requirement have been considered on a case by case basis.

Package inserts are legally required with drugs in several European countries including France, Germany and Holland. However, the inserts need not be patient-oriented and are often complicated. In Italy, separate leaflets are provided for physicians and for patients. The Nordic countries, however, do not routinely provide patient package inserts but information is widely available to patients in the form of leaflets at the pharmacy and patient compendium. In Belgium, patient package inserts have been produced for new products introduced since 1986. Despite calls for patient information leaflets to be introduced in the UK (Anonymous 1980) patients in this country only receive written information about a few groups of drugs, such as oral contraceptives and inhaled bronchodilators.

1.32 The effects of written information

During the past 15 years the potential benefits and disadvantages of providing

patient information leaflets have been the subject of intense debate and speculation amongst doctors, pharmacists, lawyers, drug manufacturers and the layman (for example see: Sherman 1970; Carlova 1974; Dorsey 1977; Fleckenstein 1977b; Ligouri 1977; Morris and Gagliardi 1977; Vincent 1977; Weibert 1977; Braucher 1981; Goyan 1981; Drury 1984; Dworkin 1986). Those in favour of patient information leaflets predict that the benefits will include improvements in patients' knowledge about their medicines; better compliance with dosage instructions; improved satisfaction with the information provided and improvements in doctor-patient communications. In addition, patients may be encouraged to store and dispose of medicines safely, and informed patients will be able to avoid hazardous interactions with other substances such as alcohol or food. Some predict that information will facilitate early recognition and reporting of side-effects, and offer reassurance about the benefits of appropriate drug treatment. The placebo response may even be enhanced due to the "attention-placebo" effect (Haynes et al 1979).

By contrast, opponents argue that providing information about the risks of drug therapy will make the patient unnecessarily anxious; that patients given such information will not comply with their doctors' instructions, and that they may reject a beneficial drug treatment altogether. Some argue that detailed information about side-effects will cause patients to experience them by suggestion. Other possible disadvantages include the creation of more demanding patients; the promotion of inappropriate self-medication; prescription drug exchange among patients, and the "de-mystifying" of the medication and diminution of the placebo effect. Widespread waste of resources and increases in legal liability prosecutions have also been predicted. Finally some argue that patients do not really want to be informed about their drugs and remain sceptical that the leaflets will be read.

Limitations of previous research studies

One reason why the benefits and drawbacks of leaflets remain largely a matter

of speculation is the inadequacy of the research evidence currently available. Few studies have been conducted to evaluate the effects of information leaflets about medicines, and those that have suffer from several drawbacks. Firstly, many of the existing studies have evaluated a wide selection of educational interventions ranging from modest dosage instruction cards to complete educational programmes (including video presentations and face-to-face consultations) as well as written information. The effect of written information is often difficult to disentangle in such studies (eg Sackett et al 1975). In addition, the leaflets evaluated in the different studies vary in both content, format and intention, making comparisons of their educational effectiveness difficult.

Secondly, problems arise from the lack of methodological rigour shown in many of the studies. In some cases inadequate description of methods precludes assessment of the validity of the study. In others poor design, notably a lack of control groups for comparison, prevents alternative explanations for the observed results from being ruled out with confidence. In addition, the heavy reliance on small sample sizes makes it likely that the findings could be due to chance. Reliance on insensitive measures of outcomes can also mean that a real effect may have been missed.

Thirdly, cultural and health service differences make it difficult to transfer the results of research studies (the majority of which have been conducted in the USA) to the UK situation. Also the concentration on the effects of leaflets amongst certain groups in the population, notably hospital patients, the elderly (eg Wandless and Davie 1977), children (eg Colcher and Bass 1972; Mattar et al 1974) or young women (eg Fleckenstein et al 1976; Morris et al 1977) may mean the results cannot be transferred to a wider general practice population. Similar problems can arise from the use of a mixture of short term treatments (eg Dodds 1986) and drugs used for chronic conditions such as hypertension (eg Clark and Bayley 1972). Finally, the interpretation of results is often limited by a lack of theoretical context[1]

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[1] *Whilst a variety of approaches could be applied - some examples include the Health Belief Model from social psychology (Becker 1974); Explanatory frameworks from medical anthropology (Kleinman 1978); and the Sociology of Knowledge from medical sociology (Friedson 1970) - few authors have attempted to draw on existing theory to help make sense of their findings. More usually, the simplistic assumption implicit in many of these studies that leaflets will improve knowledge about drugs, which in turn will lead to improvements in compliance, remains unchallenged.*

These limitations should be borne in mind when considering the findings of previous studies.

Effects of leaflets on patients' knowledge about their medicines

A review of the effectiveness of health education, sponsored by the Health Education Council (now the Health Education Authority), concluded that written material was not generally very effective at improving knowledge (Gatherer et al 1979). However, health education leaflets and booklets on a wide range of topics have been shown to be a useful adjunct to verbal advice given by general practitioners (Fowler 1985). Improvements in knowledge about nutrition (Jacoby et al 1977), child health (Pike 1980) and awareness of breast cancer screening (McMaster et al 1985) have been recorded when written information has been issued. There is evidence also that information leaflets can increase patients knowledge about medicines (Institute of Medicine 1979). A review of 32 studies which assessed the effects of written information in patient populations concluded that the provision of written information about medicines increased knowledge in all but one of the studies (Ley and Morris 1984).

Most of the studies which have investigated the effect of leaflets on knowledge about medicines have been conducted outside the UK. Gotsch and Ligouri (1982) demonstrated an improvement in awareness amongst American patients who received leaflets with short term courses of antibiotics. They conducted a three group comparison study of 186 patients receiving new prescriptions for penicillins and assessed the effect of patient package inserts and pharmacists' instructions on knowledge. Improved awareness about the proper use of drugs was reported amongst patients who received a leaflet with penicillin V or ampicillin. Furthermore, whereas only one third of the respondents in the control group knew that antibiotics should be taken on an empty stomach, this was known by 88% of those who received leaflets (Gotsch and Ligouri 1982). By contrast, although a Swedish study demonstrated that inserts could lead to

better knowledge of side-effects and contraindications, there was no effect on knowledge of the drug's name and indications for use (Eklund and Wessing 1976).

Leaflets have been associated with improvements in knowledge amongst patients taking longer-term therapy for chronic conditions. Sackett et al (1975), in a well designed randomised clinical trial of 230 Canadian steel workers found that a booklet and slide presentation was highly effective in teaching about the management of hypertension. At 6 months, 85% of the hypertensives exposed to information had "mastered" this in contrast to only 18% in the control group. Johnson et al (1986) evaluated one page drug information sheets giving information about either digoxin and propranolol. They tested in-patients and out-patients from the Brigham and Women's hospital, Boston using six multiple choice questions before and after receiving the written leaflet. After one month, the patients who had received the sheet had a significantly higher knowledge score than those who did not. However, it is not clear how patients were selected for this study and the response rate is not quoted. In addition (and in common with many of the other studies) the number of patients actually receiving leaflets was very low; only 17 in the main study.

Newcomer and Anderson (1974) administered a drug counselling programme, which included printed material, to 47 American surgical in-patients. After discharge, the study group was found to have a better knowledge of the name of the drug and optimal dosage intervals. Wiederholt and Kotzan (1983) used a 5 page questionnaire which contained a knowledge and comprehension exam to evaluate the effectiveness of a benzodiazepine patient package insert in 158 people. Generic leaflets giving details about benzodiazepines issued at a community pharmacy were found to increase knowledge and understanding of treatment when compared with a control group who did not receive the leaflets (Wiederholt and Kotzan 1983). In an Irish study, printed information for patients with hypertension was evaluated amongst 100 consecutive patients

attending a blood pressure clinic. The patients were randomised into two groups, one of which received a booklet about hypertension. The booklet included details about antihypertensive drugs. Sixty-five percent of patients who received the leaflet could name their treatment compared with only 34% in the control group. Those who received the booklet were also more aware of the asymptomatic nature of their condition, that it usually lasts for life and that treatment should not be stopped (O'Hanarahan et al 1980). Other studies which have shown knowledge improvements include those conducted by Fox 1969; Clark and Bayley 1972; Madden 1973; McKenney et al 1973; Boyd et al 1974; Mattar et al 1974; Newcomer and Anderson 1974; Sackett et al 1975; Clinite and Kabat 1976; Paulson et al 1976; Weibert 1977; Romankiewicz et al 1978; St.George 1983).

Some British studies have recorded increases in knowledge about medicines after patients have received educational programmes which included written information. In a small, well-designed study involving 56 out-patients, Ellis et al (1979) supplied either verbal or supplementary written information on discharge from hospital and compared the groups later. The "written group" were found to score significantly higher in knowledge about diagnosis and drug treatment. Another study investigated the treatment of urinary tract infections (Gauld 1981). Sixty-two women consulting their general practitioner with symptoms of urinary tract infection were assigned at random to either an experimental group, who were given a set of pre-standardized instructions both verbally and in written form, or a control group, who received the same advice in the verbal form only. Those in the written advice group remembered more information about their medicine.

A special group who already receive written information with their prescriptions are women using oral contraceptives (Fleckenstein et al 1976; Morris et al 1977). Although there are no control groups for comparison, these American studies suggest that inserts may have had a positive impact on patients' knowledge about

oral contraceptive use. Morris et al (1977), in a retrospective American nationwide survey of 1720 current and 949 former oral contraceptive users found that two-thirds of those who read an insert recalled the directions for use and a half were aware of side-effects. In a more recent survey of 50 American women, 84% of whom had taken or were currently using oral contraceptives, Sands et al (1984) reported that most of the women performed poorly on their knowledge exam, but those who had read an insert performed significantly better.

Package inserts for a variety of drugs have been evaluated in a major series of studies conducted by the Rand Corporation for the US Food and Drugs Administration. Increased awareness about oestrogen treatment (Udkow et al 1979; Kanouse et al 1981), flurazepam (Berry et al 1981) and erythromycin (Winkler et al 1981) was reported, but in general the improvement was small (Mullen and Green 1984). Moreover, many of the findings of these studies, all of which employed similar methodologies, remain largely unconfirmed. Nevertheless, some support for these findings is provided by De Tullio et al (1986) who found that nearly three-quarters of those who received an American Medical Association Patient Medication Instruction leaflet for diuretics felt they knew more about their medicine. In addition, a pilot study conducted within the setting of British general practice found that patients who received a generic leaflet giving information about penicillins or non-steroidal anti-inflammatory drugs (NSAIDs) were more likely to know the name of their medicine and the side-effects (George et al 1983). In addition, a pharmacy survey confirmed that additional information about antibiotics was associated with improved knowledge about name of medicine, awareness of what to do if a dose was forgotten and the side-effects (Dodds 1986).

Comparison of the results of these studies is difficult because no uniform definition of patient medication knowledge has been applied. Knowledge has been variously defined as awareness of the drug name; purpose; administration

schedule; adverse effects; special instructions or a combination of these items (Ascione et al 1986). Moreover, some researchers have measured the knowledge components separately, others have used an index or score comprising several components (Johnson et al 1986), while the remainder have explored patients understanding, comprehension and recall (Ley et al 1973; Ley 1979). The level of knowledge has been assessed using a variety of methods including free recall (Morris et al 1977); prompted recall (Weiderholt and Kotzan 1983); patients own assessments (Busson and Dunn 1986) and various combinations of the above (Ridout et al 1986). The apparent success or failure of a particular intervention in improving drug knowledge will have been affected by the way knowledge has been defined and measured. Moreover, it is not always clear which aspects of knowledge are improved by leaflets, and which are of significance in terms of subsequent behaviour and attitudes.

Despite these limitations, the research currently available points towards an association between written information and improvements in knowledge about medicines.

Effects of leaflets on patients' experience of side-effects

A considerable body of psychological evidence has shown that people are highly suggestible (Loftus and Fries 1979). Moreover, it is recognised that psychological factors contribute to the occurrence of adverse reactions to medicines (Shapiro 1960). Despite this, the few empirical investigations which have recorded patients' experiences of side-effects do not suggest that informed patients experience side-effects due to suggestion (Paulson et al 1976; Weibert 1977; Dwyer and Hammel 1978; Morris and Halperin 1979; Ley and Morris 1984; Johnson et al 1986)

The effect of forewarning about the side-effects of medications was investigated in a series of studies of British patients (Myers and Calvert 1973; 1976; 1978; 1984). In their earlier studies, patients were allocated alternately to one of two

groups. Patients in one group were forewarned about the drugs side-effects and those in the other were not. In the later study, verbal and written information on the side-effects and verbal and written information on the benefits of the medicine were compared with a control group. The information provided did not affect the reported incidence of side-effects in any of these studies.

Some support for these findings comes from two other British studies. Patients who received a leaflet about penicillins or NSAIDs in a pilot study in general practice were no more likely to experience adverse effects than those who were not given the information (George et al 1983). A study of the effects of pharmacy leaflets, which gave information about antibiotic therapy, found no significant differences between the number of side-effects reported by patients who received the information and patients in the control group (Dodds 1986).

An American study in which informed patients did report more side-effects was conducted by De Tullio et al (1986). Significantly more patients who received an American Medical Association Patient Medication Instruction leaflet reported side-effects compared with the control group. Similar observations were made in an earlier study conducted by Newcomer and Anderson (1974). However, in the latter case, the authors pointed out that it was the reporting of adverse reactions that was increased and not their incidence.

Patients who experience side-effects and receive information appear to be more likely to attribute their symptoms to the drug. Morris and Kanouse (1982) investigated the effects of a patient package insert which gave information about thiazide diuretics, amongst 249 newly diagnosed hypertensive patients. Two-thirds of the patients were given the leaflet that described the drug and its possible side-effects and one-third were not. Although patients who received the package insert reported experiencing about the same number of side-effects as those who did not, more of those who received the written information attributed experienced reactions to their medicine. When side-effects were

reported by patients who received a leaflet in the pilot study conducted by George et al (1983), they were also more likely to be recognised as being due to the medicine. However, it is not known how well patients are able to discriminate drug related effects from extraneous new symptoms. Symptoms that are labelled as side-effects may actually be those of the disease under treatment (Morris and Kanouse 1982).

Does written information cause increased levels of anxiety?

A study of the effects of information disclosure to patients receiving an angiogram found that 35% of the patients in sample were disturbed by the information presented (Alfidi 1971). Visser (1980) also found higher levels of anxiety amongst patients who received written information before an operation. By contrast, written information reduced anxiety levels amongst pre-operative patients (Leigh et al 1977) and women about to undergo gynaecological surgery (Wallace 1986). In addition, patients who received an American Medical Association Patient Medication Instruction leaflet were no more concerned about the side-effects of treatment than those who did not receive written information (De Tullio et al 1986). In a review of the psychological effects of written information, studies in which patients were given access to their medical charts and records found no increases in anxiety or depression as a result (Ley and Morris 1984). Nor were frequent adverse emotional reactions found when patients were told they had cancer. Ley and Morris conclude that although there are occasionally patients who have adverse reactions to frightening information, this appears to be the exception rather than the rule. However, they point to the paucity of research data available in this area.

Concern has been expressed about the ability of patients to make adequate risk / benefit decisions when informed about drugs (Drury 1984). Epstein and Lasagna (1969) found that healthy subjects given details of the risks of a drug were less willing to volunteer to take that drug than those given more general explanations. In addition, Weintraub et al (1981) reported significant levels of

apprehension about oestrogens amongst a third of women who had read a patient package insert. By contrast, a study of Canadian schizophrenics found that the "educated" patients were less fearful of side-effects and addiction (Seltzer et al 1980). The question of how best to present information about risks is at present unresolved. However, research has shown that different ways of presenting the same information can influence the way a risk is perceived (Fischoff et al 1981; Slovic et al 1981). For example "abnormal bruising" when listed as a side-effect of drug treatment caused much more concern than "a tendency to develop black and blue marks" (Keown et al 1984).

From the few studies that have been conducted, there is little evidence of patients refusing or discontinuing treatment when information about side-effects is provided. Of 232 patients who received a consent form that described the risks of angiography in detail, only 2% refused to undergo the procedure (Alfidi 1971). Two American surveys of oral contraceptive users and former users found that although some women who had read the patient package insert had stopped taking the pill, most had discontinued contraception in response to actual side-effects rather than the insert warning (Fleckenstein et al 1976; Morris et al 1977). In fact, Fleckenstein identified a group of women who were of the opinion that the benefits of oral contraceptives did not outweigh the risk to their health, but who continued taking them anyway. In the UK, Myers and Calvert (1978) found that depressed patients receiving written information about side-effects were significantly less likely to discontinue medication than were patients who received verbal or no information.

The effects of leaflets on patients' medicine taking behaviour

In their review of the effectiveness of health education, Gatherer et al (1979) concluded that there is some evidence that written information can influence certain health behaviour. Visits to the dentist, contraceptive sales and breast examination have all been influenced by the provision of written information. Against these are the failures of literature to affect behaviour in relation to the

wearing of seat belts; child rearing; influenza vaccination for hospital personnel, and the prevention of childhood accidents at home (Gatherer et al 1979).

The hope that written information about drugs will improve patients' compliance with medicine taking regimens has made this area a popular one for research (Morris and Halperin 1979). However, the evidence that leaflets encourage patients to take their medicines correctly is confused. Written information has been found to improve compliance with short course antibiotic therapy (Colcher and Bass 1972; Madden 1973; Linkewich et al 1974; Sharpe and Mikeal 1974; Morris and Halperin 1979; Gotsch and Liguori 1982). In a well controlled study of children receiving penicillin for streptococcal infections, children whose mothers received specific counselling and a one page sheet emphasising the need for the medication to be taken for a full ten days, were more compliant than those who received only verbal information (Colcher and Bass 1972). Other less well controlled studies have confirmed these findings (Leistyna and Macaulay 1966; Mattar et al 1974). British patients have been found also to be more likely to comply with antibiotic regimens when information is provided. The effects of carefully designed leaflets giving information about penicillins were evaluated in a well controlled pharmacy study of 61 patients discharged from hospital (Dodds 1986). Compliance, assessed by tablet count and personal interview, was significantly better in the group who received leaflets. Similar results were reported when leaflets on penicillins were issued in a general practice setting (George et al 1983).

Whilst written information has been found improve compliance with antibiotic regimens, information about drugs prescribed for chronic conditions has not been shown to have the same effect (Morris and Halperin 1979; Mullen et al 1985). Indeed, the literature is rife with unsuccessful attempts to improve compliance with long term treatment by giving written information on its own (Sackett et al 1975; Mazzuca 1982; Mullen and Green 1984) or as part of an educational package (Hecht 1974; Maiman et al 1979; Norell 1979; Gauld 1981; Roberts et

al 1982). In fact, some studies have pointed to a tendency for lower compliance amongst those who received leaflets, although this trend was not statistically significant (Clinite and Kabat 1976; George et al 1983).

Some successes have been reported. Seltzer et al (1980) conducted a two group comparison of 67 schizophrenic in-patients to assess the effect of instruction about their disease and its pharmacologic treatment. Following a course of lectures and data sheets, the "educated" patients tended to be more compliant on out patient follow up. In Britain, Ley et al (1976c) found leaflets classified as "easy" to read led to improved compliance with antidepressants and tranquillisers: leaflets classified as "difficult" to read had no measurable effect. The use of medication memory aids (MacDonald et al 1977; Wandless and Davie 1977; Norell 1979) have proved partially successful, particularly amongst the elderly where forgetfulness may be a problem.

Inadequacies and inconsistencies in the way patient compliance has been defined and measured cast doubt on the reliability of much of the research in this area. Definitions of "adequate compliance" are for the most part arbitrary and vary considerably from study to study. In addition, the tablet count, which has been widely used, is known to be an unreliable measure of compliance which obscures the way in which the dosage regimen was implemented (Gordis et al 1969). "There is no certainty that what has left the bottle has been through the patient!" (Roth et al 1962). Patients' self-reported compliance, elicited during interviews or by questionnaires, has been found to be even more unreliable when compared with more objective measurements such as urine analysis or blood tests (Gordis et al 1969). The main problem appears to be that people report taking more medicine than they actually have (Gauld 1981). Whilst some have tried to get around the problem by using a combination of measures (Dodds 1986), and recent studies have tended to make more use of objective direct measures (Mullen and Green 1984), the accurate assessment of patient compliance remains a problem.

In conclusion, it would appear that written communication by itself does not guarantee that patients will take their medicines as directed. The research has shown, however, that combinations of verbal and written information have been more successful at improving compliance than written information alone (Institute of Medicine 1979). Effective communication may be considered a necessary, but not sufficient, condition for compliance (Morris and Halperin 1979).

The effects of leaflets on storage, disposal and sharing of medicines

Few studies have examined the impact of leaflets on safe storage, disposal or sharing of medicines. For the most part, investigations have focused on the ability of written information to improve awareness of the need to store medicines out of reach of children (Ellis et al 1979; Dodds 1986). No studies were found where the effect of written information on place of storage in the home was assessed, nor did any of the studies reviewed evaluate effectiveness by referring to figures for accidental poisoning of children.

The widespread hoarding of medicines in peoples' homes has been uncovered by several surveys (Dunnell and Cartwright 1972; Leach and White 1978; Hindmarch 1981). With the exception of MacDonald et al (1977), who found that counselling was useful in reducing the use of old medicines and other peoples' medicines, there have been few attempts to evaluate the effectiveness of information on safe disposal practices. Poster and media "DUMP" campaigns, designed to encourage patients to return unused medicines to the pharmacy have, however, proved popular and successful (Anonymous 1978a).

Effects of leaflets on satisfaction

There is evidence that informed patients are more satisfied (Korsch et al 1968; Kincey et al 1975; Ley et al 1976a; Bertakis 1977; Smith et al 1981). Korsch et al (1968) conducted a series of studies in which consultations with the mothers

of children visiting an American paediatric clinic were tape recorded and systematically rated. In interviews conducted immediately after, and again two weeks later, mothers who felt the communication had been good during the consultation were more satisfied. However, this work has not been replicated and the details of how the satisfaction rating was evolved are not described. Nevertheless, others have reported that various aspects of a doctor's behaviour during the consultation, including the perceived adequacy of communication, can affect satisfaction (Stiles et al 1979; Stewart 1984).

Few studies have investigated the effect of written information on patients' satisfaction (Institute of Medicine 1979). In their review of the effects of written information for patients, Morris and Halperin (1979) found that in six American studies which examined pharmacist dispensed sheets, results were mixed as to whether the information increased patient satisfaction (Morris and Halperin 1979). In one of the studies reviewed, 95% of the patients who received leaflets felt they had been provided with adequate information about their drugs, whereas only just over half of the control patients believed they had adequate information (Weibert 1977). In a more recent study, patients who received Patient Medication Instruction sheets from their physician were significantly more satisfied than the control group with their overall perceived drug knowledge (De Tullio et al 1986). A pilot study conducted in two British general practices suggests improved satisfaction might be expected to accompany information provision in this country. Patients who received written information about penicillins or NSAIDs were significantly more likely to be completely satisfied with the information received ($p<0.05$), and with their treatment in general, although the latter trend did not reach statistical significance (George et al 1983).

The way satisfaction has been defined and measured has varied between studies. Definition of the concept of satisfaction is rare (Locker and Dunt 1978). Some researchers have attempted to measure a single global view about health care (Ware and Synder 1975), whilst others have probed different dimensions of

satisfaction, such as satisfaction with the doctors' bedside manner or with technical competence (Hulka et al 1976; Ben-Sira 1980; DiMatteo and DiNicola 1982). In some cases complex satisfaction scales and measures have been developed (Hulka et al 1970; Stiles et al 1979). These differences make it difficult to predict the effect of written information on patients' satisfaction.

The effects of leaflets on outcome of treatment

The exchange of information between the doctor and patient has been found to be an important factor influencing the results of treatment (Inui et al 1982; Heszen-Klemens and Lapinska 1984; Wallace 1986). When patients are given information before an operation, they require fewer analgesics and report less pain (Janis 1958; Egbert et al 1964). Information which aids understanding can reduce pain and speed recovery (Skipper and Leonard 1968). Similar findings have been reported more recently (Ridgeway and Mathews 1982; Devine and Cook 1986; Hathaway 1986; Wallace 1986). No studies which examined the effects of written information on clinical outcome were found.

The use made of leaflets

Research has shown that the majority of patients read the information they receive about drugs (Sharpe and Mikeal 1974; Eklund and Wessling 1976; Fleckenstein et al 1976; Morris et al 1977; Udkow et al 1979; Kanouse et al 1981; Gotsch and Liguori 1982; George et al 1983; Morris and Olins 1984; Sands et al 1984; De Tullio et al 1986). The percentage of patients claiming to read leaflets in these studies (which gave information about a wide range of medicines) varied from 70% to 95%. Similar results have been reported for leaflets on other health-related material (eg Turner et al 1981).

There is some evidence to suggest that leaflets are kept for further reference. Whilst a health education booklet, which described the management of six common symptoms, did not lead to an increase in knowledge amongst mothers receiving it, a questionnaire revealed that over three-quarters of the mothers had

consulted it at some time during the year of study (Anderson et al 1980). Leaflets about medicines have been used in a similar manner. The percentage of patients who keep their leaflets appears to vary between 45% and 95% (Weibert 1977; Dwyer and Hammel 1978; Romankiewicz et al 1978; Kanouse et al 1981; Morris and Olins 1984; De Tullio et al 1986). Around a third of the respondents in the study by Kanouse et al (1981) claimed to have read their leaflet more than once. The reason most frequently given was to check on drug side-effects. In a study of American oral contraceptive users, 6% of current users referred to the insert when they missed a pill, 4% when they had physical discomfort and 1% used it as a reference when they could not contact the doctor (Morris et al 1977).

Virtually all studies of patients' reactions to patient package inserts or insert-like materials show that most patients find such written instructions to be a useful source of drug information (Institute of Medicine 1979). Moreover, the favourable reactions to written drug information extend across a range of drugs and patient populations. Around four out of every five patients who receive leaflets have been found to evaluate them positively (Hladik and White 1976; Mazis et al 1978; Udkow et al 1979; Gotsch and Liguori 1982; George et al 1983; Sands et al 1984; Dodds 1986).

The impact of sex, age and social class

Few studies have examined the effects of demographic characteristics on the impact of leaflets. In a small British study it was found that whilst age was correlated inversely with knowledge obtained from leaflets, multiple regression confirmed that at any given age, patients who received written information scored significantly better than those who did not (Ellis et al 1979). Nevertheless, the view that leaflets may only be of use to younger, educated and relatively healthy people is widely held, and some are sceptical of their usefulness in other groups (Dorsey 1977; Taylor 1983). Indeed, Joubert and Lasagna (1975b) found that most interest in leaflets occurred amongst younger,

better educated respondents. However, widespread interest in leaflets amongst all demographic groups has been demonstrated in other surveys (Morris and Olins 1984; Ridout et al 1986).

Longer-term effects of leaflets

Little is known about the long term effects of written information. It is likely however that awareness may decline over time. For example, it is known that knowledge gained from written information on dental health was largely forgotten after six weeks (Gatherer et al 1979). A five group randomised controlled trial of 98 clinic and hospital neurological patients tested the effect of oral and written instruction from a pharmacist on "long-term" memory of drug information (Woroneicki et al 1982). They found that the mean knowledge scores of the patients in the test group were increased by over 25%. However, patients were tested only two months after the information was received but not followed up after that time. No studies have been found which have evaluated leaflets a year after issue, for example.

Distribution of leaflets

Leaflets giving information about drugs could be distributed by the general practitioner, the pharmacist or the pharmaceutical manufacturer. However, few studies have examined the feasibility of leaflet distribution from these three sources.

It has been reported that the majority of doctors are opposed to the routine use of patient information leaflets (Ryan and McMahon 1977). Sixty-one percent of the 100 specialists in obstetrics and gynaecology who were questioned by Carlova (1974) were against extending patient package inserts beyond oral contraceptives. Pharmacists have expressed similar views about patient leaflets (Ryan and McMahon 1977). However, since both of these studies were conducted in the United states in the 1970's, it is possible that they do not reflect current opinion.

There is some evidence that leaflets currently available may not always be issued. Fleckenstein et al (1976) found that only 64% of oral contraceptive users were aware of the existence of a patient leaflet. By contrast, 93% of respondents said they had received a leaflet at the pharmacy in the survey conducted by Morris et al (1977). It is impossible to determine from these studies whether the women really did not receive a leaflet, whether it had been forgotten or gone unnoticed. In a later study, Morris et al (1980) tried to ascertain the reasons why 61% of pharmacists did not spontaneously issue a leaflet with oestrogen products (as required by the Food and Drugs Administration regulations). Around a quarter of the pharmacists said they had forgotten and 7% believed that it was to be issued at the request of the patient. None claimed to have neglected to distribute the leaflets because of opposition to their use.

One study investigated the effects of the source of the leaflet (DeTullio et al 1986). One hundred and fifty-two American Medical Association Patient Medication Instruction sheets giving information about diuretics were issued either from the general physician or from the pharmacy. Leaflets distributed by the doctor resulted in higher knowledge levels and greater satisfaction than those distributed in a bag with the medicine by a pharmacist.

An alternative to doctor or pharmacist distribution would be for pharmaceutical manufacturers to include a leaflet in the pack with the medicine. No studies have been found which compared the effects of leaflets distributed by doctors or pharmacists with those produced by manufacturers.

Summary

This review has shown that despite the widespread prescription of medicines, patients' knowledge about the medicines they take is inadequate. Awareness of potential side-effects is particularly poor. Many patients feel that they do not receive enough information about medicines from doctors and pharmacists, and even when information is given verbally it is often forgotten or misunderstood.

One solution welcomed by patients might be to provide information leaflets with prescribed medicines. Outside the UK, benefits such as improvements in patients' knowledge about medicines, their compliance with treatment and satisfaction with the information received have been reported. But the leaflets tested have varied considerably in content, readability and intent. Furthermore, it is often difficult to disentangle the effects of written information from those of the larger health education programmes of which they were sometimes part. Much of the research into the effects of leaflets has focused on a limited range of medicines, mainly those prescribed for acute conditions. Since the effects of leaflets are likely to vary according to the characteristics of the drugs prescribed and the patients taking them, the range of medicines investigated needs to be broadened to include those prescribed on a long-term basis. It is unclear at present whether any initial benefits associated with leaflets will be stable over time. Furthermore, the optimum method of leaflet distribution has not been determined. Since few systematic studies have examined the effects of leaflets in this country, there is a need to evaluate the effects of patient information leaflets in the setting of British general practice.

1.4 AIMS OF THESE STUDIES

The aims of the research presented in this thesis were:

(I) To design Prescription Information Leaflets (PILs) for a range of commonly prescribed medicines (Chapters 2 and 3).

(II) To evaluate the effects of the leaflets in the setting of general practice (Chapters 4 and 5). Specifically:

- to determine the effects of leaflets on patients' knowledge about their medicines, including the nature and purposes; the dosage instructions; side effects and what to do if they occur; awareness of how to store and dispose of medicines safely.
- to assess the extent to which the leaflets influenced patients' medicine taking behaviour and encouraged safe storage and disposal of medicines.
- to evaluate the effects of the leaflets on patients' satisfaction with the information received, and treatment in general.
- to establish whether the effects of the leaflets are influenced by the type of medicines prescribed.
- to study the influence of sex, age and social class on the impact of the leaflets.

(III) To investigate the long-term effects of the leaflets on patients' knowledge and satisfaction (Chapter 6).

(IV) To assess the feasibility of distribution by general practitioners or pharmacists and to compare the effects of leaflets issued from these two sources (Chapter 7).

CHAPTER 2

LEAFLET DESIGN

CHAPTER 2

From the literature reviewed in Chapter 1 it is clear that patients want and need more information about their medicines than they currently receive. Moreover, the majority would welcome supplementary written information. However, few patient oriented leaflets giving information about prescribed medicines have, until recently, been available.

The leaflets that are provided have been criticised for being either too complex or too simplistic. The oral contraceptive package insert, for example, appears to have been designed more to protect against litigation than to inform the patient and is consequently difficult to understand (Institute of Medicine 1979). By contrast, when information is provided with other medicines, such as inhalers, it is confined to simple instructions about their use. Also, written information is often badly designed and presented, ignoring much of the research on the comprehensibility and structuring of written materials which comes from a broad range of areas such as psychology, education, ergonomics and advertising (Wright 1977; Hartley 1980). Finally, few designers appear to have considered the type of information patients actually want to receive when deciding what topics to cover in a leaflet.

Several successful attempts to provide patient-oriented information about prescribed medicines have been made in the United States (Morris 1982). There is a need for well designed prescription information leaflets to be provided in this country. This chapter outlines suggestions from professionals, and from the patients themselves, about the items which should be covered in such leaflets. In addition, the literature which has examined the best ways to present written material is reviewed.

2.1 LEAFLET CONTENT

There has been considerable interest but disagreement among experts about the kind of information that should appear in patient information leaflets about medicines. Indeed, how to decide what to include and exclude out of all the possible options has proved to be a major problem when leaflets have been produced in the United States (Morris and Kanouse 1981). Moreover, whilst the opinions of professionals sometimes concur with patients ideas about leaflets, there are often areas of disagreement, notably about the desirability of providing information about risks. These issues are reviewed below.

2.11 Professionals' views

Many items of information have been recommended for inclusion in leaflets by doctors, pharmacists, pharmacologists and other interested professionals over the past 15 years. A selection are reviewed below.

Topics to be covered in a prescription information leaflet

A major contribution to this debate was made by Hermann et al (1978). They developed guidelines for the minimum information needed by patients in order to make treatment with a prescribed drug effective and safe. These included: how to take the drug; how to store the drug; how the drug is expected to help; and how to recognise problems caused by the drug.

Name and physical characteristics

There is a consensus on the general information about medicines which might usefully be provided in leaflets. Leaflets should contain the name of the medicine (Smith 1975; Fleckenstein 1977b; Hermann et al 1978; Bullen 1980; Anonymous 1981a). This should include both the trade name and the generic name, and the class of drug to which it belongs (Hermann et al 1978). In addition, the colour and shape of drugs should be stated, since patients, particularly the elderly, have been found to identify tablets in this way

(Hallworth and Goldberg 1984). More controversial items include a complete list of all ingredients, including "inactive" substances, and the clear identification of newly introduced drugs.

Uses of the medicine

It is generally thought appropriate to mention the specific purpose for which the medicine was prescribed in a leaflet (Smith 1975; Romankiewicz et al 1976; Hermann et al 1978; Bullen 1980). Disagreement arises over the listing of other uses of the medicine. Although some would not object to a list of usual uses of the drug others fear that such information might lead to inappropriate self-medication. In a survey of over 200 American physicians and pharmacists most preferred that a patient be told why he had been prescribed the drug, for example ß-adrenoceptor antagonists for hypertension, rather than other ways in which the drug could be used (Fleckenstein 1977a). (In the case of ß-adrenoceptor antagonists other uses would include the prevention of angina; the control of irregular heart beats, and the prevention of anxiety). However, the low response obtained from the physicians to this survey (27% of those approached replied) suggests the results should be treated with some caution.

Conditions under which the drug should not be used

Hermann et al (1978) argue that patients should be able to avoid taking medicine that is unlikely to help them or which may cause them harm. Over half of the physicians and pharmacists in Fleckensteins' study agreed this information should be included in a patient leaflet (Fleckenstein 1977a). The need to give clear warnings to special groups who may be at particular risk for example those suffering from asthma, kidney or liver damage, drug allergy, pregnant women or the elderly has been emphasised. However, information about the conditions under which the drug should not be used is not universally welcomed.

How to take the medicine

It is agreed that patients need to know when, how and with what to take their medicines. A complete and unambiguous written record of directions has been suggested (eg Noyce 1982), but a leaflet detailing all the possible regimens and ways of taking a drug for all the available dose forms is likely to be confusing (Hermann 1980). Inclusion of "usual doses" (Joubert and Lasagna 1975a) or the normal range of dosage (Fleckenstein 1977a) have been suggested as alternatives. A clear statement of the maximum daily dose has also been advocated (Cyr and McLean 1978). Others argue that despite there being evidence that instructions given are frequently misunderstood (Hermann 1973; Mazzullo et al 1974) the medicine label, as the traditional method of informing patients about their drug regimen, is the best solution to this problem (Hermann 1980).

The consequences of "non-compliance"

Hermann et al (1978) have suggested that leaflets should give patients some idea of the possible consequences for them of "non-compliance". For example, the danger inherent in sudden cessation of drugs such as ß-adrenoceptor antagonists should be stressed. Advice about what to do if a dose is missed or what to do incase of overdose are further topics which have been suggested for inclusion.

How to tell if the medicine is working

There is disagreement about the need to include advice on how to tell if the medicine is working. Those in favour exhort the benefits of patients able to differentiate the intended effect of the medicine from adverse reactions. In addition, they argue that informed patients should know not to expect a rapid response from drugs with a delayed effect (eg tricyclic antidepressives) or a response at all from drugs which frequently have no obvious effects (eg hypertensive drugs) (Hermann et al 1978). However, only 45% of the American pharmacists and physicians who responded in Fleckensteins' survey thought that a leaflet should give this sort of information (Fleckenstein 1977a).

Information about risks

Considerable controversy exists about the need to include details about possible risks of therapy in patient information leaflets. One of the main reasons in favour of providing information about side-effects is that informed patients should be able to recognise problems caused by the medicine and to know what to do if they occur so as to avoid harm (Hermann et al 1978; Hermann 1980). However some doctors feel strongly that an information leaflet is not the appropriate place to outline the risks of therapy or to provide lists of potential side-effects (Loftus and Fries 1979; Drury 1984). These objections are often based on the belief that the information about risks might have adverse effects on the patient.

Even amongst those who advocate inclusion of side-effects there is disagreement about how detailed this information should be. There is a tendency to emphasise the benefits of treatment and to be reassuring about the risks (Bullen 1980; Muir-Gray 1982). Various commentators have suggested limiting the list of adverse reactions given in a leaflet to "those that the patient should report to his physician if they occur" (Romanckiewicz et al 1976) or "selected side-effects" (Cyr and McLean 1978), but without specifying which ones. Common risks and benefits were thought by the pharmacists and physicians responding to Fleckenstein's survey to be more important to be included than all possible risks (Fleckenstein 1977a). Other risks, such as the possibility of dependence when using psychotropics and certain pain killers for prolonged periods and other possible long term problems should be discussed with a patient, but few doctors and pharmacists recognise a need to cover these topics in a patient leaflet.

Interactions with other substances

It is generally agreed that leaflets should contain information about other medicines, foods or beverages that may enhance or antagonise the effects of a drug (Fox 1969; Smith 1975; Romanckiewicz et al 1976; Fleckenstein 1977a;

Hermann et al 1978). Some of this information is provided in Britain in cautionary and advisory labels added to the medicine by the pharmacist (British National Formulary 1986).

How to store and dispose of the medicine safely

The labelling of all medicines with the warning "Keep out of reach of children" is a legal requirement on all dispensed medicines (British National Formulary 1986). Nevertheless, several commentators in the UK and the United States have called for further warnings to appear in leaflets. (Joubert and Lasagna 1975b; Cyr and McLean 1978; Dodds 1986). Other storage advice, such as suggestions to keep drugs such as glyeryl trinitate away from light or moisture, or to keep antibiotic syrups in a fridge could be given in a leaflet. Patients could be advised to observe any change in the appearance of the medicine and not to use medicines when the expiry date has passed. However, Hermann et al (1978) feel that advice about safe storage and disposal would be best mentioned by the pharmacist and not addressed in a leaflet.

It appears that no one has previously thought it worthwhile for leaflets to advise patients against sharing their prescribed medicines with family and friends. This is despite the fact that this does occur and is potentially harmful (Busson and Dunn 1986).

The amount of information

Considerable disagreement has been expressed amongst experts over how detailed information leaflets should be. A widely held view is that information should be short, summarised and simple or limited to that which enables the patient to take the medicine correctly to ensure maximum benefit (Epstein and Lasagna 1969; Fleckenstein 1977a; Loftus and Fries 1979; Anonymous 1980). Arguments in favour of selective information include the belief that more detailed leaflets may cause unnecessary alarm (Drury 1984); information overload (Jacoby 1977), or would simply not be read (Ligouri 1977). Nevertheless, the

view that "paternalism" should be avoided and that leaflets should contain the fullest information is held by a vocal minority (eg Muir-Gray 1982). Between these two divergent views, some health professionals have suggested a compromise. Nearly a quarter of the respondents in Fleckensteins' survey thought providing both detailed and summarised information was a good idea (Fleckenstein 1977a).

Specific versus general instructions

As with much of the debate, the disagreement over whether general or specific information should be provided has arisen because of the different functions leaflets are perceived to fulfil by different commentators. Whilst the majority advocate the provision of specific advice about medicines, those who perceive leaflets as vehicles for more general education about medicines do not agree. Herxheimer and Davies have suggested that patients need to grasp a few concepts about medicine use, including the notion of the benefit/risk relationship; that the body gets rid of drugs, and that the speed with which this happens affects the frequency of doses; that a drug can have effects on the body that are not intended; and that medicines do not keep for ever (Herxheimer and Davies 1982). However as a doctor with "years of experience" Muir-Gray has pointed out that in his view it is nearly always a mistake to give general exhortations that aggravate anxiety (Muir-Gray 1982).

2.12 What patients want to know about their medicines

Surveys of public opinion

Whereas much has been written on the information patients need to know about their medicines, few systematic studies have asked patients what they would like to see in leaflets. Those that have been conducted have found there to be a consensus between patients and experts about many of the items for inclusion in leaflets. In North America, opinions about the content of patient information have been sought amongst oral contraceptive users (Morris et al 1977; Mazis et

al 1978; Sands et al 1984), hospital in-patients and out-patients (Joubert and Lasagna 1975a; 1975b; Cyr and McLean 1978; Fisher et al 1982) and the public (Benson et al 1977; Udkow et al 1979; Fisher et al 1982).

In the UK, several studies have confirmed patient interest in this area (Laher et al 1981; Cartwright 1983). The information people want to receive about their prescribed medicines was assessed directly in a systematic postal survey of 443 people in the Southampton community (Ridout et al 1986). Of the nine items listed on the questionnaire (all suggested as important for inclusion in an information leaflet by Hermann et al 1978), seven were considered important by three-quarters of the 368 respondents who replied to this question. The results are shown in table 2.1. In contrast to the other items, only one, how to tell if the medicine is not working, was thought to be important by 58% of those who replied. The authors suggest this item could be omitted in the interests of brevity. They also suggest that, since the majority of the patients taking medication for chronic conditions, notably asymptomatic hypertension, would be regularly reviewed by their general practitioners, it might be more appropriate for the doctor to discuss this item during the consultation (George 1985). By contrast to the suggestion of Hermann et al (1978) that information about safe storage and disposal of medicines could be left out of a leaflet, these items were frequently mentioned as important for inclusion by the patients questioned by Ridout et al (1986).

Information about risks

This is the main area where the experts and the patients disagree. Whereas there is a tendency for health professionals to emphasise the benefits of therapy, the public consistently attach greater importance to warnings and to "bad news" than to information providing reassurance or benign general education (Fisher et al 1982). Patients clearly want to be informed of the risks of treatment (Alfidi 1971). In their survey of 137 American in-patients and out-patients, Joubert and Lasagna found that 86% wanted to know common risks of treatment and 77%

Table 2.1

Response to nine items suggested as potential contents of prescription information leaflets (368 replies)

Information items	Number agreeing (%)	
When and how to take the medicine	334	(90.8)
Side-effects and what to do about them	325	(88.3)
Precautions such as possible effects on driving	320	(87.0)
Problems with alcohol or other drugs	309	(84.0)
Name of medicine	305	(82.9)
Purposes of treatment	293	(79.6)
How long to take it	278	(75.5)
What to do if a dose is missed	237	(64.4)
How to tell if it is not working	215	(58.4)

(after Ridout, Waters and George, 1986)

all possible risks (Joubert and Lasagna 1975a). Eighty-one percent wanted to be informed about the possibility of rare lethal side-effects. Information about rare side-effects is not usually considered desirable by the experts (Fisher et al 1982). Ridout et al (1986) found that there was considerable demand for information about side-effects amongst their British respondents. Eighty-eight percent wanted to be informed about side-effects and what to do about them (Ridout et al 1986).

Despite some research on how people perceive the risks of treatment (Slovic et al 1981; Keown et al 1984) the question of how best to present the chances of being harmed by a drug remains unclear. Morris (1978a) points out that whilst epidemiologists would classify a drug which can cause a serious adverse reaction or fatality in one person out of every 10,000 as low risk, patients may not. However, Slovic et al (1981) found that people wanted to know about the serious side-effects of drugs, such as blood clots and liver damage, even if the frequency of occurrence was as low as one in every 10,000,000 users.

The amount of information

Whilst most of the experts identified a need to provide short, simple information about medicines, there is a tendency for patients to favour more detailed information. In an American investigation of the desired form and style of written information about oral contraceptives, longer, more detailed information was preferred to a short insert by over three-quarters of the oral contraceptive users surveyed (Mazis et al 1978). This preference for longer, more elaborate contraceptive information was found in other studies (Benson et al 1977; Morris et al 1977; Sands et al 1984). However, it is difficult to extrapolate these findings because of the likelihood of oral contraceptive users being an unrepresentative group.

In the survey conducted by Ridout et al (1986), 54% of the respondents wanted detailed information about medicines whereas 43% stated a preference for short,

summarised points. In Joubert and Lasagnas' (1975a) survey, 60% of favoured both summary and detailed information. Similar findings were reported by Udkow et al (1979).

Opinions from consumer organisations

Further support that people would like to receive much more information about their medicines comes from consumer organisations. In the USA, the Consumers Union has long campaigned for comprehensive written information to be provided with medicines (Cohen 1977). In the UK, the Drug and Therapeutics Bulletin, produced for doctors by the Consumers Association has argued for leaflets written in a simple readable style but which contain detailed drug information (Anonymous 1981a). Indeed, the need for "full disclosure" has been argued by representatives of consumer groups on the basis that anything less does not enable the consumer to make a truly informed choice (Medawar 1984). However, because the members of consumer groups are largely drawn from social classes I and II (Taylor 1979) these views may not be representative of the population as a whole. Moreover, it is difficult to assess whether or not the views of consumer group leaders correspond to those of organisations' membership. However, the evidence from patient surveys does suggest that around half of the population would like to receive detailed information with prescribed medicines (Ridout et al 1986).

In conclusion, much has been said about what patients need to be told about their medicines. For the most part, experts and patients are concordant in their views about which items should go in a leaflet. However, two important differences between the perspectives are apparent; firstly the emphasis placed on the benefits of drugs by health professionals compared with patients' interest in the risks; secondly the demand for detailed information from some patients compared with the simple information recommended by some experts. If patient leaflets are to be accepted, information requested by patients must be incorporated as well as that deemed essential by doctors and pharmacists.

2.2 THE DESIGN OF LEAFLETS

Whilst it is the information provided in leaflets that is of paramount importance, communication will be enhanced if the message is written clearly, in a way in which it can be easily understood by the target audience, and if the leaflet it is well presented. Several techniques used to enhance communication of the written message could be applied to the patient information leaflet. These are reviewed below. Where possible, research evidence for the effectiveness of the different measures in improving readability, acceptability or recall is presented, but where this is lacking, designers "rules of thumb" are outlined.

2.21 Writing a readable message

Various factors have been found to influence the readability of a message. These include its aims (whether it is intended to enhance informed choice; to change behaviour; to protect against litigation, or to enable the information to be recalled), the people at whom the message is aimed, their reading ability, their own background knowledge, interest and presuppositions, as well as the context in which the information is given (Tichy 1966).

Reading ability of the population

Since most people will take a prescribed medicine at some time in their life, the audience for prescription information will necessarily encompass a wide range of reading ability. To enable as many people as possible to read the leaflet, the information must be simple enough to be understood by the poor reader, but not so simple as to put off the better reader.

Various estimates have been made of the average reading ability of adults in the USA and in Britain (Department of Education and Science 1976). Experts in adult literacy have estimated that the average "reading age" of the adult population is 9 years (Adult Literacy Support Services Fund 1984). Reading age (which is obtained by transposing reading test scores on to a scale expressed in

terms of years of development), is the measure most commonly employed when standards of reading are being discussed, but it can be misleading and frequently obscures more than it reveals (Department of Education and Science 1976). If a reading age of, for example, 9 years is to have any real meaning, then the characteristics of "9 year old reading" must be known and defined. Since the average 9 year old reader exists only as a statistical abstraction, this would be difficult to achieve (Department of Education and Science 1976). Though such estimates are of limited value they are nevertheless commonly employed.

Another way to assess reading is to examine the ability to read certain texts. In a comprehensive review compiled by the Department of Education and Science of the understanding and effective use of English, at least a million adults in the UK were reported to be unable to read simple recipes, "social pamphlets", tax return guides, claims for industrial injuries and most of the Highway code (Department of Education and Science 1976).

Readability of the text

Readability may be defined as all the elements of written material that affect the extent to which readers understand it, read it at an optimum speed, and find it interesting (Ligouri 1978). The language used, the sentence structure and grammatical complexity are the primary elements which affect readability. However, the ease with which a text can be read is affected by the interaction of these elements with design features such as text organisation, typography and the use of colour and illustrations.

The choice of words

Research has shown that the use of familiar words assists the reader, whereas the use of less well known or simply more cumbersome terms will hinder the reader (Solomon and Postman 1952; Hall 1954; Wason and Johnson-Laird 1972). Medical English, particularly in the written form, has certain characteristics which mark it apart from general English, notably the regular uses of an extensive body

of words particular to medicine (Cripwell 1981).

There have been empirical studies of the words and phrases which are most open to misinterpretation. One such study, conducted by the Adult Literacy Support Services Fund (1980), found that adults with reading problems misinterpreted the words "symptoms", "directed", "persist", "alkaline" and "inhale". Statements frequently found on medicine labels such as "unless otherwise directed by the doctor"; "Do not exceed the stated dose", and "Consult your doctor if symptoms persist" were very difficult for these people.

Misunderstandings are not confined to those with reading difficulties. When Raynor and Silletto (1982) asked 80 hospital patients to interpret a number of standard medicine label instructions, 40% misunderstood "complete the prescribed course". "Caution - Avoid alcohol" was interpreted as it being alright to consume some alcohol by 39%, and a third of the patients did not understand "use sparingly"; one thought this meant "slap it on". "Stools" was not understood by 44% of the sample, but as Raynor and Silletto point out, the choice of an understandable alternative is not an easy one. Finally, 41% misinterpreted "to be taken with meals". In the survey conducted by Mazzullo et al (1974), half of the patients thought "with meals" meant the medicine was to be taken before meals. Other surveys have reported similar misunderstandings amongst the population in North America and in the UK (Samora et al 1961; Boyle 1970).

More general words can also be a problem. Two notable examples are the interpretation of a chronic condition as being one that hurts a lot (Pyrczak 1978) and the word drug itself. There appears to be a differentiation in the public mind between "medicine" as something which makes you better, while a "drug" has more sinister implications (Jones 1979; Helman 1981b).

Suggested replacements

Hallworth and Goldberg (1984) have suggested that misunderstandings can be

reduced if medical terms are replaced with lay terms, such as "sleeping tablets" or "water tablets". Further suggestions for simpler words and phrases include replacing such statements as "irrigate the eye" by "wash the eye with cold water" and "Not to be taken internally" with "Do not drink" (Wright 1981). However, not all technical terms can be simplified. Moreover, their occasional use can sometimes be helpful (Wright 1977). As Muir-Gray points out, it is obviously patronising to use terms like "tummy" when the technical term, stomach, is in common use (Muir-Gray 1982).

The Plain English Campaign in Britain (Cutts and Maher 1980) and similar organisations in the USA (Pyrczak 1978) have long campaigned for the simplification for a wide range of documents, including medical texts. However, they often report resistance to their efforts. This is usually because the need for simplification is either dismissed as unnecessary, or it is claimed that the matters are too complicated to be simplified. Furthermore, the problem is sometimes envisaged as lying with the readers who are perceived as not trying hard enough to understand the material.

Vocabulary list

Several graded word lists are available for technical writers to consult if they wish to substitute difficult terms with commonly used words. One example is the General Service List, which gives the 2000 most frequently used words in English (West 1953; Pyrczak 1978). However, such lists are of limited use for those designing leaflets about medicines because they have been prepared by educators for children. It is quite possible that some medical terms not familiar to children in the lower grades of school are familiar to even poorly educated adults because of common adult life experiences. Nevertheless, such a list could be developed and used by designers of patient information. In Belgium, the trilingual Van Hauwermeiren's vocabulary list has been developed specifically for this reason (Bogaert et al 1989).

Sentence structure

Sentence structure has been found to influence readability. Shorter sentences are more easily understood than long ones (Flesch 1948; Klare 1974). The length of the sentence is important because length is related to syntactic complexity (Pyrczak 1978). However, in his examination of a wide body of medical writing, Cripwell (1981) has found that medical writers tend to use long sentences. Wright (1977) recommends that as a rule writers should scrutinise sentences with more than one verb because such information can often be split into more than one sentence.

Another characteristic of written medical English is the use of complicated sentences (Cripwell 1981). One example, "If symptoms persist, consult your doctor" was found to be difficult to understand by the respondents in the study conducted by the Adult Literacy Support Services Fund survey (1980). This is because the sentence combines some difficult words with a complex conditional sentence. In addition, directions such as, "Every four hours as needed for pain" and "Two three times daily" have been found to cause problems (Hermann 1973; Mazzullo et al 1974).

Clauses

When sentences cannot be simple and must contain more than one clause, research has shown that people have difficulty dealing with clauses nested one inside the other (Blumenthal 1966). Sentences with subordinate clauses are more easily understood if relative pronouns, such as which or that, are used to resolve potential ambiguity (Blumenthal 1966; Hakes and Foss 1970).

Active sentences

Active sentences are more easily understood and remembered (Herriot 1970). The degree of personalisation of a message is known to correlate with the attention paid to it by the reader. This technique is widely applied by advertising specialists who make frequent use of personal pronouns. Medical

English however, tends to use passive rather than active verbs (eg it is agreed) despite the fact that such constructions rarely occur in spoken language (Wright and Barnard 1975). This problem is illustrated using the direction "The notes should be read". This could be replaced by "Read the notes". Research has shown that passive questions are especially difficult to understand (Barnard 1974). Nevertheless, occasional use of the passive is said to focus the readers attention on an agent, but there has been little research in this area (Tichy 1966).

Use of negatives

Affirmative statements are easier to understand than negative ones (Wason 1961; Jones 1966). Medical writing makes considerable use of negatives (not) and quasi-negatives (deny) (Cripwell 1981). Wright cites the example "Rub well into the affected area not more often than every 4 hours" (Wright 1977). She points to data which suggest that given an instruction like this people would be likely to ignore the "not more than" and concentrate on the "every 4 hours". Similarly, the warning, "Do not exceed the stated dose" may cause problems (Cutts and Maher 1980).

Negative qualifications are sometimes used for emphasis and for correcting misconceptions. Although double or treble negatives cause the most problems and should generally be avoided (Hartley and Burnhill 1978), double negatives in imperatives (eg Do not.....unless...) are easier to understand than single ones (Wright and Barnard 1975).

The measurement of readability

The ease with which a leaflet can be read can be evaluated using readability measures. A variety of readability formulae have been used in education since the 1950s as a convenient, quantitative way to assess the level of difficulty of a text (eg Flesch Score (Flesch 1948); The SMOG index (Simple Measure of Gobbledegook) (McLaughlin 1969); and other measures developed by Dale and

Chall (1948) and Klare (1974). A detailed consideration of these is beyond the scope of this review. Briefly, most formulae give weight to such variables as the number of unfamiliar words, the length of sentences and their complexity. An estimate of the difficulty level of the material, sometimes expressed as the ease of reading, is produced. Some of the leaflets currently available have been tested using readability formulae. As a result, several have been criticised for being too difficult (Pyrczak 1978; Udkow et al 1979). For example, the American patient package insert for oral contraceptives was found, using the Flesch readability formulae, to be pitched at the 10-12 grade level (Ligouri 1978).

Problems associated with readability measurement

Since readability formulae are easy to use, there is a tendency for writers to seek a single "reading age" or ease of reading score when designing written materials for the public. The appropriateness of this procedure for patient information leaflets has been questioned. To try and establish whether readability measures are able to predict the level of difficultly experienced, patient information sheets designed using readability formulae for people of differing reading abilities have been tested on patients (Ley et al 1976c; Morris et al 1980). Although Ley et al (1976c) reported a relationship between compliance and readability, Morris et al (1980) found there to be problems associated with relying on readability scores alone to assess the level of difficulty patients experience in understanding the leaflets.

One of the major short comings of these formulae is that they fail to take into account the technical aspects of written language. It is recognised that such information does not lend itself easily to being simplified into the style of prose having good readability on any of the standard indices (Wright 1977). Also, readability formulae tend to be surface measures which take little account of whom the text is aimed at or for what purpose it was constructed (Scotland 1985). Since typically the formulae only account for around a third of the

variance in the difficulty of a set of passages, and the application of different tests can give markedly different results for the same text (Morris et al 1980), there is a need to determine which test or group of tests serves as the most valid index to be applied to patient-oriented drug information (Morris et al 1980).

Several workers have devised computerised readability measures specifically to assess and develop readable medical texts. One example is the "Computer assisted Style editing" procedure described by Cripwell (1981). This system combines four measures of readability: the percentage of words outside the General Service List (West 1953); the degree of complexity of the text as measured by the Loban Weighted Index (Loban 1963); a measure of the impersonality of the text; and the length of the sentences. The computer programme marks the written material on these four criteria, thus enabling the editor to use this information as a basis for further simplification. It is claimed that combining four measures in this way should increase the validity of the technique, but this hypothesis remains untested.

Whilst the development of more appropriate, validated readability formulae will be an advance, scores from such tests can only give guidance about the level of difficulty of the text. There is clearly no substitute for piloting the material on the intended audience. Morris et al (1980) recommend that material should be written for audience acceptance rather than for favourable reading scores.

Further considerations

The tone of the message

Whereas factors influencing the ability to read and understand written material have been subject to objective investigation using readability formulae, the tone or style of the message is a much more subjective variable. The way in which information is written (formal, threatening, reassuring, patronising, the overall

style) gives the reader a clue about the purpose and accessibility of the document. A "stiff style" of writing may lead some readers to conclude that a document is too difficult to read; a patronising tone may suggest something is being hidden (Pyrczak 1978).

The effect of variation in the tone of a leaflet was demonstrated by Morris and Kanouse (1981). By presenting the same basic information about the drug Flurazepam but varying the "tone", they found the latter had a strong impact on the way the leaflets were perceived by American college students. The students saw the "frank" versions as written more for an adult audience and to be more complete. Although it is not clear whether these results can be extrapolated from a well-educated college sample to the general population, the study does demonstrate that changing the writing style of a document has an effect on how it is perceived. But tone is not a pure variable and other variables such as the type, order and length of the information will affect the overall style of a leaflet.

Presuppositions about the subject

Finally, since it is recognised that people will not read a document if they think they know about the subject material (Wright 1981), readers' presuppositions and beliefs about the area should be explored and taken into account when writing a message. Some of the research into patients knowledge and beliefs' about prescribed medicines was reviewed in Chapter 1.

Provision for those who cannot read the text

Written information leaflets will be of limited use to the estimated 2 million adults in Britain whose first language is English and have serious problems with reading and writing (Goodings 1981). The use of pictograms to communicate prescription information to illiterate and poor readers is discussed below. Furthermore, translation of text into different languages would enable many patients whose first language is not English to receive the information. Finally,

leaflets produced in Braile would give the blind access to information about drugs.

2.22 Text organisation and layout

The way a message is presented can affect how it will be perceived, if it will be read and whether it will be remembered. While careful attention to presentation cannot clarify an obscure message, it is widely recognised that even the best messages can be obscured if they are not well presented. Although research into the effects of the structural features of text is patchy (Wright 1977), several studies suggest that a well organised, clearly laid out text can assist comprehension and memory (Kintsch 1977; Meyer 1977; Danks 1978; Wright 1981).

The format of text

The size of the leaflet

The most obvious constraint on the amount of information provided and the way it is laid out is the size of the leaflet. It is usually recognised that the space available will be limited. A5 size is recommended for leaflets and inserts which will need to fit into packages with the minimum of bending.

The order in which information is presented

The order in which the information is presented is important and must be logical to the readers who have to follow it (Wright 1981). Any potential difficulties encountered in trying to follow the instructions need to be anticipated, making the writing of adequate instructions a more complex task than it is frequently thought to be. There is also a primacy effect in recall of medical information, with people remembering what they are told first best (Ley 1979).

Use of headings

Headings serve several functions. Most obviously, they assist readers who are

looking for particular sections (Hartley and Burnhill 1978). Headings also provide an explicit structure which assists the reader in integrating the information as he reads (Dooling and Lachman 1971; Hartley and Trueman 1985). A clear concise title at the beginning serves to orientate the reader and affects subsequent recall (Hartley and Burnhill 1978). Headings appear to be less critical in a well written leaflet but their presence has been found to have a positive motivational effect on peoples' expectations about how easy a document will be to read and to understand.

Use of questions

Questions encourage people to examine what they are reading and to look for related facts and ideas. As such they can be useful as headings, and readers usually remember more when they are included in discursive text (Anderson and Biddle 1975; Hartley and Burnhill 1978). However, questions about more than one thing at a time are often counterproductive. For example in Wright and Barnards' investigation into the design of forms the question "Are you over 21 and under 65?" caused difficulties for those over 65, many of whom answered each part of the question in turn (Wright and Barnard 1975).

Sections

The grouping of information into self-contained sections containing related points signposted by headings allows people to scan the text and pick out the parts of interest (Sticht 1976). Brake (1980) has found that many readers jump about the text looking for information which catches the eye and appears salient, rather than starting at the beginning and working through the document. Others consult relevant sections only when they have a particular query in mind.

According to Wright (1977), when there is no requirement to clarify the way in which sections are nested together or to refer to sections elsewhere in the text, numbering them seems to be unnecessary. However when sections are numbered, Arabic numerals are better understood than Roman numerals (Perry

1952) and numbering points appears to be more helpful than lettering them (Wright 1977).

It has been suggested that the underlying structure of text is more readily seen when paragraphs are identified by the use of a line space rather than indentation of the first line (Hartley 1978). It is thought that indentation especially impedes the recognition of structure when each paragraph contains no more than a line or two of text, but conflicting claims have been made about this.

Use of space

Little research has been conducted into the effects of varying the white space in documents. Working from experience, graphic designers recommend white space between sections because it helps the reader see how the document is organised. In addition, because the space surrounding a title isolates it, its importance is emphasised. A text with too little white space can look cramped and uninviting (Document Design Centre 1982).

Line length

Graphic designers recommend avoiding making lines of type too long or too short. According to Simply Stated (an advice document produced by the American Document Design Centre) the best line length for most text is 50-70 characters. Short line lengths cause difficulties by forcing the eye to jump back and forth, while long lines strain the eye as it tries to stay on course. At either extreme, there is the possibility of missing a line of text.

Justified text

It is claimed that some readers find unjustified text (ragged right margins) easier to read than text which has been right justified (Document Design Centre 1982). This appears to be because when lines end at different places it is easier for readers to keep their place in the text. In addition the eye does not have to adjust to different spacing between letters, as it does with justified type.

Text length

As was mentioned earlier in this chapter, the length of a text has been found to influence readability. In addition, if too much information is provided, there is a danger of "information overload" which can detract from the ability to use the information properly. Some support for this claim is provided by studies of food labelling which report consumers not making full use of labelling if it was too lengthy (Jacoby et al 1977). By contrast, Jonsen (1978) argues that a comprehensive leaflet may facilitate information processing. If consumers are to grasp the importance of the information provided it may be necessary to supply adequate details to support important conclusions. In addition, brevity and ease of comprehension may not always go hand in hand, because the process of splitting a long sentence into two or more shorter ones to improve readability may use up more space (Wright 1977).

Can the structural factors influence whether or not a leaflet will be read?

Since there is evidence that people are reluctant to read instructions (Barnard et al 1979), one of the main justifications for taking care over presentation is to make a leaflet seem inviting and easily accessible to the audience. Structural and display factors combine to give an overall impression of the nature and purpose of a leaflet. For example, it is widely assumed that long texts will be perceived negatively and discourage people (particularly those of below average educational attainment) from reading them (Morris 1977). However, 325 American College students judged a longer leaflet to be more helpful, truthful and informative than three shorter versions (Morris and Kanouse 1981).

Summaries

The effectiveness of short, summarised information to improve understanding has been demonstrated, and summaries have been found to be particularly useful when the text must be remembered (Ausubel 1960; Hartley and Trueman 1982).

Typographical and display factors

While thoughtful use of typography, and other display variables, may not be able to rescue a reader who is entangled with information presented in an unhelpful format, a difficult typeface, inconsistent use of space or confusing illustrations can hinder a reader who is dealing with an otherwise optimal format. Moreover, typographical factors have been found to be highly influential in the decision about whether to read the material at all (McLaughlin 1969). However, few designers consider these factors from anything but the aesthetic point of view and many operate by "rules of thumb" accumulated from experience. Their recommendations, together with the limited research in this area, are reviewed below.

Size of print

Legibility of text depends in part on the size of the print. Several studies have found that the elderly, many of whom have problems with failing eyesight, have difficulty reading small typewritten instructions on medicine bottles (Poulton 1969; Veitch and Wright 1982). Type size was found also to be an important influence on whether drug information sheets were understood by a group of 80 predominantly lower income American patients (Sharpe and Mikeal 1974). Furthermore, continual reduction in the size of print (because of limited space) can render instructions and warnings virtually unreadable (Adult Literacy Support Services Fund 1980). Nevertheless, simply increasing the type size can itself cause problems, particularly when it results in very short line lengths (Hartley and Burnhill 1978). It is known that material printed larger than 12 point tends to slow reading (Spencer 1968) and for most documents, 8 to 10 point type face is the most readable size (Document design centre 1982).

Type face

Legibility problems can arise with an inappropriate choice of type face. Since several surveys found that handwritten labels on medicines were inadequate, all medicines in the UK now have to have type written labels (British National

Formulary 1984). Despite enthusiasm for the scheme amongst patients (Hallworth and Goldberg 1984), concern has been expressed about the clarity of some mechanically printed labels, particularly among patients with reduced visual acuity (Veitch and Wright 1982; Downie and Roden 1983). The advice given by the American Document Design Centre is that the typeface chosen should be bold and clear. Serif typefaces rather than sans serif typefaces are recommended because they make the individual letters easier to distinguish and enhance the horizontal flow of a line making it easier to read (Document Design Centre 1982).

Lower and upper case lettering

It has long been established that people read lower case more easily than upper case print (Starch 1914; Tinker and Patterson 1928; Tinker 1965; Poulton 1969; Scotland 1985). This is because the shapes of the letters in text written in capitals do not vary very much. Since one of the ways that readers differentiate between letters is by their shape, using all capitals makes a text harder to read. Because of this it is recommended that capital letters should be reserved for the initial letter or letters of proper nouns and for the first letter of a sentence or a heading (Hartley and Burnhill 1978).

Highlighting

A variety of highlighting techniques (eg bold, italics, underlining) can be used to emphasise important points in a leaflet. Graphic designers usually recommend some form of highlighting technique if only because it will contribute to the attractiveness of a leaflet by providing visual relief in what otherwise might be a uniform page of text (Document Design Centre 1982). There is evidence also that people remember highlighted text better (Foster and Coles 1977) but there has been little comparative research into the effectiveness of the different methods of highlighting (Wright 1977). What is clear is that any technique adopted should be used sparingly and consistently or else the highlighting function will be lost. For example, a whole section in italics will not stand out,

and will be more difficult to read than text set in ordinary type (Tinker 1965). In addition, if the reader is unclear why certain items have been singled out, highlighting will have little effect (Foster and Coles 1977). Furthermore, too many different highlighting techniques used in the same leaflet can make the text look cluttered and lead to confusion (Document Design Centre 1982).

Use of colour

Colour is one variable which can be used to highlight text. It can be used for the print or for the background. However, as Hartley and Burnhill (1978) point out, no colour has the contrast value of black on white and the brightness contrast of the print with the background will have an influence on legibility of the text (Wright 1981). A minimum of 65% contrast between text colour and paper colour has been found to be necessary (Tinker 1963). This applies also if a coloured background is used in patches to indicate important sections (Wright 1977).

However, defective colour vision can impair the contrast between colours as well as the recognition of some colours. The 8% of males who are colour-blind are most often confused by green and red, and extreme shades of these colours often look grey to these people (Waller et al 1982). In addition, the elderly may experience problems with blue-green colour distinctions since the lens of the eye tends to yellow with age, making vision less clear and glare more of a problem (Botwinick 1978; Hurd and Blevins 1984). With these exceptions, there appears to be little empirical research to guide the designer in the choice of colours to use to enhance communications. Anecdotal evidence suggesting the attribution of shared meanings to certain colours (eg red for danger) has not been verified, although there is some evidence that certain colours can elicit a higher response to a questionnaire (Eastwood 1940).

Research has confirmed the strong impression that colour can attract attention to a document and motivate people to read the text (Flemming and Levie 1978;

Waller et al 1982). The widespread feeling that the "attention getting" function of colour is stronger than for other highlighting techniques is one of the main arguments in favour of the use of colour in patient information leaflets (Danks 1978).

Waller et al (1982) point out that the use of a second colour in text, does not, however, appear to have any effect on learning. Colour is only one of a range of graphic factors which can be used, the effectiveness of which have been inadequately researched. They conclude that the choice of highlighting technique is in the end dependent on the experience of the designer, the needs of document and the reader and finally the cost. If colour is used, however, the same rules apply as to other highlighting techniques. Excessive use can cause problems for readers so it should be used sparingly but consistently and its function made clear to the reader (Hartley and Burnhill 1978).

Illustrations, diagrams and "Pictograms"

Like colour, illustrations can serve several functions. One of the most important reasons for their inclusion is to enable the message to be understood by poor readers and the illiterate (Bratt 1979; Goodings 1981; Wright 1981; Anonymous 1983; Sloan 1984). However, illustrations are liable to misinterpretation. Several studies which have looked at the pictorial or diagrammatic representation of short instruction procedures (eg Szlichcinski 1979) suggest that different pictures communicate different things to different people, and may not be very successful at communicating the intended message (Barnard and Marcel 1978). It therefore seems likely that diagrams developed to help the illiterate understand what to do with medicines (eg Adult Literacy Support Services Fund 1980) would also be open to misinterpretation, but they have not been tested.

Good diagrammatic or pictorial representation of complicated procedures can replace difficult to follow text (Wright 1977) and should therefore be of benefit to all readers. Recognising this need, several manufacturers (often in

conjunction with patient groups), and some pharmacists have produced stepwise diagrammatic instructions on how to use certain types of medicines, such as inhalers, eye, ear or nose drops, as well as rectal and vaginal inserts. Such pictorial instructions have the added advantage of removing the necessity for potentially embarrassing lessons in anatomy in the pharmacy (Anonymous 1983). They might also discourage patients from inserting suppositories without first removing the wrapper (Medawar 1984). Although the sequences which appear in these leaflets have obviously been designed with the best intentions, little research has been conducted into whether or not the instructions are understood and enable patients to use the products correctly. It is widely recognised that pictures which confuse people are worse than no pictures at all (Dwyer 1971; Snowman and Cunningham 1975; Willows 1978).

In an attempt to overcome these problems, and because the space on a label or in a leaflet is limited, there have been calls for the development of simple, stylistic "pictograms" based on the idea first proposed in 1936 by Neurath of an international system of typographic picture education, known as Isotype (Wright 1977). Pictograms for medicine labelling have been developed by a working group of Pharmacists (Anonymous 1983). The feeling behind this venture is that children and old people would eventually become as familiar with pictograms as they were with road signs. While it is possible that with the development and use of international conventions people will become better at using pictograms, the available data on peoples' knowledge of traffic signs does not offer support to this assumption (Mackie 1966). Bratt (1979) points out that while there is clearly a place for stylised signs, such symbols are frequently difficult to understand (eg those used to instruct about washing clothes). In addition, he argues that refined international conventional style graphics are inappropriate for prescribed medicines because they are too "inhuman" and insensitive, and because they need to be learned over a period of time.

It is not clear whether pictograms, such as those designed by Bratt (1979), would be useful in different countries because pictures are particularly sensitive to cultural differences in interpretations (Sinaiko 1975). It seems that despite intensive efforts in this direction, the development of pictures which can stand alone from the text has so far eluded the researchers in this area.

Illustrations, like colour, can draw attention to text (Danks 1978). For this reason it may be better to produce information leaflets with illustrations which arouse curiosity and reinforce the message given in the adjoining text. It has been suggested that since many patients identify their tablets by their appearance, photographs of the tablets themselves, in colour if necessary, could be provided to serve both these functions. However, despite many claims about the functions of colour, little empirical research has been conducted on the effects of colour illustrations or cartoons on the number of people claiming to read health information leaflets.

In conclusion, this review has highlighted the need for the designers of prescription information leaflets to first, take into account patients' views about the information they require; second, to consider the readability of the text they produce; and finally, to present the information in an optimal format. Whilst firm guidelines cannot be made about their effectiveness, a summary of the structural features which may enhance communication is given overleaf:

(1) familiar words

(2) short, active sentences

(3) information presented in a logical order

(4) headings and questions

(5) sections

(6) unjustified text

(7) summaries

(8) 8 to 10 point type size

(9) serif typefaces

(10) lower case lettering

(11) consistent use of highlighting

(12) colour and illustrations

CHAPTER 3

PRELIMINARY STUDIES

CHAPTER 3

3.1 INTRODUCTION

It is clear from the evidence reviewed in the preceding chapters that people want and need more information about medicines than they currently receive. Furthermore, although many would welcome written information, the leaflets currently available are often difficult to obtain, inadequate and few meet patients information needs and expectations. In addition, few existing leaflets easy to read or presented in a manner helpful for the patient. Well-designed leaflets, containing information requested by patients as well as the items suggested by experts, are required.

This chapter describes the design of Prescription Information Leaflets (PILs) for two commonly prescribed medicines: penicillins and non-steroidal anti-inflammatory drugs (NSAIDs). Two formats for the leaflets are developed and their effectiveness is compared in the setting of general practice. In addition, the feasibility of general practitioners issuing leaflets is assessed.

3.2 METHODS

3.21 Prescription Information Leaflet design

Drug groups

Six groups of medicines were selected for leaflet development. These were oral penicillins, non-steroidal anti inflammatory drugs (NSAIDs), ß-adrenoceptor antagonists, inhaled ß stimulant bronchodilators, diuretics, and benzodiazepines. This range of medicines was selected initially because all are commonly prescribed in general practice. Second, they are used for a range of different problems by different patients eg penicillins are often prescribed to treat acute

infections in children, whereas diuretics are more often prescribed on a long term basis for elderly patients with water retention. Third, a wide range of different side-effects are associated with these drugs. Finally, each of these medicines represents a different problem for patients in terms of compliance eg accepting the need to continue treatment for asymptomatic hypertension may be a problem for ß-adrenoceptor antagonist takers, whereas incorrect use of an inhaler may be the biggest problem for bronchodilator users.

In order to determine the optimal format for the leaflets, two of these groups of medicines, oral penicillins and NSAIDs, were chosen initially and leaflets were developed. Since these two medicines are used in quite different ways (penicillins usually for acute infections whereas NSAIDs are more frequently used for chronic conditions, such as rheumatoid arthritis and osteoarthritis), their use in the preliminary studies enabled a wide range of patients' views to be recorded. The leaflets were based on those piloted by George et al (1983). They were "generic", that is they gave information about a group of related medicines rather than each individual product.

Contents of leaflets

The contents of the leaflets were those suggested by Hermann et al (1978), with the exception of "how to tell if the medicine is working". This omission was agreed within a Steering Group (a list of members is given in Appendix 3) and took into account the findings of Ridout, Waters and George (1986). However, the leaflets did include other items, such as information about safe storage and disposal of medicines, which were identified as being important by patients.

Presentation of information

The leaflets were constructed according to general principles for design of technical information reviewed in Chapter 2 (Hartley 1978; Wright 1981). In particular, the type face chosen was bold and clear. A graphic artist advised on the other important typographic variables such as the use of space and upper

and lower case letters. Each leaflet was "style edited" by an educational psychologist using readability formulae (Cripwell 1981). Short sentences were used and specific information was given rather than general statements; other features included the use of the second person and questions, so that the leaflets were interactive (Hartley and Burnhill 1978). The contents were organised into self-contained sections of related information so that people could scan the information and pick out the points of interest (Sticht 1976) as well as to increase expectations about the ease of readability and comprehension (Charrow and Redish 1980). Comments on early drafts of the leaflets were obtained from the Steering group, the Plain English Campaign (Maher and Cutts 1984), and by patients attending for out patients appointments in the Southampton hospitals. Consequently, some changes to the sequence of information were made.

Two designs

Since some patients favour detailed information, while others prefer short summarised points (Ridout et al 1986), and some would like both summary and detailed information (Joubert and Lasagna 1975a), two formats were developed to accommodate the different requirements identified in these surveys : a one-sided "details only" leaflet and a two-sided "details plus summary" version. The contents and presentation of the "detailed" side of the double sided leaflet were essentially similar to those of the one-sided leaflet, with the addition of a summary of the main points presented on the reverse. The summary was illustrated with pictures and a second colour was added, to attract attention and to motivate the patient to read the accompanying prose (Danks 1978). Different colours were used on each leaflet: green was used for the penicillin leaflet and red for the leaflet about NSAIDs.

Finally, because the leaflets did not cover everything (for example rare side-effects) a reference to a popular paperback book on medicines was included at the bottom of the detailed side of both versions of the leaflets.

3.22 Study 1: Initial reactions to the leaflets

In order to assess patients' initial reactions to leaflets, 100 patients waiting to see a doctor at a general practice in central Southampton were approached in the practice waiting room. The patients were invited to help with a study of patients' opinions of leaflets about medicines. Those who agreed to take part were escorted to a vacant consulting room and given three minutes to examine one of the four versions of the leaflets, which were distributed in a systematic order throughout (1,2,3,4,1,.....). Most of the patients approached were not taking a medicine described in any of the leaflets.

Data Collection

The interviewer observed each patient reading the leaflet. The way in which the text was examined was noted. After three minutes, patients were asked what they thought about the content of the leaflet they had read, and whether they approved of the way in which the information had been presented. Towards the end of the interview each patient was shown the alternative version of the leaflet for penicillins or NSAIDs and asked to compare the two versions. An attempt was made to assess how much information each patient gained from their brief exposure to a leaflet. Knowledge was assessed by five questions about each medicine, the answers to which appeared in the leaflet. A crude knowledge score was produced by counting the number of correct answers obtained. A high knowledge score was arbitrarily defined as >3 questions correct, a medium score was 2 or 3 correct, whereas <2 correct was considered a poor knowledge score. Patients' opinions about the content and presentation of the leaflets were sought. They were asked to give a score (out of 10) for the content of the leaflet and another score for the way the information was presented in the leaflet. Patients were encouraged to comment freely during these interviews and their comments were noted.

3.23 Study 2: A preliminary study in general practice

Design of the study

Approval was obtained from the local ethics committee to conduct a series of surveys to evaluate the effects of prescription information leaflets in small Hampshire towns.

Selection of towns

Initially, thirteen small Hampshire towns were identified as being suitable for these investigations. Each of the towns selected (a) had no more than 3 general practice surgeries or 3 pharmacies (b) was for practical reasons within a 30 mile radius of Southampton and (c) had a population of under 15,000 (Office of Population Censuses and Surveys 1985). In addition, the towns had similar population profiles (Office of Population Censuses and Surveys 1980). The cooperation of the local general practitioners was sought in discussions with the Hampshire Family Practitioner Committee and the Wessex Faculty of the Royal College of General Practitioners. As a result of these discussions, eight of the thirteen towns were identified where, in principle, general practitioners were willing to take part in the study. Two of the eight towns, towns A and B, were selected for the preliminary study. They were of similar size, each had five doctors and only one general practice surgery. The remaining six towns participated in the main evaluation of the leaflets, described in detail in chapters 4 and 5. (The eight study towns are shown in figure 3.1).

Experimental design

In the preliminary study, leaflets were issued in both town A and town B. The two-sided leaflet for penicillins and the one-sided for NSAIDs were tested in Town A. In town B, the leaflets issued were the one-sided version for penicillins and the two-sided NSAID leaflet. This gave a balanced experimental design (Table 3.1).

Figure 3.1
Location of the Hampshire Study Towns

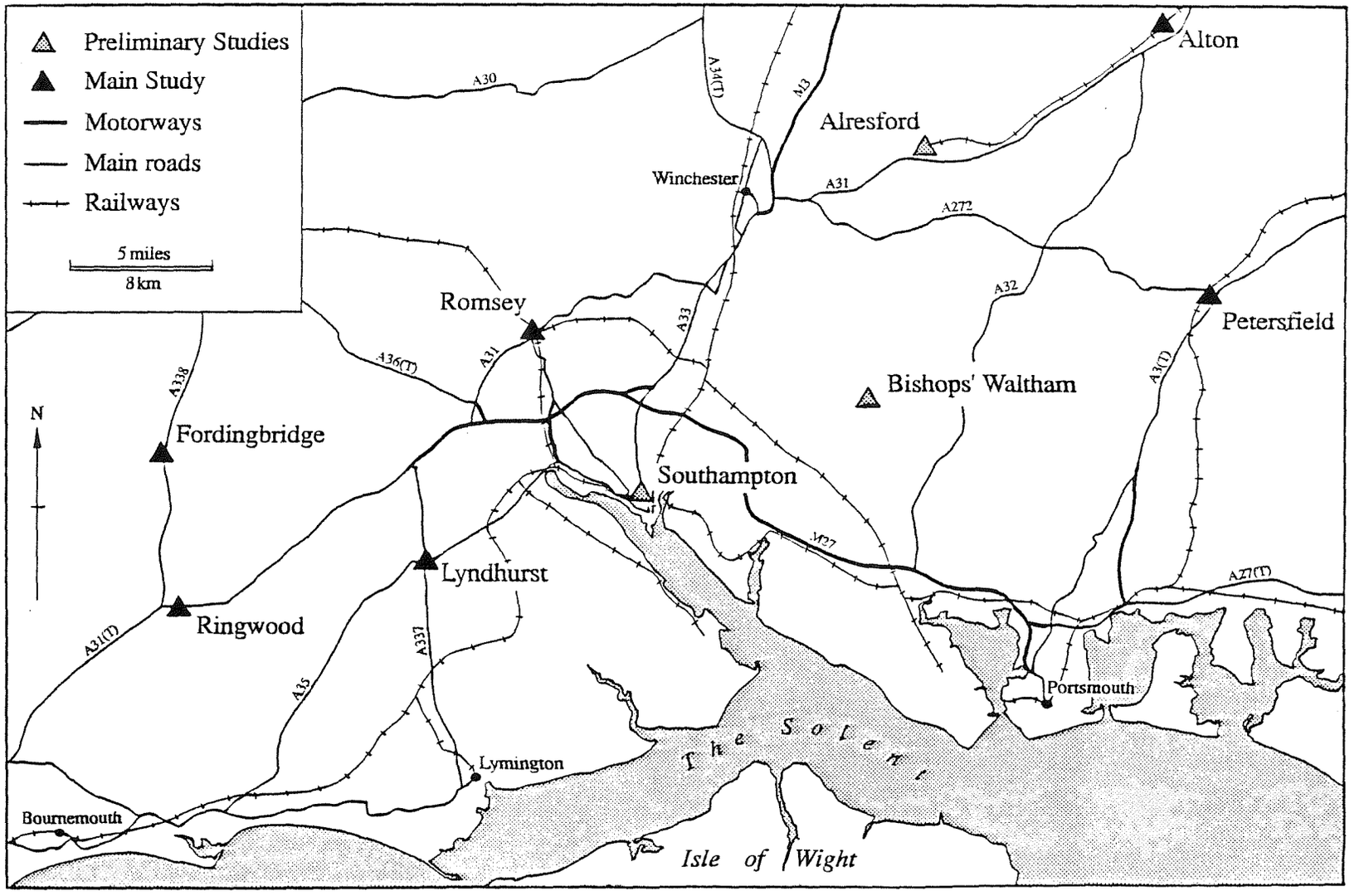


Table 3.1

Study 2 : The experimental design - leaflets issued by the general practitioners in each town

Design of leaflet	One-sided, details only	Two-sided details plus summary
Town A	NSAIDS	Penicillins
Town B	Penicillins	NSAIDS

Survey procedure

Before commencement of the survey, meetings were held with the general practitioners in each town. Each was invited to take part in the study and details of the protocol were provided. During these meetings, the doctors were encouraged to ask questions and minor modifications to the survey procedure were accepted. In addition, because local press interest was anticipated, the local media were informed in advance of the survey (Figure 3.2). The survey ran for twelve weeks in each town. In town A, the survey was conducted between May and July 1985 and in town B between August and October of the same year.

The sample

Patients who received a prescription for a penicillin (British National Formulary section 5.1.1) or a NSAID (BNF sections 4.7.1 and 10.1.1) during a consultation with their general practitioner were included in the survey. Patients were excluded if they or any of their close relatives were already in the survey. Doctors were instructed to include patients only once even if, as was sometimes the case, they were prescribed more than one study drug. Children under 16 years old were included in the survey, but details about their treatment were obtained from a parent or guardian. Although the doctors involved were asked to include as many patients as possible, they retained the right to exclude patients thought to be "unsuitable". Each doctor was asked to keep a record of any such exclusions and their reasons.

Patient consent

General practitioners asked their patients to consent to an interview with "a research worker from Southampton University interested in their treatment". In order to avoid drawing attention to the leaflets, patients were not told of the specific aims of the study. Hence, the general practitioners were asked not to go through the leaflet with the patient or give any more verbal information than was their usual practice. Names, addresses and telephone numbers of consenting

Figure 3.2

Article published in the Southampton Evening Echo prior to the commencement of the preliminary study

Survey spotlights drug ignorance

PRESCRIPTION FOR DISASTER

TAKING DRUGS incorrectly can be a prescription for disaster — but most patients are kept in the dark about their use.

That's the conclusion of a survey by two top Southampton doctors spearheading new research on medicine safety.

In the study of more than 700 patients, they found three out of four were ignorant of any side-effects of drugs they were taking.

And almost all those questioned felt doctors could have kept them better informed.

By Libby Wiener

Now the medics, Professors Charles George and Estlin Waters, are embarking on further research with a £74,000 grant to determine if issuing detailed leaflets with prescriptions would help.

Prof. George said: "We found a lot of people felt they did not get enough information and some were considerably dissatisfied.

"A leaflet would provide a safety net where a patient wasn't told about the possible side-effects or perhaps didn't understand."

Prof. George suggests if patients were better informed they would notify GPs more readily when things went wrong.

In addition, clearer warnings about the dangers of drugs could help cut accidental poisonings in children and encourage people to dispose of medicines correctly.

patients' were recorded and collected on weekly visits to the surgery. Survey bulletins were supplied regularly, giving the doctors up to date information about the number of patients entering the study.

Data collection

Data were collected by means of a personal interview using a structured interview schedule. The questionnaire assessed patients' knowledge of the name of their medicine, the dosage regimen, its potential side-effects and safe methods of storage and disposal of the medicine. Where possible, the name and the dosage regimen were checked against the medicine bottle by the interviewer. Side-effects were assessed using a combination of cued and free recall techniques (Morris and Kanouse 1982). Tablet counts and direct questioning were used to assess patient compliance, and during the interview the place where the tablets were stored was noted. Satisfaction with the treatment and information received about their medicine was measured on a five point scale from completely satisfied to completely dissatisfied. Finally, patients were asked for their opinions of the leaflet they received. The alternative format was shown and patients were asked to compare the two formats. Modifications to the order and wording of the questions were made as a result of extensive pilot testing amongst hospital out-patients.

Most patients were contacted by telephone within a few days of the consultation and, if willing, they were interviewed in their homes. Patients not on the telephone were sent a written invitation to take part. A freepost envelope was enclosed for the reply. If no contact could be made with the patient, up to three visits were paid to the address (at different times of day) before the patient was eliminated from the survey. Each interview lasted approximately 30 minutes. A standard approach to the interviews, with uniformity in asking the questions and recording the answers, was developed during the pre-pilot work conducted with out-patients in Southampton, when a tape recorder was used to monitor development of the usual interviewing techniques found to improve

validity (Oppenheim 1966).

3.24 Data analysis

The coded questionnaires were sent to a commercial data punching agency (Data Speed Ltd) where they were double punched onto magnetic tape. The data were transferred to the University of Southampton ICL computer. Descriptive statistics were generated using the SPSS-X statistical package and scores for content and presentation of the leaflet in study 1 were examined using the Mann-Whitney U test. Associations in study 2 were tested using the Chi-squared statistic (with Yates correction for 2 x 2 tables).

3.3 RESULTS

3.31 The leaflets

The one-sided "details only" and two-sided "details plus summary" leaflets giving information about penicillins and about NSAIDs are shown in Figures 3.3 - 3.6

3.32 Study 1: Initial reaction to the leaflets

All one hundred patients approached agreed to take part in the study. Of these, 42 were male and 58 female; the majority came from the surrounding working class area of Southampton. Six-percent of this sample (2 males and 4 females) said they were unable to read the leaflets because they "came without their glasses". They have been excluded from further analysis.

Patients' knowledge

A knowledge score was calculated for each respondent as the sum of their responses to the 5 questions asked about the medicine. Using this crude measure, patients were found to know more about penicillins than about NSAIDs, irrespective of the type of leaflet read, but this difference was not statistically significant. Mean knowledge scores out of 5 were 3.24 (SD 1.39) for penicillins and 2.96 (SD 1.27) for NSAIDs respectively. Overall, 39% achieved high knowledge scores (>3 questions correct), 46% medium scores (2 or 3 correct) and 15% had poor knowledge scores (<2 correct). Patients were well informed about the safe storage and disposal of the medicines and over 85% responded correctly to questions on these matters. However, knowledge of side-effects and reasons to avoid the medicine were poor. No significant differences between knowledge scores and the type of leaflet received were recorded. Nevertheless, 22 (48%) of patients who read the two-sided "details plus summary" leaflets could name the main side-effect of the medicines compared with 14 (29%) of those who read a one-sided leaflet. During the interviews patients appeared particularly interested in the information provided about side-effects. After scanning the summary, the interviewer observed several

Figure 3.3

One-sided "details only" leaflet giving information about Penicillins

Penicillins.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

Your medicine is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Before taking your medicine

- Has anyone ever told you you are allergic to Penicillin? If so, tell your doctor or pharmacist. You can be given another medicine instead of Penicillin.

Taking your medicine

- You must take your medicine regularly. The label will tell you when to take your medicine. It will also tell you how much to take. *Ask your doctor or pharmacist if you are not sure.*
- This medicine works best swallowed with water when your stomach is empty. This is 1 hour before a meal or 2 hours after a meal. But sometimes your doctor will tell you to take it at other times.
- If the medicine is for a baby the best time to give it is between feeds.
- Shake all liquid medicines before you take a dose.
- Keep taking your medicine until it is finished. Don't stop just because you feel better. The medicine may not have killed all the germs. If you stop too soon the infection may start up again.
- If you forget to take a dose take another as soon as you remember. Then go on as before.

* After taking your medicine

A few people can be upset by this medicine. They have frequent loose bowel motions or feel like being sick.
If you suffer from either of these very badly or you vomit the medicine tell your doctor.
Tell your doctor if you START suffering from any of the following:

- Rashes, itching, or any other skin trouble.
- Wheezing.
- Pain in your joints for the first time.

Tell your doctor about any other unusual problems as soon as you can.

Storing your medicine

- Keep liquid Penicillin in the refrigerator but **not** in the freezer compartment. Liquid Penicillin lasts only a few days even in the refrigerator. The label will tell you how long. Don't take the medicine after this date.
- Keep your medicine in a safe place where children cannot reach it. Your medicine could harm them.
- If your doctor decides to stop the treatment, flush any left-over medicine down the toilet or return it to the pharmacist. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

Figure 3.4

Two-sided "details plus summary" leaflet giving information about Penicillins

What you should know about Penicillins.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____
This is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Things to remember about Penicillin.

1 **Do not take Penicillin** if you are allergic to it.

2 **Look at the label** on your Penicillin. It will tell you when to take it.

3 **Keep taking your Penicillin** until it is finished. **Don't stop** just because you feel better.

4 **Penicillin sometimes causes problems**
You can find these listed on the back of this leaflet. ✽

5 Keep your Penicillin **out of reach of children.**

You will find more about Penicillin on the back of this leaflet.

Your medicine is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Before taking your medicine

- Has anyone ever told you you are allergic to Penicillin? If so, tell your doctor or pharmacist. You can be given another medicine instead of Penicillin.

Taking your medicine

- You must take your medicine regularly. The label will tell you when to take your medicine. It will also tell you how much to take. *Ask your doctor or pharmacist if you are not sure.*
- This medicine works best swallowed with water when your stomach is empty. This is 1 hour before a meal or 2 hours after a meal. But sometimes your doctor will tell you to take it at other times.
- If the medicine is for a baby the best time to give it is between feeds.
- Shake liquid medicine before you take a dose.
- Keep taking your medicine until it is finished. Don't stop just because you feel better. The medicine may not have killed all the germs. If you stop too soon the infection may start up again.
- If you forget to take a dose take another as soon as you remember. Then go on as before.

✻ After taking your medicine

A few people can be upset by this medicine. They have frequent loose bowel motions or feel like being sick.
If you suffer from either of these very badly or you vomit the medicine tell your doctor.
Tell your doctor if you START suffering from any of the following:

- Rashes, itching, or any other skin trouble.
- Wheezing.
- Pain in your joints for the first time.

Tell your doctor about any other unusual problems as soon as you can.

Storing your medicine

- Keep liquid Penicillin in the refrigerator but **not** in the freezer compartment. Liquid Penicillin lasts only a few days even in the refrigerator. The label will tell you how long. Don't take the medicine after this date.
- Keep your medicine in a safe place where children cannot reach it. Your medicine could harm them.
- If your doctor decides to stop the treatment, return any left-over medicine to the pharmacist or flush it down the toilet. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

4.3 RESULTS

4.31 The leaflets

The leaflets are shown in figures 4.3 - 4.5.

4.32 Sample Characteristics

Response from general practitioners and pharmacists

All 42 general practitioners and the nine pharmacists agreed to take part in the study.

Response from patients

The overall patient response rate to interview was 82% (Table 4.1). A total of 719 patients were interviewed, 419 in leaflet towns and 300 in the control town. Three hundred and thirty-two patients had been prescribed an NSAID, 222 a ß-adrenoceptor antagonist and 165 an inhaled bronchodilator. Of these, 232 NSAID patients, 122 patients prescribed a ß-adrenoceptor antagonist and 65 patients using bronchodilators were given leaflets. The number of patients recruited in towns D and F, where leaflets were issued by general practitioners, was low, particularly those receiving leaflets about bronchodilators (town D=4 and town F=11). No significant differences in response rate were observed between the study towns for patients prescribed NSAIDs or bronchodilators. However, the response from patients prescribed ß-adrenoceptor antagonists was significantly lower in the control town (73%) than that in the leaflet towns (83%) (X^2_1=6.24, P<0.05).

Demographic characteristics of the respondents

Demographic characteristics of patients interviewed in this study are shown in Table 4.2. Sixty-three percent of the respondents were women and 35% were 65 and over. More patients were interviewed from the non-manual social classes (classes I, II and IIINM made up 53%) than from the manual social classes

Figure 3.5

One-sided "details only" leaflet giving information about NSAIDs

Anti-Inflammatory Analgesics.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

Your medicine is an Anti-Inflammatory Analgesic. Anti-Inflammatory Analgesics can relieve pain such as headache, toothache, arthritis, and period pain. They can also reduce fever.

♦ Before taking your medicine

- Are you already taking aspirin or another drug used to treat arthritis?
- Have you had an allergic reaction or wheezing after taking aspirin?
- Have you experienced stomach discomfort, felt like being sick or had heartburn after taking asprin?
- Have you had a stomach ulcer previously?
- Are you on medicines for thrombosis (eg Warfarin) or gout?
- Are you pregnant?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, *ask your doctor or pharmacist.*
- Tablets or capsules should be swallowed with a glass of water or milk. Soluble tablets should be dissolved in water before taking them.
- If you forget to take a dose take another as soon as you remember. Then go on as before.
- In the event of an accidental overdose contact your nearest hospital casualty department or tell your doctor immediately.

✱ After taking your medicine

This medicine sometimes causes side-effects in some people.

If you get any of the following, tell your doctor as soon as possible:

- Ringing in the ears or dizziness.
- Skin troubles such as rash or itching for the first time.
- Wheezing.
- You develop stomach discomfort or heartburn for the first time.
- You vomit blood or pass tarry stools.

Storing your medicine

- Keep your tablets in a safe place where children cannot reach them. Your tablets could harm them.
- If your doctor decides to stop the treatment, flush any left-over tablets down the toilet or return them to the pharmacist. Only keep them if your doctor tells you to .

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

Figure 3.6

Two-sided "details plus summary" leaflet giving information about NSAIDs.

What you should know about Anti-Inflammatory Analgesics.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____
This is one in a group of medicines called Anti-Inflammatory Analgesics. These can relieve pain such as headache, toothache, arthritis and period pain. They can also reduce fever.

Things to remember about Anti-Inflammatory Analgesics.

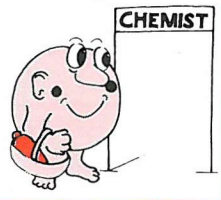
1 **Make sure it is safe for you** to take Anti-Inflammatory Analgesics *(see the back of this leaflet).* ♦

2 **Look at the label** on your tablets. It will tell you when to take them.

3 **Anti-Inflammatory Analgesics sometimes cause problems** You can find these listed on the back of this leaflet. ✱

4 Keep your tablets **out of reach of children.**

5 **Remember to return any unused tablets** to the pharmacist or flush them down the toilet.



You will find more about Anti-Inflammatory Analgesics on the back of this leaflet.

Your medicine is an Anti-Inflammatory Analgesic. Anti-Inflammatory Analgesics can relieve pain such as headache, toothache, arthritis, and period pain. They can also reduce fever.

◆ Before taking your medicine

- Are you already taking aspirin or another drug used to treat arthritis?
- Have you had an allergic reaction or wheezing after taking aspirin?
- Have you experienced stomach discomfort, felt like being sick or had heartburn after taking aspirin?
- Have you had a stomach ulcer previously?
- Are you on medicines for thrombosis (eg Warfarin) or gout?
- Are you pregnant?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, *ask your doctor or pharmacist.*
- Tablets or capsules should be swallowed with a glass of water or milk. Soluble tablets should be dissolved in water before taking them.
- If you forget to take a dose take another as soon as you remember. Then go on as before.
- In the event of an accidental overdose contact your nearest hospital casualty department or tell your doctor immediately.

✱ After taking your medicine

This medicine sometimes causes side-effects in some people.
If you get any of the following, tell your doctor.

- Ringing in the ears or dizziness.
- Skin troubles such as rash or itching for the first time.
- Wheezing.
- You develop stomach discomfort or heartburn for the first time.
- You vomit blood or pass tarry stools.

Storing your medicine

- Keep your tablets in a safe place where children cannot reach them. Your tablets could harm them.
- If your doctor decides to stop the treatment, return any left over tablets to the pharmacist or flush them down the toilet. Only keep them if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

respodents turn their attention directly to the section about side-effects on the detailed side of the two-sided leaflets.

Opinions of the leaflets

The mean scores out of 10 for content and presentation are shown in table 3.2. The content of all four leaflets was rated highly by the patients. The penicillin "details only" leaflet received the highest mean score of 8.40 (SD 2.07) followed by NSAID "details only" with 8.32 (SD 1.34), the penicillin "details plus summary" with 8.24 (SD 1.63) and finally the NSAID "details plus summary" with the lowest mean score for content, 7.88 (SD 1.86). However, these results were not statistically significant. The comments made most frequently about content were that more information could be given in general since there is "never enough on the label". More information was requested on drug interactions, particularly the possible problems of mixing the medicine and alcohol. Patients wanted even more information about side-effects.

All four leaflets were thought to be clear, composed in a sensible order and easy to read and to understand. Nevertheless, patients preferred the presentation of the two-sided "details plus summary" leaflet. This was mainly because the colour and pictures attracted their attention - "You want to know what the pictures are all about" and "I think it's joyous - you'd put it on the wall and keep it!". Nine patients said they preferred the two-sided leaflet because it had a summary. Twenty-eight people claimed that they would not bother to read the "details only" leaflet because there was too much writing and it looked "boring and clinical". One man turned the leaflet over and exclaimed, "Oh God! Have I got to read all that?". Not all of the patients liked the summary. Two patients dismissed this as being "just common sense", while 1 patient thought the cartoons insulted her intelligence "but the general public would read the picture one, obviously". Despite this, when asked to compare the two designs of leaflet, 85% thought the two-sided "details plus summary" version had the better design.

Table 3.2

Study 1 : Initial reaction to the leaflets

Mean scores out of 10 for content and presentation of the leaflets

Design of Leaflet	One-sided, details only	Two-sided, details plus summary
Number of patients interviewed	48	46
Content	8.50 (SD 1.66)	8.39 (SD 1.58)
Presentation	7.75 (SD 1.87)	8.56 (SD 1.75)

3.33 Study 2: A preliminary study in general practice

Number of patients interviewed

A total of 174 patients were included in this study: 92 from Town A and 82 from Town B. One hundred and thirteen patients (65%) had been prescribed a penicillin and 61 (35%) a NSAID. One hundred and forty-two (82%) of the patients eligible for interview agreed to be seen; 5 declined and 27 were unobtainable, mainly in the summer months. Eighty-nine of these patients were prescribed penicillins and 53 NSAIDs. A total of 62 patients were in the one-sided leaflet group and 80 were in the two-sided leaflet group.

Characteristics of the respondents

The demographic characteristics of the sample are shown in table 3.3. Sixty-eight percent of the patients were female. Three-quarters of the patients had only one prescribed medicine, 16% were receiving one other medicine and 11% were taking three or more prescribed medicines. Almost two-thirds (63%) had previous experience of either penicillins or NSAIDs. Thirty-four prescriptions were written for children under 16 years of age.

Patients remembering receiving the leaflet

Although all 142 patients who were interviewed should have received a leaflet with their medicine, 25 of them (18%) claimed not to have had one. Twelve were in the one-sided "details only" group and 13 in the two-sided "details plus summary" group. A further 14 said that they had not actually read their leaflet; 6 from the one-sided group and 8 from the two-sided group. Thus, 39 (27%) either did not receive a leaflet or had not read it. Fifty-nine of 68 patients (87%) who remembered receiving a two-sided leaflet read it, compared to 44 of 51 (86%) who remembered receiving a one-sided version. Only those who claimed to have read a leaflet were included in the analysis.

Table 3.3

Study 2 : Demographic characteristics of the patients interviewed (percentages are shown in brackets)

Total number of patients interviewed		142	
Sex	Male	45	(32)
	Female	97	(68)
Age (years)	<30	36	(25)
	30-60	78	(55)
	>60	28	(20)
Social class	Non-manual	88	(62)
	Manual	51	(36)
	Unclassifiable	3	(2)
Number of prescribed medicines	1	103	(73)
	2	23	(16)
	3 or more	16	(11)
Previous experience of medicine		89	(63)
Medicine prescribed for a child		34	(24)

Patients' knowledge

With the exceptions of the name of the medicine, its purpose and problems associated with sharing medicines (secondary use), patients who read a two-sided "details plus summary" leaflet knew more about their medicine than those who read the one-sided "details only" version (Table 3.4). More patients who read the two-sided leaflets knew the main side-effects of their medicine. Twenty-six patients (79%) who read a two-sided penicillin leaflet knew that penicillins can cause a rash compared to 21 patients (60%) receiving the one-sided leaflet. Eleven (42%) who read a two-sided NSAID leaflet knew that these drugs can cause indigestion compared with 2 (22%) in the one-sided leaflet group.

Patient compliance

No differences were seen in the patterns of compliance for the two leaflet groups. The opportunity was taken in this study for the interviewer to practice the tablet count technique for assessing patient compliance.

Patients' satisfaction

There was a high level of satisfaction with treatment and with the information received (Table 3.5). For both leaflet groups, more than two-thirds of patients said that they were satisfied with their treatment and the information they had received about it, but the level of satisfaction with information was significantly higher ($p<0.05$) amongst those who read the "details plus summary" two-sided version.

Opinions of the two leaflet formats

When asked to compare the two leaflets directly, 99% of the patients preferred the two-sided version.

Did the general practitioners issue the leaflets?

The number of leaflets issued by the general practitioners in both towns was low. The number of patients entering the study in Town B in each of the 12 weeks

Table 3.4

Study 2 : Patients' knowledge about their medicine (Numbers are those giving correct answers [percentages are shown in brackets])

Design of leaflet	One-sided, details only	Two-sided, details plus summary
Number of patients receiving leaflets	44	59
Name of medicine	43 (97.7)	49 (83.1)
Purposes of therapy	32 (72.7)	33 (55.9)
When to take it	44 (100.0)	59 (100.0)
Take with fluid	26 (59.1)	45 (76.3)
What to do if a dose is missed	31 (70.5)	50 (84.7)
Main side effects	23 (52.3)	37 (62.7)
Storage out of reach of children	9 (20.5)	21 (35.6)
Safe method of disposal	38 (86.4)	54 (91.5)
Aware not to share medicines	37 (84.1)	48 (81.4)

Table 3.5

Study 2 : Patients' satisfaction with treatment and information received (percentages are shown in brackets)

Satisfaction	With treatment		With information received	
Design of leaflet	One-sided, details only	Two-sided, details plus summary	One-sided, details only	Two-sided, details plus summary
Number of patients receiving leaflets	44	59	44	59
Level of satisfaction				
Completely satisfied	16 (36.3)	27 (45.8)	12 (27.3)	33 (55.9)
Satisfied	13 (29.5)	18 (30.5)	21 (47.7)	13 (22.0)
Indifferent	6 (13.6)	5 (8.5)	8 (18.2)	9 (15.3)
Dissatisfied	7 (15.9)	7 (11.9)	3 (6.8)	3 (5.1)
Completely dissatisfied	2 (4.5)	2 (3.4)	0 (0.0) *	1 (1.7)

* $p<0.05$

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

diminished over time (Figure 3.7). The behaviour pattern of the nine doctors taking part is shown in figure 3.8. This illustrates the marked differences between general practitioners in their use of the leaflets.

Seven of the general practitioners thought leaflets should ideally be distributed by the pharmacist, or in the pack with the medicine, rather than by the general practitioner at the consultation. The main reason given was that this method would ensure that the patient received the information, since most general practitioners experienced difficulty in remembering to give leaflets to their patients in this study.

Figure 3.7
Number of patients receiving leaflets from general practitioners throughout the 12 week preliminary study period

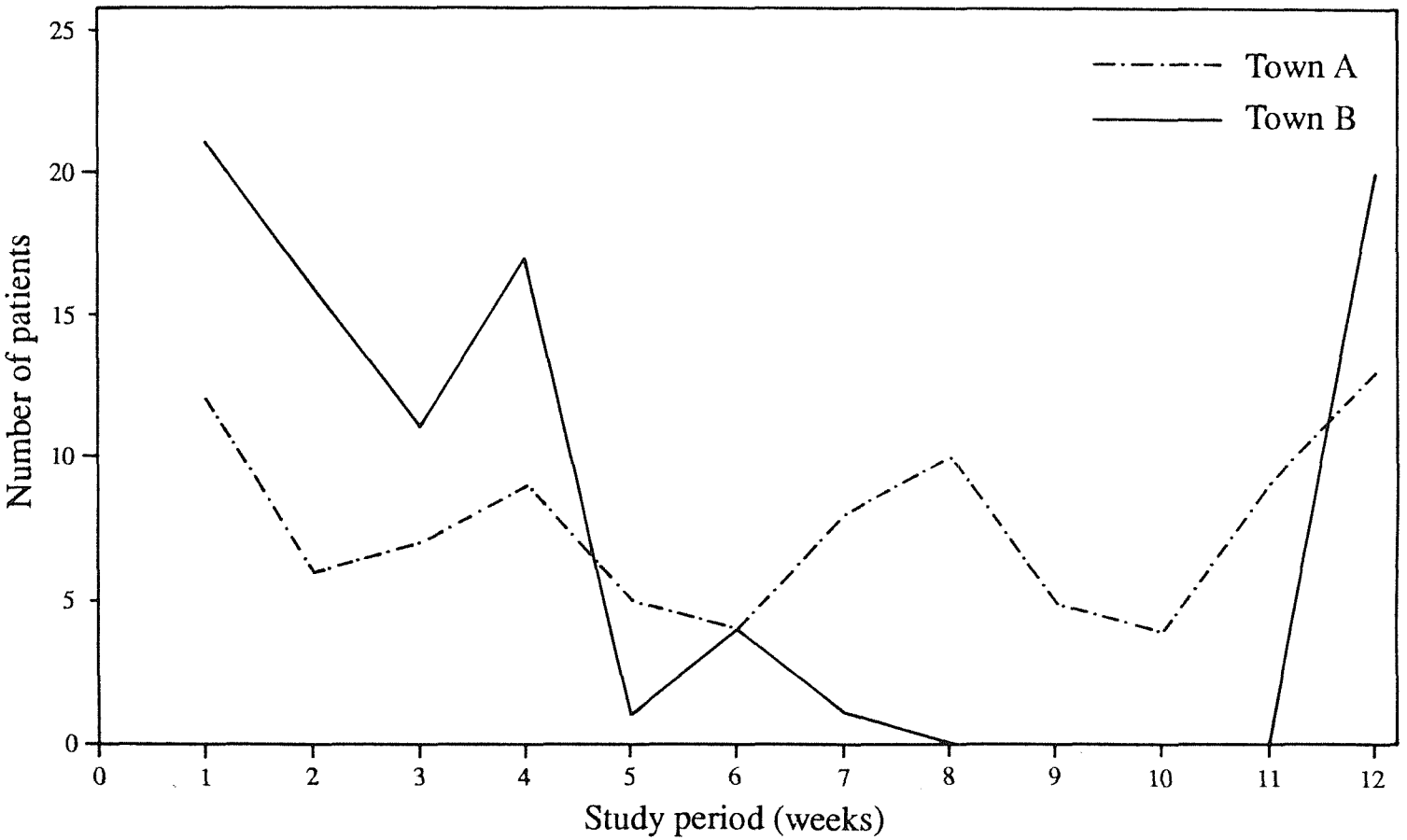
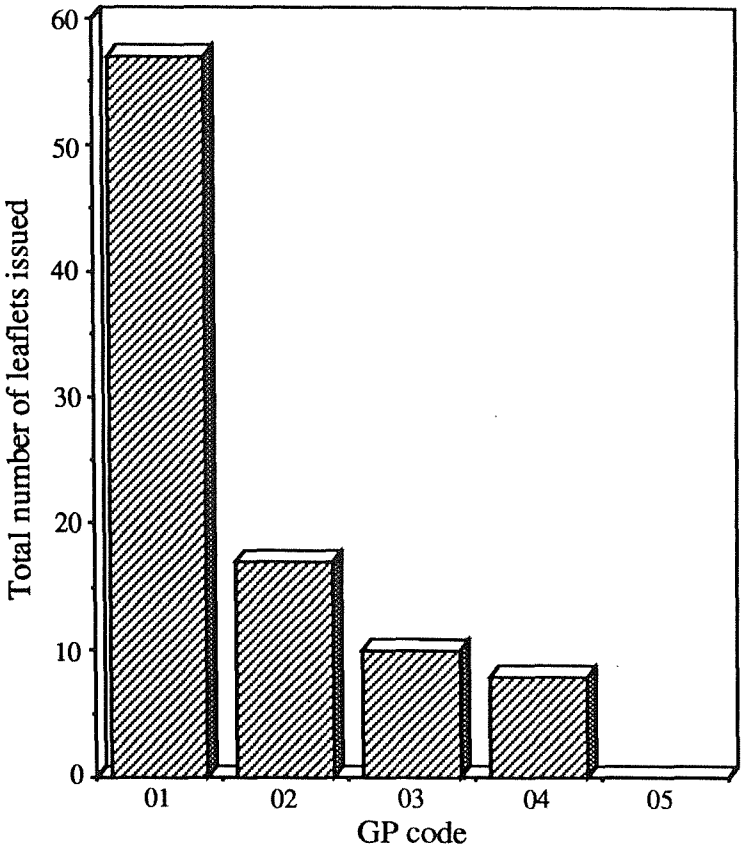
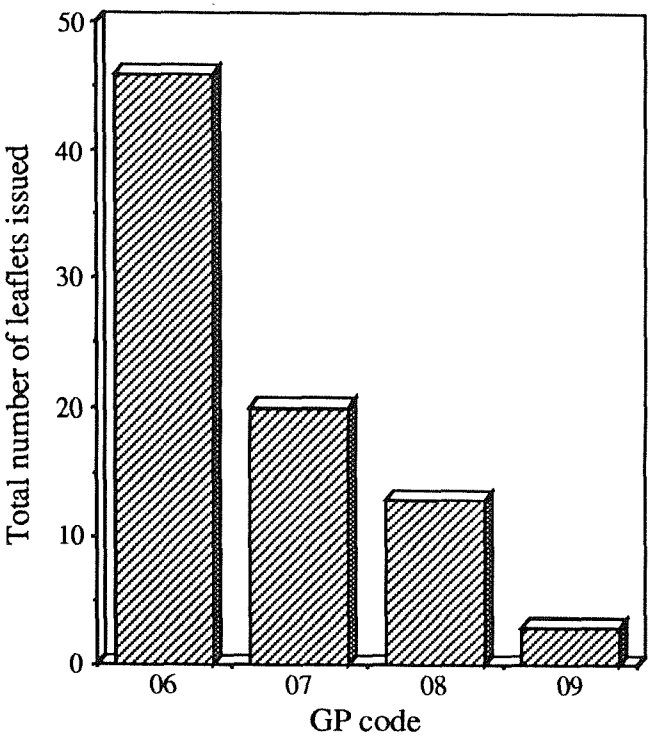


Figure 3.8
Number of leaflets issued by each general practitioner over 12 week study period

(a) Town A



(b) Town B



3.4 DISCUSSION

Patients' response rates to the two preliminary studies reported here were high, providing further evidence of patients' interest in the use of prescription information leaflets (Ridout et al 1986). Although women and those over 55 were over-represented in the samples compared with the general population, this was to be expected since women and the elderly consult their general practitioners more often and take more medicines than young men (Dunnell and Cartwright 1972; Ridout et al 1986). One of the most important findings of these studies was that patients found both the one-sided "details only" leaflet and the two-sided "details and summary" leaflet to be easy to read and understand. This is in contrast to views about some other leaflets currently available, for example, those which are supplied with the oral contraceptive tablets (Morris et al 1977).

In both the studies, patients preferred the two-sided "details plus summary" leaflet format. In addition, the two-sided leaflets appeared to confer some advantages in terms of improved knowledge and satisfaction over the one-sided "details only" versions, although few of the trends attained statistical significance. Several factors may have contributed to the success of the two-sided design. Firstly, it is possible that the improvement in knowledge of the side-effects is associated with the use of a summary. Summarising information has been found to aid recall (Ley et al 1976b). Summaries also enable a reader to identify sections of interest from a text (Hartley 1978; Wright 1981). Many patients in the initial study were observed to scan the leaflet summary and then turn straight to the side-effects section on the reverse. Secondly, the use of colour and pictures may have drawn attention to the text and encouraged people to read it (Danks 1978; Dwyer and Hammel 1978; Waller et al 1982). Finally, it may be simply that the two-sided leaflet format is able to cater for the information needs of the majority of patients. In their survey of Southampton residents, Ridout et al (1986) found that 54% of the respondents wanted detailed information, whilst 43% stated a preference for short, summarised points.

With the exception of one doctor in each town, who appeared to find it much easier to use the leaflets than the others, the general practitioners who participated in the second study experienced difficulty remembering to issue the leaflets. In the light of their experience, seven out of nine doctors who took part felt it might be easier for leaflets to be issued by pharmacists when the medicine was dispensed. This issue is discussed in detail in Chapter 7. Five doctors favoured the inclusion of leaflets with the packaging of the medicine.

The preliminary studies provided opportunity to pilot the survey procedure to be used in the main evaluation of the leaflets. Several difficulties were identified. First, accurate and full patient details were very difficult to obtain from the general practitioners. One possible solution is that the patient details be collected directly from the prescriptions. Second, some of the patients interviewed did not remember being asked to consent to an interview during the consultation. A written request for consent from the general practitioner may solve this problem. Third, enthusiasm for the survey amongst the general practitioners diminished over time. A reduction of the survey period from 12 weeks to 10 is therefore proposed. Finally the need for a better satisfaction measure was identified.

These studies have shown that a two-sided "details plus summary" leaflet format had significant advantages over a one-sided "details only" version. Furthermore, patients preferred the two-sided leaflets. In view of these findings, the two-sided format will be adopted for the prescription information leaflets to be evaluated in the studies reported in the following chapters. In the light of suggestions from the general practitioners who took part in these preliminary studies, pharmacy leaflet distribution will be examined. The advantages and disadvantages of issuing leaflets during a general practice consultation will be compared with distributing leaflets at the pharmacy when a medicine is dispensed.

CHAPTER 4

MAIN STUDY (I):
NSAIDs, ß-ADRENOCEPTOR ANTAGONISTS and BRONCHODILATORS

CHAPTER 4

4.1 INTRODUCTION

In the previous chapters, it has been demonstrated that patients want and need more information about the medicines they are commonly prescribed. A format of leaflet that seems to satisfy the needs of the majority of patients has been developed. This chapter examines the benefits or otherwise of leaflets for three categories of medicines: non-steroidal anti-inflammatory drugs (NSAIDs) (which are used both in the treatment of mild or intermittent pain and for continuous or regular pain associated with inflammation), ß-adrenoceptor antagonists (which are often prescribed for asymptomatic hypertension) and inhaled bronchodilators (used both to alleviate and "prevent" asthma) (British National Formulary 1986). A leaflet giving information about NSAIDs was developed and tested in the preliminary studies (Chapter 3). Two further leaflets were produced along the same lines, giving information about ß-adrenoceptor antagonists and inhaled bronchodilators respectively. The effects of these three leaflets on patients' knowledge, behaviour and satisfaction are evaluated in the setting of general practice.

4.2 METHODS

4.21 Leaflet development

The design of the leaflets was described in detail in Chapter 3. Briefly, they were "generic" and contained information requested by patients as well as the items suggested by professionals. Early drafts were tested and modified after comments from out-patients attending Southampton hospitals. The leaflets were constructed according to the general rules for the presentation of technical information reviewed in chapter 2. A two-sided format, giving detail on the reverse and summarised information on the front, which appeared to confer

advantages over its one-sided counterpart in the preliminary studies was adopted. The summary was supported by coloured illustrations. A different colour was chosen for each leaflet: the leaflet giving information about NSAIDS was coloured red, that for β-adrenoceptor antagonists was blue and the inhaled bronchodilator leaflet was coloured orange/brown.

4.22 Study design[1]

Selection of towns

The selection of study towns was discussed in detail in chapter 3. Briefly, suitable towns had no more than three general practice surgeries and three pharmacies, were within a 30 mile radius of Southampton and were small, with populations of less than 15,000 (Office of Population Censuses and Surveys 1985). In addition, towns were only included if the general practitioners were, in principle, willing to take part in the studies. Of the eight towns which satisfied these criteria, two participated in the preliminary study. Three further towns were randomly selected for the present study, town C (population 12,964), town D (population 2,965) and town E (population 14,719) (Office of Population Censuses and Surveys 1985).

Experimental design

The three towns were randomly allocated to follow one of three procedures:
(1) Leaflets were given to patients by general practitioners during a consultation
(2) Leaflets were issued by pharmacists when the medicine was dispensed
(3) No leaflets were issued

In Town C the leaflets were distributed by pharmacists when the medicine was dispensed. General practitioners issued leaflets during the consultation in Town D and Town E was the 'control' town, where no leaflets were distributed. Because of the small size of town D the study was extended and a further town, town F (population 5,091), was randomly selected. Leaflets were issued by

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[1] *A flow chart outlining the methods is given in an Addendum*

general practitioners in town F.

4.23 Survey procedure

General practitioners and pharmacists in each of the study towns were contacted 3 months before the proposed start date of the survey in their town. Practice meetings were held prior to the survey in each town during which the co-operation of local doctors and pharmacists was sought. During these meetings, all aspects of the survey were discussed and information packs were provided. As press interest in the study was anticipated locally, the media were informed in advance, as for the preliminary studies (Figure 4.1). The survey ran for 10 weeks in each town and in one town at a time. In town C, the survey was conducted between January and March 1986, in town D, from May to July 1986, in town E, from September to November 1986 and in town F from January to March 1987.

The sample

Patients who received a prescription for an NSAID (British National Formulary sections 4.7.1 and 10.1.1), a ß-adrenoceptor antagonist (BNF section 2.4) or an inhaled bronchodilator (BNF section 3.1.1) during the survey period in each town were included. The decision to include or exclude eligible patients was made by each participating general practitioner. Doctors were requested to include as many patients as possible but retained the right to exclude those thought to be "unsuitable". As in the preliminary study, each general practitioner was asked to keep a record of any such exclusions and their reasons. Patients were excluded if they or any of their close relatives were already in the survey. "Repeat" prescriptions not obtained during a consultation (identified at the pharmacy from differences between receptionists and doctors handwriting) were excluded from the sample. However, patients with continuing prescriptions who obtained a prescription during a consultation were not excluded.

Figure 4.1

Article published in Southampton Evening Echo

prior to the commencement of the main study.

Plain English could be a real tonic

YOU have been to the chemist. Picked up the prescription your doctor gave you, get home, sit down in the kitchen and take the bottle of pills out for inspection.

Simple enough. But how many people really understand what they are taking, how to take it and when, and what side-effects their medicines have?

Not nearly enough, claims Professor Charles George, Dean of Medicine at Southampton University.

He argues that prescriptions should be accompanied by leaflets spelling out, in simple English and not medical jargon, the whys and wherefores of a particular course of medication.

Obviously he realises it is impossible, not to say impractical to produce an individual leaflet for each particular tablet or kind of medicine.

But he does think it is possible to produce a type of general leaflet covering a particular group of medicines which have the same or very similar characteristics.

Professor George believes that the public want to know more about the pills and potions they are taking and has done extensive research into the subject.

Professor George and his colleagues conducted a survey among 740 adults to which 60 per cent of the people sent written questionnaires replied.

The result showed:

By health reporter Kevin Hasler

- 62 per cent said not enough was explained about medicines by doctors and pharmacists.
- 73 per cent of people currently taking a medicine had no idea of any possible side-effects.
- 37 per cent did not know how to get rid of unwanted medicines.
- 83 per cent thought an information leaflet would be useful.
- 54 per cent wanted detailed information and 43 per cent said they preferred short, summarised points.

Some information leaflets are already available with some medicines but Professor George says some are difficult to follow for the patient.

"There is no need to blind people with long words. What they really want to know is what it is for. How it is taken. What might go wrong and what to do if it does. How to store it. How to get rid of the remains," he said.

The work of Professor George, which is still continuing, is part of an exhibition held this week in London as part of the Campaign for Plain English's (CPE) assault on labelling in the health service.

It claims the NHS could save millions of pounds if labels on prescriptions were in plainer English.

On 1984 figures £1,181m was spent on prescription medicines in England and CPE claims up to £300m may have been wasted because patients did not take their medicines correctly, if at all.

The group says an example of the traditional wording is with eye drops telling patients they should be "instilled" into the eyes, but then adds that the drops should not be taken.

In plain English the same message is: "Drop one or two drops a day into both eyes four times a day. Don't swallow this".

The group asked Health Minister Tony Newton to review other wordings which may be difficult to understand when he opened the Clarity of Medical Information exhibition in London.

Prescriptions were inspected on a weekly basis at the local pharmacies and names, address, prescribing doctor and drugs prescribed for eligible patients were recorded. In the interests of confidentiality, an undertaking not to divulge patient information was signed. A maximum of 100 patients were recruited per study drug group during the study period (an estimate of the number required per group to detect differences at the 5% level (Machin and Campbell 1987)).

Throughout the survey, information about progress was provided to participating doctors and pharmacists on request. Informal meetings were held weekly with the general practitioners, the pharmacists and the surgery receptionists during which problems were discussed. All the participants received survey progress bulletins every four weeks and at the end of the survey.

Patient consent

Patients included were asked for their consent to take part in the study by way of a standard letter (Figure 4.2). The letters were prepared on practice headed notepaper and signed by the doctors. Letters were sent to the patients from the surgery within a week of the consultation.

4.24 Data Collection

Data were collected by means of a personal interview using a structured questionnaire developed in the preliminary study (Appendix 1). The questionnaire assessed knowledge about the medicine, medicine taking behaviour and satisfaction with information received using a mixture of open and closed questions. Tablet counts were conducted to assess patient compliance and patients were asked their opinions about the provision of information in general and about the leaflets. A Likert scale was developed to measure patients views about specific aspects of their most recent consultation. The scale was based on the Medical Interview Satisfaction Scale (described and validated by Wolf et al 1978), from which fourteen statements were selected and adapted for a British audience.

Figure 4.2

Standard letter sent to patients to ask for their consent to take part in the main study

DR. PETER J. WHITE
DR. SUSAN A. TIPPETT
DR. RICHARD H. PEACE

NIGHTINGALE SURGERY, GREATWELL DRIVE,
OFF CUPERNHAM LANE, ROMSEY, HAMPSHIRE SO5 8QN
Telephone: ROMSEY 517878

Dear

The Department of Clinical Pharmacology in the University of Southampton is carrying out research on medicines which are commonly prescribed. As part of their research, they would like to talk to you about the medicine which you are taking. One of the team (either Sharon Gibbs or Clare Minihane) will contact you within the next few days to see if you would be willing to have a visit at a time to suit yourself. Obviously, if you are not happy about receiving a visit, they would fully understand and respect your wishes. However, if you do decide to take part in this important research (and I hope you will) it should take no more than half-an-hour of your time and any information you give will be treated in strict confidence.

Yours sincerely,

Dr. Susan A. Tippett

Patients were contacted 1-2 weeks after their consultation and, if willing, interviewed in their homes within the next few days. In order to reduce delay, most patients were contacted by telephone but if this was not possible, a written invitation to take part in the survey was sent suggesting a date and time for a visit. A "freepost" envelope was included for the reply. Up to three visits were paid to each household at different times of the day before a patient was classified as "unable to contact". When a study drug was prescribed for a patient under 16 years old, the parent or guardian was interviewed on their behalf. Each interview lasted approximately 30 minutes. Answers were recorded during the interview and coded immediately after each visit by the interviewer.

Patients were not informed of the true nature of the study. When contacted, they were told "The Department of Clinical Pharmacology in the University of Southampton is carrying out research on medicines which are commonly prescribed. As part of our research, we would like to talk to you about the medicine which you are taking". General practitioners and pharmacists were requested not to discuss the nature of the survey with their patients, and were discouraged from going through the leaflet with the patient or providing any more verbal information than was their usual practice.

The interviews were conducted by two interviewers. Both were female and of similar ages (25 years). A training period of two weeks was followed, during which time patients were visited by both interviewers together. Coding of these interview schedules was compared for consistency. In addition, 50 (7.0%) randomly selected interview schedules were audited to ensure a consistent approach with minimum drift from the questionnaire.

4.25 Data Analysis

The data were double punched onto magnetic tape by a commercial punching agency (Data Speed Ltd, Southampton) and transferred to the University of Southampton IBM 3090 mainframe computer.

Initial analysis was conducted using the SPSS-X statistical package. Frequencies were produced for the response to each variable and outlying values identified. Comparisons between patients who received leaflets and others who did not were made and associations were tested using the Chi-squared statistic (with Yates correction for 2 x 2 tables). Throughout the analysis patients intended to receive leaflets were assumed to have done so. Where significant X^2 values were produced for contingency tables with more than 2 rows or 2 columns, the cells were partitioned in order to determine whether non-independence of the two variables occurred throughout or in a specific part of the table (Everitt 1977). The data obtained from the global satisfaction measures were investigated by applying a more sensitive test than the usual X^2 statistic, a "test for trend". This test assumes that "satisfaction" when ranked from "completely satisfied" to "completely dissatisfied" has the characteristics of a continuous variable. This makes it possible to allot numerical values to each category so as to detect trends in the tables. Student's t-tests were applied to detect significant differences between continuous variables. The 5% level ($p<0.05$) was considered significant throughout these analyses.

Satisfaction scale

Factor analysis, a statistical technique based on intercorrelating items, was used to investigate the validity of the satisfaction scale (Cattell 1952; Oppenheim 1966). A correlation matrix (a systematic grid layout of the correlations between all possible pairs of items) was produced, from which the underlying common factors of the scale were identified using "factor extraction" and "factor rotation" techniques. "Factor loadings", which indicated the importance of each factor in the item concerned, were produced for each item on each factor. This procedure was performed using the SPSS-X statistical package on the University of Southampton mainframe computer.

Demographic variables

An initial examination of the effect of the leaflets on knowledge and satisfaction was conducted by controlling for sex, age and social class. 2 x 2 contingency tables were produced for males and females, two age groups (under 55 years and 55 and over), and the non-manual and manual social classes. X^2 values and odds ratios (Fleiss 1981) were calculated for each partial table. The odds ratios were compared across the partial tables with estimates of the common odds ratio, calculated using the Mantel-Haenszel method (Mantel and Haenszel 1959).

Logit modelling techniques (Cox 1970; Gilbert 1981) were applied to investigate the effects of receiving a leaflet, sex, age and social class of the medicine on knowledge and satisfaction outcomes. The GLIM statistical package (Baker and Nelder 1978) was used to fit models which took these variables into account. The significance of each variable was assessed by eliminating each in turn from the model. The effect of the leaflet within each sex, age and social class category was tested by adding each variable in turn to a model which always contained the leaflet. The association between variables and knowledge and satisfaction outcome was expressed as the odds ratio and 95% confidence intervals were calculated.

4.3 RESULTS

4.31 The leaflets

The leaflets are shown in figures 4.3 - 4.5.

4.32 Sample Characteristics

Response from general practitioners and pharmacists

All 42 general practitioners and the nine pharmacists agreed to take part in the study.

Response from patients

The overall patient response rate to interview was 82% (Table 4.1). A total of 719 patients were interviewed, 419 in leaflet towns and 300 in the control town. Three hundred and thirty-two patients had been prescribed an NSAID, 222 a ß-adrenoceptor antagonist and 165 an inhaled bronchodilator. Of these, 232 NSAID patients, 122 patients prescribed a ß-adrenoceptor antagonist and 65 patients using bronchodilators were given leaflets. The number of patients recruited in towns D and F, where leaflets were issued by general practitioners, was low, particularly those receiving leaflets about bronchodilators (town D=4 and town F=11). No significant differences in response rate were observed between the study towns for patients prescribed NSAIDs or bronchodilators. However, the response from patients prescribed ß-adrenoceptor antagonists was significantly lower in the control town (73%) than that in the leaflet towns (83%) (X^2_1=6.24, P<0.05).

Demographic characteristics of the respondents

Demographic characteristics of patients interviewed in this study are shown in Table 4.2. Sixty-three percent of the respondents were women and 35% were 65 and over. More patients were interviewed from the non-manual social classes (classes I, II and IIINM made up 53%) than from the manual social classes

Figure 4.3

PIL giving information about NSAIDs

What you should know about Anti-Inflammatory Analgesics.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____ _____
This is one in a group of medicines called Anti-Inflammatory Analgesics. These can relieve pain such as headache, toothache, arthritis and period pain. They can also reduce fever.

Things to remember about Anti-Inflammatory Analgesics.

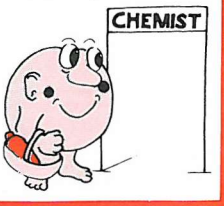
1 **Make sure it is safe for you** to take Anti-Inflammatory Analgesics *(see the back of this leaflet).*♦

2 **Look at the label** on your tablets. It will tell you when to take them.

3 **Anti-Inflammatory Analgesics sometimes cause problems** You can find these listed on the back of this leaflet.*

4 Keep your tablets **out of reach of children.**

5 **Remember to return any unused tablets** to the pharmacist or flush them down the toilet.



You will find more about Anti-Inflammatory Analgesics on the back of this leaflet.

Your medicine is an Anti-Inflammatory Analgesic. Anti-Inflammatory Analgesics can relieve pain such as headache, toothache, arthritis, and period pain. They can also reduce fever.

◆ Before taking your medicine

- Are you already taking aspirin or another drug used to treat arthritis?
- Have you had an allergic reaction or wheezing after taking aspirin?
- Have you experienced stomach discomfort, felt like being sick or had heartburn after taking aspirin?
- Have you had a stomach ulcer previously?
- Are you on medicines for thrombosis (eg Warfarin) or gout?
- Are you pregnant?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, *ask your doctor or pharmacist.*
- Tablets or capsules should be swallowed with a glass of water or milk. Soluble tablets should be dissolved in water before taking them.
- If you forget to take a dose take another as soon as you remember. Then go on as before.
- In the event of an accidental overdose contact your nearest hospital casualty department or tell your doctor immediately.

✻ After taking your medicine

This medicine sometimes causes side-effects in some people.
If you get any of the following, tell your doctor.

- Ringing in the ears or dizziness.
- Skin troubles such as rash or itching for the first time.
- Wheezing.
- You develop stomach discomfort or heartburn for the first time.
- You vomit blood or pass tarry stools.

Storing your medicine

- Keep your tablets in a safe place where children cannot reach them. Your tablets could harm them.
- If your doctor decides to stop the treatment, return any left over tablets to the pharmacist or flush them down the toilet. Only keep them if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Figure 4.4

PIL giving information about Beta-adrenoceptor antagonists

What you should know about Beta Blockers.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____

This is one of a group of medicines called Beta Blockers.
Beta Blockers can help you in a number of ways:

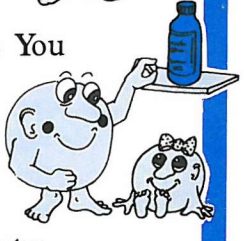
- They can reduce high blood pressure.
- They can lessen or prevent chest pain (angina).
- They can control heart beats which are irregular or too fast.
- Some medicines of this type are used to calm people who are anxious or worried.

Things to remember about Beta Blockers

1 **Make sure it is safe for you** to take Beta Blockers *(see the back of this leaflet).*♦

2 **Look at the label** on your Beta Blockers. It will tell you when to take them.

3 **Keep taking your Beta Blockers** until they are finished or your doctor says otherwise. **Don't stop** just because you feel better.



4 **Beta Blockers can cause problems.** You can find these listed on the back of this leaflet.*

5 Keep your Beta Blockers **out of reach of children.**

6 **Remember to return any unused Beta Blockers** to your pharmacist or flush them down the toilet unless your doctor has told you to keep them.

You will find more about Beta Blockers on the back of this leaflet.

Your medicine is one in a group of medicines called Beta Blockers. Beta Blockers can help you by reducing high blood pressure, by lessening or preventing chest pain (angina) or by controlling heart beats which are irregular or too fast. Some medicines of this type are used to calm people who are anxious or worried.

◆ Before taking your medicine

- Do you suffer from asthma or attacks of wheezing?
- Are you diabetic and taking insulin or tablets?
- Are you pregnant?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, *ask your doctor or pharmacist.*
- Take the tablets or capsules with a glass of water.
- Keep taking your medicine until your doctor tells you to stop. Don't stop just because you feel better. If you stop too soon your condition may get worse.
- If you forget to take a dose take another as soon as you remember. Then go on as before.
- If you take an overdose by accident contact your nearest hospital casualty department or tell your doctor immediately.

✱ After taking your medicine

Although most people benefit from taking this medicine, a few people can be upset by it. If you get any of the following *tell your doctor.*

- Dizziness or lightheadedness or wheezing.
- A very slow pulse (under 50 beats per minute)
- Skin trouble such as rash or itching for the first time.

Very occasionally, this type of medicine can cause sleeplessness or vivid dreams. Don't be worried because they are not serious. But tell your doctor when you go next time.

If you are taking this medicine for chest pains **don't** stop it suddenly, otherwise the pain will get much worse. Your doctor will tell you how to reduce the dose slowly. This will take about two weeks.

Storing your medicine

- Keep your medicine in a safe place where children cannot reach it. Your medicine could harm them.
- If your doctor decides to stop the treatment, return any left over medicine to the pharmacist or flush it down the toilet. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Figure 4.5

PIL giving information about Bronchodilators

What you should know about Bronchodilators

Please read this carefully before you start using your inhaler. If you have any questions or are not sure about anything ask your doctor or pharmacist.

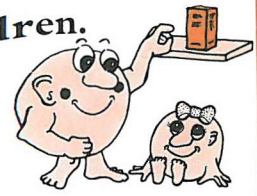
The name of your medicine is _____
This is one in a group of medicines called Bronchodilators.
Bronchodilators relieve asthma by relaxing muscle spasm in the lungs. If you use this medicine regularly it may also help to prevent attacks of asthma.

Things to remember about Bronchodilators

1 **Make sure you know how to use your inhaler.**
There are instructions in the box it came in.

2 **Bronchodilators sometimes cause problems.** You can find these listed on the back of this leaflet. *

3 Keep your medicine **out of reach of children.**



4 **Dispose of old inhalers safely.** Do NOT throw inhalers on to the fire.

You will find more about Bronchodilators on the back of this leaflet.

Your medicine is a Bronchodilator. Bronchodilators relieve asthma by relaxing muscle spasm in the lungs. If you use this medicine regularly it may also help to prevent attacks of asthma.

Taking your medicine by inhaler

- Use your inhaler at the right times. Your doctor will tell you how often to use it. Ask if you are not sure.
- Make sure you know how to use your inhaler.

The medicine will only work if it reaches your lungs. The leaflet which comes with your inhaler will tell you how to use it properly. If you are not sure ask your doctor or pharmacist to show you.

- If you forget to take a puff, take another as soon as you remember. Then go on as before.
- Don't take more puffs than your doctor tells you to. If your usual dose doesn't work, tell your doctor.

✱After taking your medicine

Most people benefit from using this medicine but it can cause side-effects. If you get any of the following, tell your doctor.

- Rapid or irregular heart beats.
- Feeling extremely nervous.

Some people get a bad taste in their mouths after using their inhaler. This is not dangerous. You can get rid of the bad taste by rinsing your mouth out with water. Some people find that their hands become a little shaky. This is not dangerous and usually wears off after a few days.

Storing your inhaler

- Keep your inhaler in a safe place out of reach of children. It could harm them.
- Don't use your inhaler after its expiry date.
- Make sure you throw your old inhalers away. Do NOT throw them on to the fire, because they may explode.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptons are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Table 4.1

Number of patients interviewed in the study towns (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Number of patients interviewed	232 (86.0)	100 (78.0)	122 (85.0) *	100 (73.0)	65 (84.0)	100 (83.0)

* $p<0.05$

Table 4.2

Demographic characteristics of the patients interviewed **(percentages are shown in brackets)**

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Sex						
Male	81 (34.9)	27 (27.0)	45 (36.9)	43 (43.0)	22 (33.8)	42 (42.0)
Female	151 (65.1)	73 (73.0)	77 (63.1)	57 (57.0)	43 (66.2)	58 (58.0)
Age (years)						
16-24	12 (5.2)	4 (4.0)	1 (0.8)	0 (0.0)	5 (7.7)	14 (14.0)
25-34	24 (10.4)	5 (5.0)	2 (1.6)	5 (5.0)	9 (13.8)	21 (21.0)
35-44	42 (18.3)	14 (14.0)	7 (5.7)	7 (7.0)	10 (15.4)	31 (31.0)
45-54	34 (14.8)	14 (14.0)	24 (19.7)	19 (19.0)	5 (7.7)	10 (10.0)
55-64	41 (17.8)	26 (26.0)	34 (27.9)	25 (25.0)	10 (15.4)	10 (10.0)
65-74	43 (18.7)	14 (14.0)	40 (32.8)	28 (28.0)	11 (16.9)	5 (5.0)
75 and over	34 (14.8)	23 (23.0)	14 (11.5)	16 (16.0)	15 (23.1)	9 (9.0)

**

Table 4.2 (continued)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Social Class						
I professional	17 (7.3)	3 (3.0)	10 (8.2)	4 (4.0)	5 (7.7)	7 (7.0)
II intermediate	59 (25.4)	32 (32.0)	29 (23.8)	34 (34.0)	21 (32.3)	33 (33.0)
IIIN skilled non-manual	48 (20.7)	11 (11.0)	28 (23.0)	15 (15.0)	9(13.8)	14 (14.0)
IIIM skilled manual	63 (27.2)	20 (20.0)	34 (27.9)	25 (25.0)	20 (30.8)	29 (29.0)
IV semi-skilled	27 (11.6)	21 (21.0)	13 (10.7)	15 (15.0)	4 (6.2)	8 (8.0)
V unskilled	7 (3.0)	5 (5.0)	6 (4.9)	1 (1.0)	1 (1.5)	5 (5.0)
Unclassifiable	11 (4.7)	8 (8.0)	2 (1.6)	6 (6.0)	5 (7.7)	3 (4.0)

** $p<0.01$ + 2 missing values were excluded from the percentages

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

(42% from classes IIIM, IV and V) as classified according to the Registrar General's Classification of Occupations 1980 (Office of Population Censuses and Surveys 1980) but 5% of respondents were unclassifiable using this method, including 17 people from the armed forces. With the exception of those taking bronchodilators, no significant differences in sex or age were found between those who received a leaflet and others who did not. Bronchodilator users interviewed in the control town were significantly younger than those in the leaflet towns (X^2_6=18.62, p<0.01). Almost one third of the bronchodilator users in the control group were children under 16 whereas only 12.3% of those who received leaflets about this group of medicines were children (X^2_1=5.99, p<0.05).

There were no significant differences in social class between patients who received leaflets giving information about ß-adrenoceptor antagonists and those who did not. The same was true for patients prescribed bronchodilators. However, there was a tendency for more NSAID patients who received leaflets to come from social class III (non-manual and manual combined), whereas there was an excess of social classes IV and V in the control group (X^2_2= 9.78, p<0.01).

Over 80% of the patients prescribed ß-adrenoceptor antagonists or bronchodilators had taken their medicine before. However, only 35% of the NSAID takers had previous experience of their medicine. There were no significant differences in the number of patients who had taken their medicine before amongst those who received a leaflet and those who did not.

The non-respondents

One hundred and fifty-eight (18%) patients approached either refused to be interviewed or could not be contacted after three visits to their home. Amongst the NSAIDs and ß-adrenoceptor antagonists non-respondents, approximately three-quarters of these patients declined to participate and the remaining quarter could not be contacted. By contrast, over 50% of the non-respondents using

bronchodilators could not be contacted to arrange a visit. The ratio of males to females among the non-respondents was not significantly different from the respondents for NSAIDs and ß-adrenoceptor antagonists. However 63% of the non-respondents prescribed bronchodilators were male. The ages of the non-respondents were unavailable. No significant differences were found between the response rates obtained by each of the interviewers.

4.33 Patients' knowledge

Patients who received a leaflet were found to be better informed about their medicines than those who did not (Table 4.3).

How to take the medicine

More patients who received a leaflet were aware of how to take their medicine correctly. Eighty-one percent of NSAID takers who received a leaflet knew they should take their tablets with food compared with 68% in the control group (X^2_1=8.57, p<0.05). More of these patients were also aware of the dosage instructions (84% cf 75%, X^2_1= 3.03, p=0.08) and what to do if a dose was missed (58% cf 47%, X^2_1=2.62, p=0.11) than those who did not receive additional written information. In addition, knowledge of when to use the inhaler was found to be significantly greater amongst bronchodilator users who received a leaflet (X^2_1=6.37, p<0.05).

However, some information was well known whether or not a leaflet was received. For example, the purpose for which the therapy had been prescribed was known by over 94% of all the respondents. In addition, awareness of the correct dosage instructions for ß-adrenoceptor antagonists was found to be high in both groups. Less well known was an awareness of what to do if a dose was missed. Nevertheless, nearly half of the respondents were able to give a correct answer when asked what the procedure should be.

Table 4.3

Patients' knowledge about their medicine **(numbers are those giving correct answers [percentages are shown in brackets])**

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Name of medicine	126 (54.3)	65 (65.0)	89 (73.0)	60 (60.0)	60 (60.0)	95 (95.0)
Purposes of therapy	228 (98.3)	97 (97.0)	115 (94.3)	88 (88.0)	65(100.0)	99 (99.0)
When to take it	183 (83.6)	73 (74.5)	117 (95.9)	80 (90.8)	52 (81.3)	60 (61.2) *
Take with fluid	202 (92.2)	89 (90.8)	119 (97.5)	86 (87.8)	-	-
Take with food	177 (80.8)	67 (68.4) **	-	-	-	-
What to do if dose is missed	126 (58.1)	44 (47.3)	76 (62.3)	52 (54.2)	+ 21 (60.0)	8 (50.0)
Storage out of reach of children	200 (91.3)	82 (83.7)	110 (90.9)	86 (87.8)	51 (79.7)	66 (67.3)
Safe method of disposal	196 (89.5)	80 (81.6)	93 (76.2)	79 (80.6)	52 (81.3)	88 (87.8)
Aware not to share medicines	204 (93.2)	89 (90.8)	120 (98.4)	96 (98.0)	56 (87.5)	66 (67.3)

* $p<0.05$, ** $p<0.01$

Questions were answered by 93-100% of respondents (with the exception of + what to do if a dose is missed, which was answered by less than 50% of patients using bronchodilators). Missing values were excluded from the percentages.

Safe storage and disposal

Over three-quarters of those questioned were aware of safe methods of storing and disposing of medicines. Knowledge of the potential dangers of sharing prescribed medicines with family or friends was also found to be widespread. Nevertheless, significantly more bronchodilator users knew not to share inhalers if they received a leaflet (88% cf 67%, $X^2_1=5.04$, $p<0.05$).

Knowledge of side-effects

Awareness of the side-effects of all three medicines was significantly higher among patients who were given leaflets (Table 4.4). Significantly more NSAID patients in the leaflet group knew that their medicine could cause stomach problems ($X^2_1=13.52$, $p<0.001$), dizziness ($X^2_1=17.19$, $p<0.001$) and ringing in the ears ($X^2_1=9.17$, $p<0.01$). More β-adrenoceptor antagonist takers who received leaflets were aware that their therapy sometimes causes dizziness ($X^2_1=8.32$, $p<0.001$), wheezing ($X^2_1=4.61$, $p<0.05$), rash ($X^2_1=5.91$, $p<0.05$) and sleeplessness or vivid dreams ($X^2_1=4.33$, $p<0.05$). Shakiness was identified as a potential side-effect of bronchodilators by significantly more patients who received a leaflet ($X^2_1=6.47$, $p<0.05$). However, despite this marked improvement in awareness, the number of patients who could name any of the side-effects of their medicine remained low at around one-third, even amongst those who received leaflets.

Trends in favour of the leaflets were found for all of the knowledge items tested in the interviews, with the exception of the name of the medicine. Although almost all those using bronchodilators could name their inhaler, only about half of the NSAID patients could name their medicine correctly and more were able to do this if they did not receive a leaflet. Around two-thirds of those taking β-adrenoceptor antagonists were able to name their medicine correctly. One patient was sure her tablets were called "β bouncers", whereas another referred to his tablets as "block busters" throughout the interview. Both of these patients had received a leaflet with their medicines.

Table 4.4

Patients' knowledge of the side effects of their medicine **(percentages are shown in brackets)**

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Aware of any side effects	99 (42.7)	15 (15.0) ***	37 (30.3)	12(12.0) **	24 (36.9)	18 (18.0) *
Aware of individual side effects						
Stomach discomfort	83 (35.8)	15 (15.0) ***				
Ringing in ears	23 (9.9)	0 (0.0) **				
Dizziness	43 (18.5)	1 (1.0) ***				
Rash	14 (6.0)	1 (1.0)				
			Dizziness	21 (17.2) 4 (4.0) **		
			Wheezing	10 (8.2) 1 (1.0) *		
			Rash	9 (7.4) 0 (0.0) *		
					Shakiness	18 (27.7) 11 (11.0) *
					Nervousness	4 (6.2) 2 (2.0)
					Rapid heart beat	9 (13.8) 11 (11.0)

Table 4.4 (continued)

Medicine	NSAIDS			ß-adrenoceptor antagonists			Bronchodilators		
Leaflet	Yes	No		Yes	No		Yes	No	
Wheezing	12 (5.2)	0 (0.0) *	Slow pulse	2 (1.6)	0 (0.0)	Bad taste in mouth	2 (3.1)	0 (0.0)	
Tarry stools	26 (11.2)	4 (14.0)	Sleeplessness or vivid dreams	14 (11.5)	1 (1.0) *		-	-	

* p<0.05, ** p<0.01, *** p<0.001 Questions were answered by 100% of respondents

4.34 "Side-effects" experienced

A variety of health problems were experienced by the respondents after starting their medicine. These have been divided below into potential "side-effects" (those listed on the leaflets) and other health problems mentioned by the respondents.

Side-effects listed in the leaflets

Despite around half of the patients prescribed NSAIDs or ß-adrenoceptor antagonists claiming to have experienced at least one of the side-effects listed on the leaflet, there was no evidence of an increased reporting of any of these problems amongst those who received leaflets (table 4.5). In fact, for ß-adrenoceptor antagonists, significantly more patients who did not receive a leaflet reported wheezing ($X^2_1=5.57$, $p<0.05$) and the trend was in the same direction for side-effects mentioned in the other leaflets. Amongst those taking NSAIDs, the most common problem was stomach discomfort reported by 27% of the respondents, followed by wheezing, mentioned by 20%. Wheezing and dizziness were experienced by over 20% of the ß-adrenoceptor antagonist takers. The most common problem reported by patients prescribed bronchodilators was shakiness which was experienced by 13% of users. However, four out of every five users did not report experiencing any of the problems listed in the leaflets.

Other health problems

Generally, health problems not listed on the leaflets were more frequently reported by patients in the control group (Table 4.6). An exception to this were headaches among the NSAID takers who had received a leaflet ($X^2_1=5.41$, $p<0.05$). Subsequent analysis of these data revealed that 10 of the patients who reported this symptom had been prescribed indomethacin. Headaches are a recognised side-effect of this drug and occur more frequently in patients receiving it than those prescribed other NSAIDs (British National Formulary 1986). Nine of these patients were in the leaflet group. The increased reporting of joint pains and stomach problems by bronchodilator users who received a

Table 4.5.

Patients' experience of 'side effects' listed in the leaflets (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Experience of any of the side effects listed	117 (50.4)	61 (61.0)	55 (45.1)	56 (56.0)	10 (15.4)	19 (19.0)
Experience of individual side effects						
Stomach discomfort	55 (25.1)	29 (29.6)	Dizziness 21 (17.2)	27 (27.6)	Shakiness 6 (9.4)	15 (15.5)
Ringing in ears	24 (11.0)	17 (17.3)	Wheezing 24 (19.7)	34 (34.7) *	Nervousness 5 (7.8)	6 (6.2)
Dizziness	35 (16.0)	17 (17.3)	Rash 15 (12.3)	15 (15.3)	Rapid heart beat 3 (4.7)	2 (2.1)
Rash	25 (11.4)	18 (18.4)	Slow pulse 0 (0.0)	0 (0.0)	Bad taste in mouth 0 (0.0)	1 (1.0)

Table 4.5 (continued)

Medicine		NSAIDS			ß-adrenoceptor antagonists		Bronchodilators	
Leaflet		Yes	No		Yes	No	Yes	No
	Wheezing	42 (19.2)	22 (22.4)					
	Tarry stools	5 (2.3)	1 (1.0)	Sleepless-ness or vivid dreams	6 (4.9)	2 (2.0)		

* $p<0.05$ Questions were answered by 100% of respondents

Table 4.6

Other health problems reported by patients since starting the medicine (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Health problems reported						
Blurred vision	16 (7.3)	7 (7.1)	11 (9.0)	11 (11.2)	3 (4.7)	5 (5.2)
Wheezing	-	-	-	-	55 (85.9)	86 (88.7)
Sickness	26 (11.9)	11(11.2)	8 (6.6)	15 (15.3)	8 (12.5)	7 (7.2)
Rash	-	-	-	-	16 (25.0)	29 (29.9)
Stomach discomfort	-	-	15 (12.3)	26 (26.5) *	16 (25.0)	11 (11.3) **
Joint pain	155 (70.8)	73 (74.5)	42 (34.4)	46 (46.9)	25 (39.1)	20 (20.6) *
Cold extremities	32 (14.6)	12 (12.2)	28 (23.0)	25 (25.5)	12 (18.8)	8 (8.2)
Depression	29 (13.2)	10 (10.2)	8 (6.6)	12 (12.2)	3 (4.7)	6 (6.2)

Table 4.6 (continued)

Medicine		NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet		Yes	No	Yes	No	Yes	No
	Ringing in ears	-	-	14 (11.5)	16 (16.3)	9 (14.1)	5 (5.2)
	Drowsiness	40 (18.3)	16 (16.3)	23 (18.9)	22 (22.4)	8 (12.5)	13 (13.4)
	Nervousness	15 (6.8)	6 (6.1)	5 (4.1)	11 (11.2)	-	-
	Headaches	45 (20.5)	9 (9.2) *	19 (15.6)	21 (21.4)	19 (29.7)	27 (27.8)
	Bowel complaints	28 (12.8)	19 (19.4)	6 (4.9)	12 (12.2)	4 (6.3)	2 (2.1)
	Tarry stools	-	-	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Others	10 (5.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

* $p<0.05$

leaflet may reflect their older age.

Were the problems connected with the medicine?

For the most part, the problems reported were not connected with the medicine. Indeed, few ß-adrenoceptor antagonist or bronchodilator takers connected their treatment with any of the problems they experienced. NSAID patients were, however, more likely to connect their own experiences of "side-effects" with the medicine if they had received a leaflet. Thus, of the patients who reported stomach discomfort, 26 (47.3%) who received a leaflet associated the problem with their tablets compared with 8 (27.6%) in the control group (X^2_1=2.29, p=0.13). None of the patients prescribed ß-adrenoceptor antagonists or bronchodilators reported stomach discomfort.

There was some evidence to suggest that patients who experienced non-specific health problems whilst using their medicine were more likely to blame the medicine if they had received a leaflet. Among the 37 NSAID takers who recorded having felt sick or being sick whilst taking their tablets, 14 (37.8%) thought this problem was probably caused by the medicine. Twelve of these patients had received leaflets (X^2_1=2.68, p=0.10).

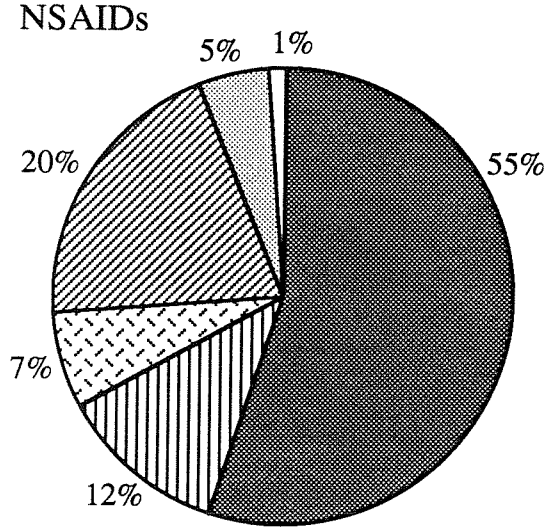
Amongst those who received leaflets, ten of the 16 NSAID takers who linked their stomach discomfort with the medicine had stopped their tablets because of this. In addition, eight of these patients mentioned this problem to their doctor. The number of patients who reported experiencing any side-effects with ß-adrenoceptor antagonists and bronchodilators was too small to detect trends in these data.

4.35 Storage and disposal

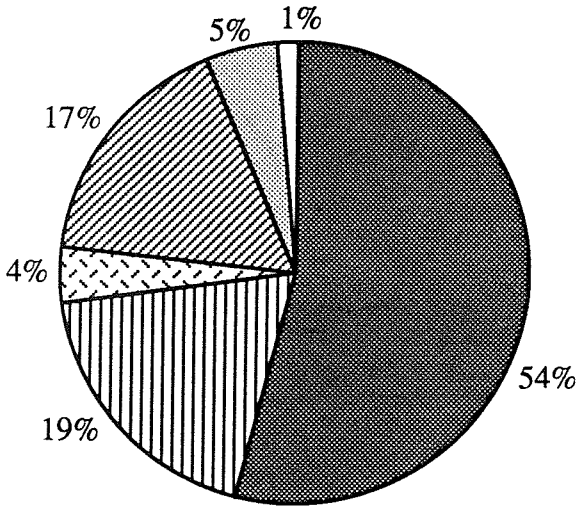
The most common place for storage of NSAIDs and ß-adrenoceptor antagonists was the kitchen. Inhalers were more commonly kept in a handbag or pocket (Figure 4.6). Eighty-nine percent of patients prescribed NSAIDs or

Figure 4.6
Place of storage of the medicines

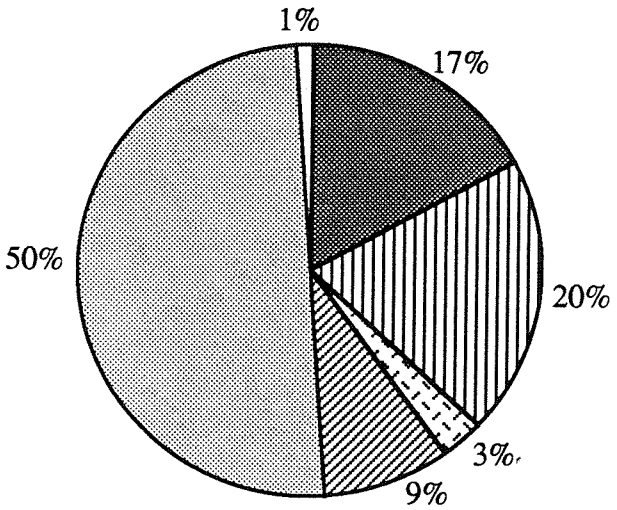
(a) NSAIDs

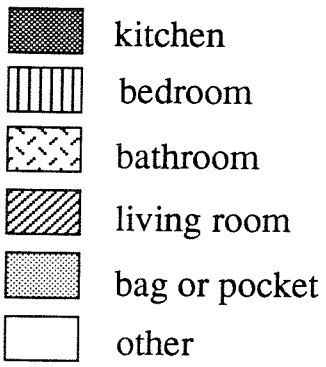


(b) β - adrenoceptor antagonists



(c) Bronchodilators





ß-adrenoceptor antagonists were aware of the need to store their medicines out of reach of children. However, on inspection the interviewers found that only about half of these patients took this precaution (Figure 4.7). All three medicines were more likely to be stored out of reach if children lived in or regularly visited the house: this factor was a more important influence on the place of storage than the receipt of a leaflet.

Figure 4.8 shows methods of disposal of unused medicines. Despite knowledge of the correct method of disposal being generally high, more NSAIDs takers who received leaflets said they would either return unused medicines to the pharmacist or flush them down the toilet ($X^2_1=3.95$, $p<0.05$). In addition, fewer patients (12.8%) who received an NSAID leaflet said that they would keep any left over medicine, compared with 24.5% in the control group ($X^2_1=5.94$, $p<0.05$). The trend was in the same direction for ß-adrenoceptor antagonists.

4.36 Patient Compliance

Medicine taking

Confirmation was obtained that each of the patients interviewed had been prescribed either an NSAID, a ß-adrenoceptor antagonist or an inhaled bronchodilator at their most recent general practitioner consultation. Whilst for the majority, the study drug was the only prescribed medicine currently being taken, one patient claimed to be taking 22 different medicines on a regular basis. They included a large variety of sedatives, major tranquillisers and antidepressants, together with an anti-migraine compound, two analgesics, a diuretic, potassium supplements and finally, propranolol.

Tablet counts

Tablet counts were conducted during 70% of the interviews with patients prescribed NSAIDs and 67% of interviews about ß-adrenoceptor antagonists. Medicines were not made available for assessment in the remaining one third of

Figure 4.7
Storage of medicine out of reach of children

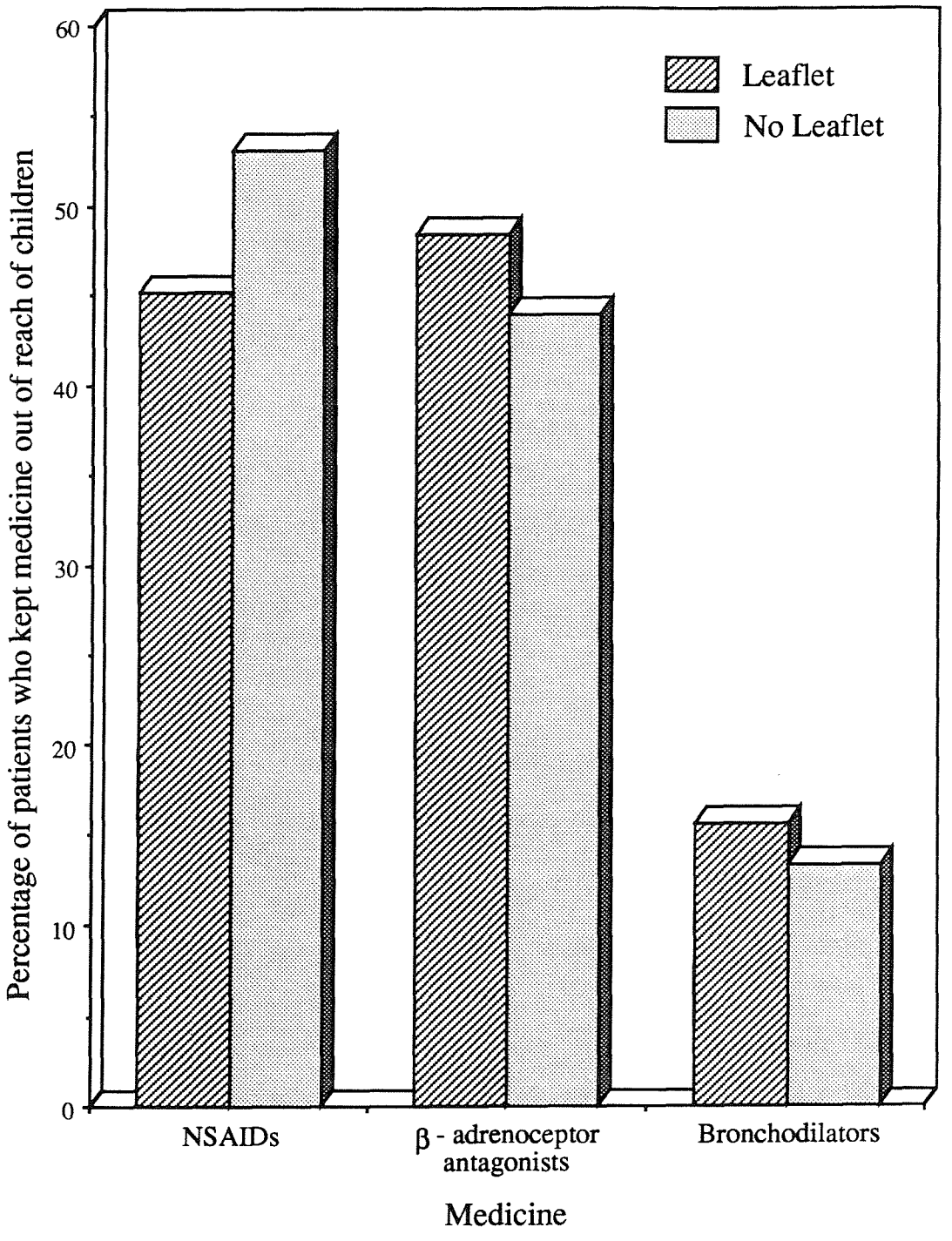
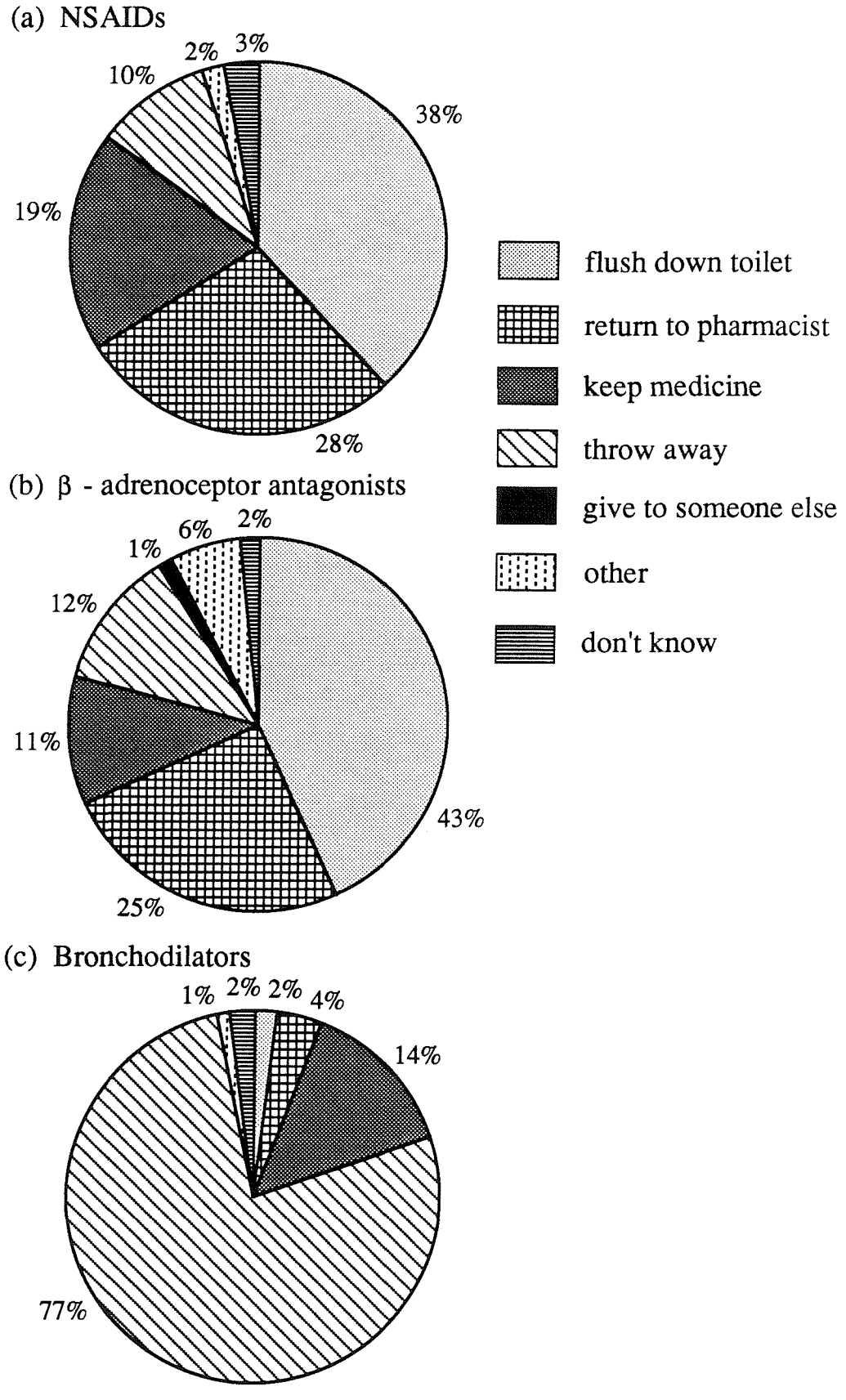


Figure 4.8
Method of disposal of leftover medicines



the interviews with these patients. No such assessment of patient compliance was possible for inhaled bronchodilators. Compliance rates were calculated from the tablet counts as:

Compliance (%) = Amount removed from container / Amount expected to be taken x 100

The amount expected to be taken was determined from the number of days after the start date (which was either the date given on the label, or one subsequent to that, agreed with each patient) X the dosage on the label.

The distribution of the compliance rates obtained for NSAIDs and ß-adrenoceptor antagonists are shown in figures 4.9 and 4.10. The rates were found to vary markedly with a range of 0-390%. More patients showed compliance rates arbitrarily defined as acceptable (between 80-120%) if they received a leaflet, but the differences between the two groups were not significant for either medicine (X^2_2=0.05, and X^2_2=4.81, p=0.09, respectively) (table 4.7). For both medicines, only about half of the compliance rates generated from the tablet counts fell in this "compliant" range. Under-compliance was common, with the tablet counts indicating that nearly half of NSAID takers and around a third of ß-adrenoceptor antagonist takers were less than 80% compliant. Over-compliance was less frequently uncovered. Nevertheless, the tablet counts recorded 8% of NSAID takers and 15% of those taking ß-adrenoceptor as having compliance rates of over 120%.

The pattern of compliance

The pattern of medicine taking as reported by the respondents on the day prior to interview is shown in table 4.8. For all three medicines, there were no significant differences in self reported compliance patterns between those who received leaflets and others who did not. Around two-thirds of the patients prescribed an NSAID described a tablet taking regimen which agreed exactly

Figure 4.9
Distribution of compliance rates calculated from NSAIDs tablet counts

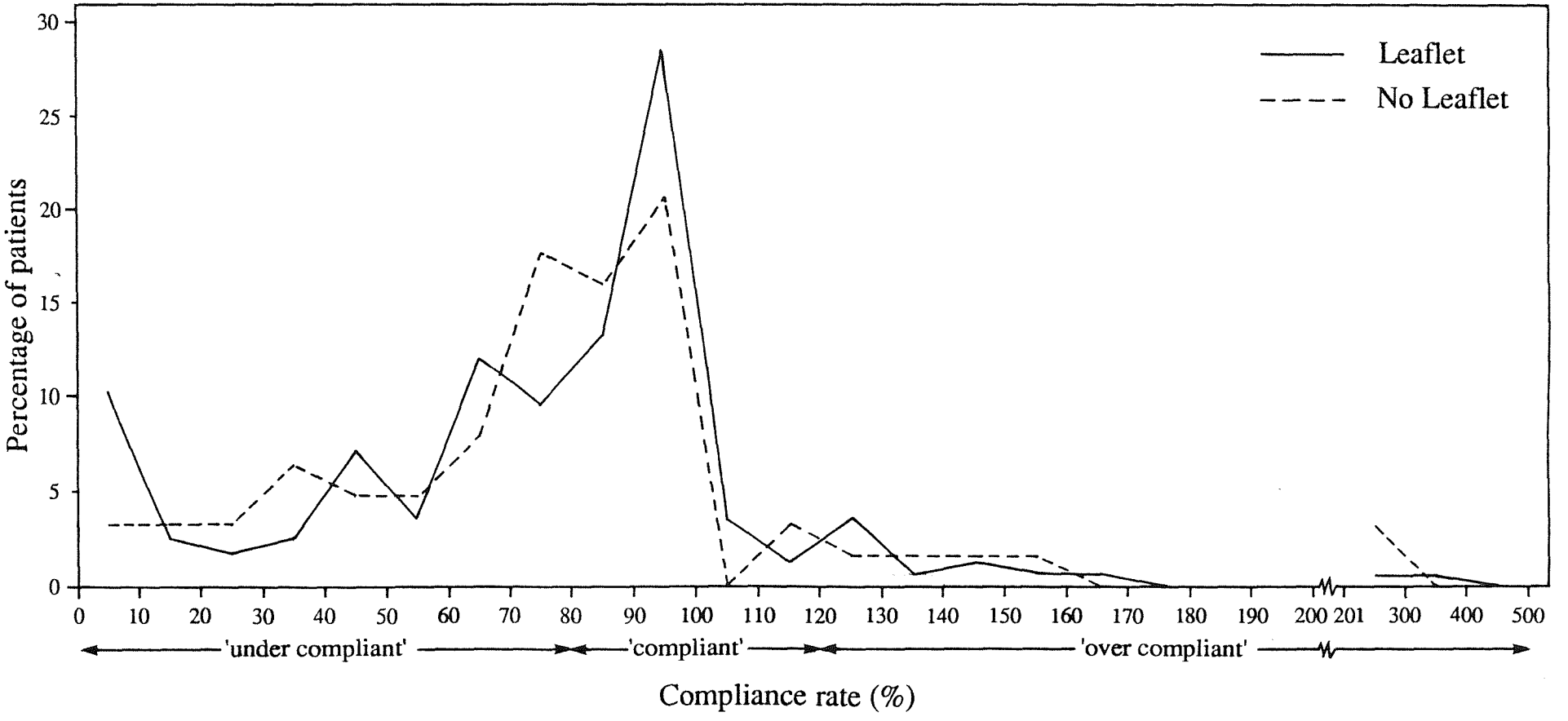


Figure 4.10
Distribution of compliance rates calculated from β-adrenoceptor antagonists tablet counts

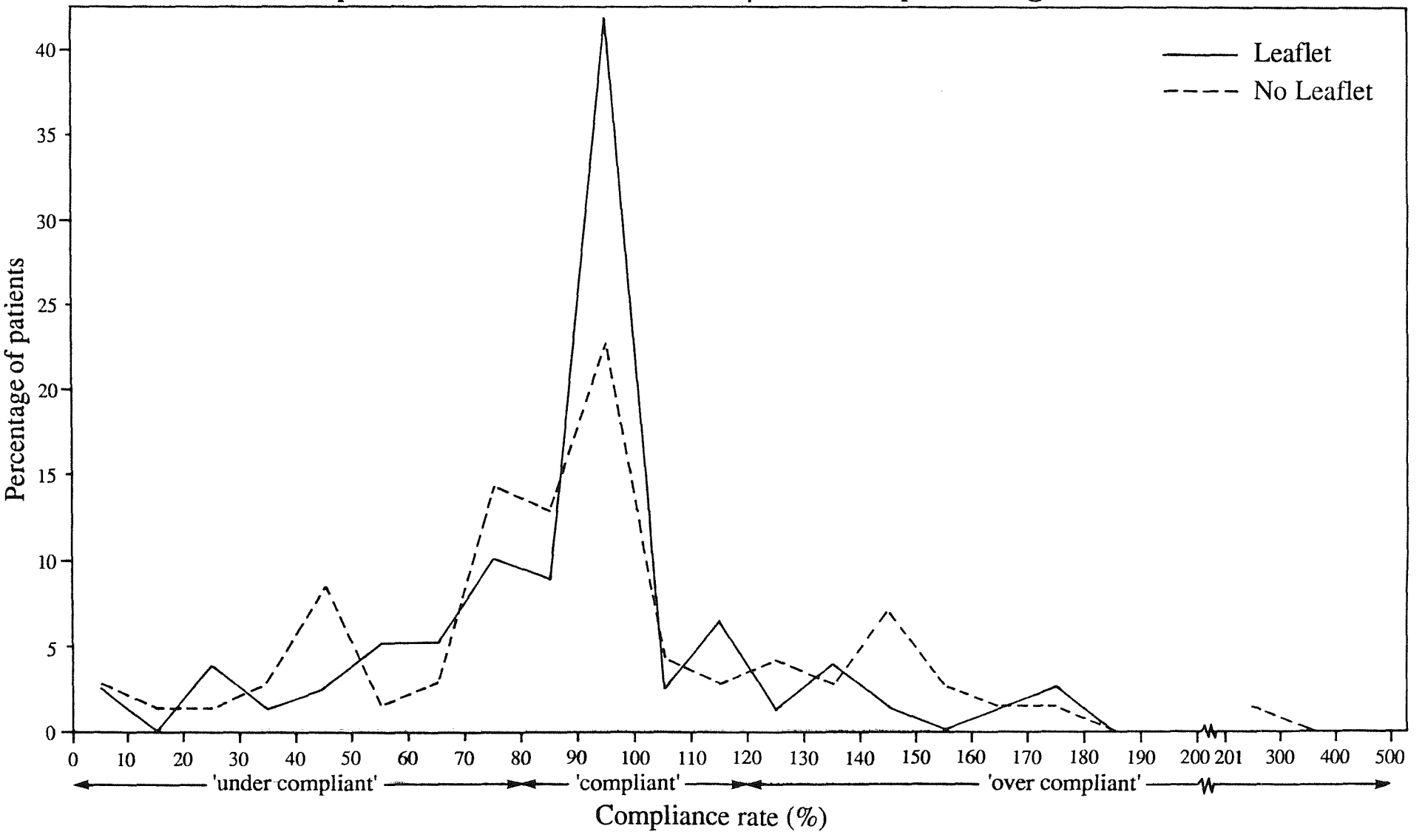


Table 4.7

Compliance rates calculated from tablet counts (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Leaflet	Yes	No	Yes	No
Total number	169	63	79	70
Under 80% compliance	75 (44.4)	30 (47.6)	23 (29.1)	23 (32.9)
80-120% compliance	81 (47.9)	27 (42.9)	48 (60.8)	32 (45.7)
Over 120% compliance	13 (7.7)	6 (9.5)	8 (10.1)	15 (21.4)

Table 4.8

Patients' reports of medicine taking yesterday as compared with instructions on the label (numbers are those giving correct answers [percentages are shown in brackets])

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Taken as directed	168 (76.7)	63 (63.6)	111 (91.0)	86 (87.8)	39 (60.9)	59 (60.2)
Dose reduced	30 (13.7)	19 (19.2)	1 (0.8)	4 (4.1)	10 (15.6)	15 (15.3)
Dose increased	3 (1.4)	2 (2.0)	6 (4.9)	4 (4.1)	12 (18.8)	14 (14.3)
Spacing of doses error	3 (1.4)	1 (1.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Regimen totally altered	5 (2.3)	8 (8.1)	0 (0.0)	2 (2.0)	0 (0.0)	0 (0.0)
Unable to remember	10 (4.6)	6 (6.1)	3 (2.5)	2 (2.0)	3 (4.7)	10 (10.2)

Questions were answered by 93-100% of respondents. Missing values were excluded from the percentages.

with the directions checked by the interviewer on the medicine label. This proportion was higher for ß-adrenoceptor antagonists with agreement in 90% of interviews, but lower amongst the bronchodilator users (60% agreement). About 15% of NSAID takers and bronchodilator users described a regimen which suggested that fewer than the prescribed number of doses were consumed during the previous day. Less than 2% of NSAID takers described regimens where more than the advised dose had been taken. This percentage was higher amongst the bronchodilator users, with nearly one fifth reporting regimens which exceeded the prescribed dose.

Did patients know if their medicine taking regimens were correct?

Four out of every five patients were sure they were following the dosage instructions for their medicine completely (table 4.9). Amongst those where discrepancies between the dose they were taking and the dosage advised on the label were discovered, only 28 (30.1%) were under the impression that they were following the dosage regimen correctly. The remainder were aware they were not using their medicine exactly in the way the doctor had advised. There was no evidence their behaviour had been influenced by receiving a leaflet.

Stopping the medicine

The number of patients who had stopped their medicine by the time of their interview is shown in table 4.10. Almost all (94.1%) of the patients prescribed ß-adrenoceptor antagonists were still taking their medicine at the time of interview and 145 (89.5%) of bronchodilator patients were still using their inhalers. There was no evidence that receipt of a leaflet influenced whether treatment was discontinued for these two medicines. However, around a third of patients prescribed NSAIDs had stopped their tablets by the time of interview, and a larger proportion of those who stopped had received a leaflet (77 (35.2%) cf 28 (28.6%), $X^2_1=1.05$, p=0.31). Of the patients who received an NSAID leaflet and discontinued the treatment, 21 patients said they had taken the prescribed amount, 17 stopped because they felt better and 10 felt the

Table 4.9

Patients' self reported compliance (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Following the dosage instructions						
Completely	176 (80.4)	79 (80.6)	117 (95.9)	86 (87.8)	47 (73.4)	67 (68.4)
Mostly	32 (14.6)	10 (10.2)	5 (4.1)	8 (8.2)	14 (21.9)	22 (22.4)
Not at all	10 (4.6)	7 (7.1)	0 (0.0)	3 (3.1)	2 (3.1)	8 (8.2)
Uncertain	1 (0.5)	2 (2.0)	0 (0.0)	1 (1.0)	1 (1.6)	1 (1.0)

Missing values were excluded from the percentages

Table 4.10

Number of patients who had stopped or did not start taking their medicine (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Stopped the medicine	77 (35.2)	28 (28.6)	6 (4.9)	7 (7.1)	8 (12.5)	9 (9.2)
Not starting the medicine	13 (5.6)	2 (2.0) *	0 (0.0)	2 (2.0)	1 (1.5)	2 (2.0)

* $p<0.05$ Missing values were excluded from the percentages

medicine was not working whereas six patients were unsure why they had discontinued treatment. Twenty-three patients claimed to have stopped their medicine because they were worried about the possibility of side-effects listed on the leaflet. Figure 4.11 shows the preparations prescribed for these patients together with the reported indications for treatment. There was little evidence of inappropriate prescription and a range of different preparations were involved. The patients who stopped their tablets because of anxiety about side effects were not found to differ significantly from the rest of the respondents in terms of age, sex and social class distribution. However, 20 of the 23 had no previous experience of the medicine prescribed.

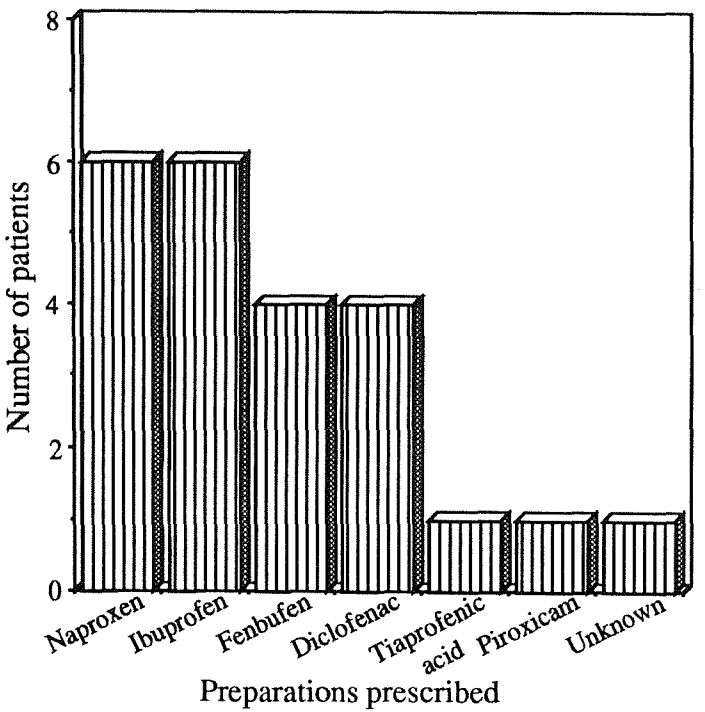
A patient who stopped her treatment concluded that, "...the tablets did help relieve pain but could cause other health problems which seem pointless. So I stopped them. I don't think tablets should be dispensed without total honesty about how serious the side-effects can be." Another patient commented, "I didn't believe these tablets (indomethacin) would give me side-effects when I took them. I went to see my doctor because I was waking up every morning with a really bad headache. He told me to stop the pills straight away." Neither of these patients received a leaflet.

Not starting the medicine

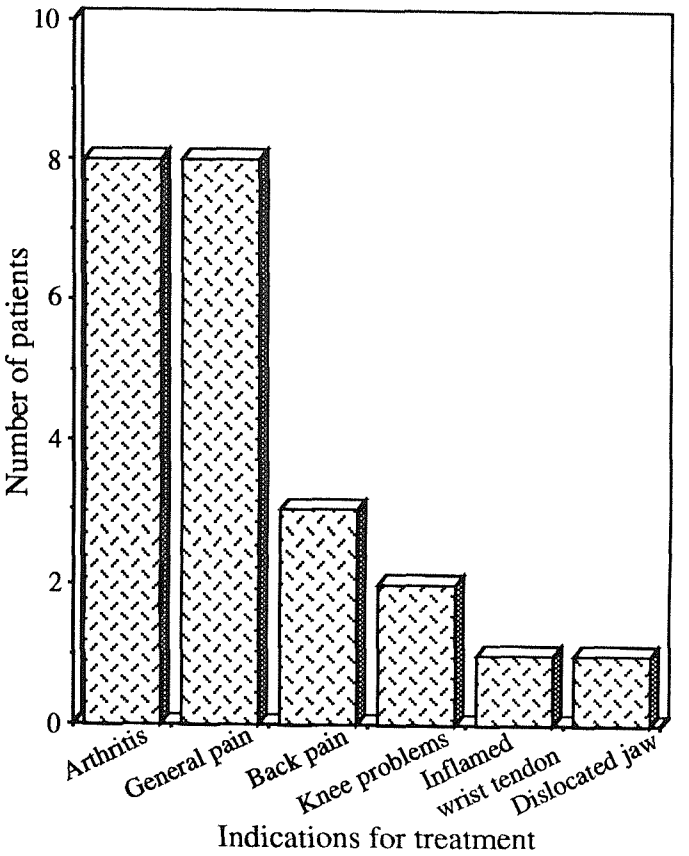
The number of patients who had not started their medicine by the time of their interview is shown also in table 4.10. Overall, 20 patients interviewed did not start their medicine at all. Fifteen of them had been prescribed NSAIDs, of whom 13 had received a leaflet ($X^2_1=1.35$, $p=0.25$). The leaflet was given as a major reason for deciding against taking the medicine by seven patients. Five of these decided their problems (arthritis, earache, hip pain, neck and shoulder pain, and "rheumatism" and backache) were not serious enough to risk the side-effects listed. "I'd prefer to see if it cleared up on its own rather than take the risk" was one comment and another patient "decided it wasn't worth taking the risk. I can put up with my backache (and I have stomach trouble anyway)".

Figure 4.11
Patients who stopped treatment with NSAIDs because of side effects listed on the leaflet

(a) Preparations prescribed



(b) Indications for treatment



The remaining two patients said they were frightened by the leaflet. One who suffered with arthritis thought the leaflet meant the drug was new, whereas the other, who had a frozen shoulder, was "scared because other medicines often give me side-effects". None of the people who gave the leaflet as the reason for not starting their medicine had ever taken these tablets before and only one person knew of someone who had experienced problems whilst taking the tablets in question. The ages of the seven ranged from 37 to 78 years, six of them were female and they all came from the non-manual social classes. Two of these patients did not collect their prescriptions from the pharmacy, one took the tablets back to the doctor but the remainder had kept their tablets.

The following comment from one patient illustrates how she came to her decision not to take the NSAID which had been prescribed.

"I did not take any of them (Fenbufen) and returned them to the chemist. I read the leaflet and had adequate discussion about them with my doctor, chemist and even my hospital consultant, whom I still see, and they all assured me they were very good. But having had years of digestive upset and now having an ileostomy, I was very reluctant to try **anything** that may upset me in any way. In the end, my doctor prescribed the well tried Brufen".

4.37 Patients' Satisfaction

Satisfaction with information received about the medicine

Highly significant improvements were found in the level of satisfaction with information received amongst recipients given leaflets (Table 4.11). These improvements were clear despite the high levels of satisfaction recorded across the board for all three medicines. Patients taking NSAIDs who received leaflets were more satisfied with the information they received than those who did not (X^2_1 test for trend=45.11, $p<0.001$). The same was true for ß-adrenoceptor antagonist takers (X^2_1 test for trend=34.27, $p<0.001$). This trend in favour of

Table 4.11

Patients' satisfaction with information received **(percentages are shown in brackets)**

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Satisfaction with information						
Completely satisfied	171 (73.7)	35 (35.0)	91 (74.6)	36 (36.0)	32 (49.2)	29 (29.0)
Satisfied	51 (22.0)	43 (43.0)	28 (23.0)	47 (47.0)	28 (43.1)	45 (45.0)
Indifferent	5 (2.2)	8 (8.0)	3 (2.5)	3 (3.0)	1 (1.5)	11 (11.0)
Dissatisfied	0 (0.0)	8 (8.0)	0 (0.0)	7 (7.0)	1 (1.5)	12 (12.0)
Completely dissatisfied	0 (0.0)	0 (0.0) ***	0 (0.0)	5 (5.0) ***	0 (0.0)	0 (0.0) **
Don't know	3 (1.3)	6 (6.0)	0 (0.0)	2 (2.0)	3 (4.6)	3 (3.0)

** p<0.01, *** p<0.001
Questions were answered by 100% of the respondents

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

the leaflets was apparent also for bronchodilators (X^2_1 test for trend=13.86, $p<0.01$), but the overall level of satisfaction was lower than that reported for the other two types of medicine.

The main difference between the patients who received leaflets and the control groups who did not was in the number of patients claiming to be completely satisfied with the information they received about their medicine. Three-quarters of the NSAID and ß-adrenoceptor antagonist takers who received leaflets were completely satisfied compared with only 35% in the control groups. Nearly half of the bronchodilator users were completely satisfied if they received a leaflet compared with less than one third of users who did not get one.

Satisfaction with information received about the illness

Slightly more patients who received leaflets about NSAIDs or ß-adrenoceptor antagonists felt they had been given all of or some of the information they wanted about their illness (for NSAIDs $X^2_2=4.55$, $p=0.10$; for ß-adrenoceptor antagonists, $X^2_2=6.19$, $p<0.05$ (Table 4.12)).

Satisfaction with the medicine

The leaflets giving information about ß-adrenoceptor antagonists and bronchodilators were associated with improvements in satisfaction with the medicine itself (Table 4.13). This trend reached statistical significance for ß-adrenoceptor antagonists (X^2_1 test for trend=5.63, $p<0.05$). Overall four out of every five patients taking ß-adrenoceptor antagonists or using bronchodilators were either satisfied or completely satisfied with the medicine they had been prescribed. However, only two thirds of NSAID takers reported this level of satisfaction with their medicine. Further, 58 (25%) patients who received leaflets about NSAIDs expressed some dissatisfaction with their medicine compared with only 14 (14%) of the control group (X^2_1 test for trend=3.74, $p=0.06$). Amongst those who gave reasons for their dissatisfaction, over half (39) felt their medicine was not working. Twenty-four patients were concerned about side-effects and

Table 4.12

Information received about illness (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Information received about illness						
All of	179 (78.5)	73 (74.5)	96 (79.3)	73 (73.0)	46 (71.9)	58 (59.2)
Some of	38 (16.7)	14 (14.3)	21 (17.4)	15 (15.0)	12 (18.8)	29 (29.6)
None of	11 (4.8)	11 (11.2)	4 (3.3)	12 (12.0) *	6 (9.4)	11 (11.2)

* $p<0.05$ The table shows the responses to the question, 'Did you get all of, some of, or none of the information you wanted about your illness?' Missing values were excluded from the percentages

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

Table 4.13

Patients' satisfaction with the medicine itself (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Satisfaction with the medicine						
Completely satisfied	49 (21.1)	27 (27.0)	49 (40.2)	29 (29.0)	31 (47.7)	34 (34.0)
Satisfied	89 (38.4)	45 (45.0)	61 (50.0)	48 (48.0)	21 (32.3)	48 (48.0)
Indifferent	27 (11.6)	11 (11.0)	6 (4.9)	8 (8.0)	4 (6.2)	5 (5.0)
Dissatisfied	47 (20.3)	8 (8.0)	3 (2.5)	6 (6.0)	2 (3.1)	8 (8.0)
Completely dissatisfied	11 (4.7)	6 (6.0)	2 (1.6)	4 (4.0) *	2 (3.1)	1 (1.0)
Don't know	9 (3.9)	3 (3.0)	1 (0.08)	5 (5.0)	5 (7.7)	4 (4.0)

* $p<0.05$ Questions were answered by 100% of the respondents

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

four patients felt the medicine was unnecessary. Few patients were dissatisfied with the ß-adrenoceptor antagonists or bronchodilators they had been prescribed.

Satisfaction with the consultation

The majority of patients interviewed were very satisfied with their most recent consultation. Nine out of every ten patients were either satisfied or completely satisfied (table 4.14). There was little evidence to suggest higher levels of satisfaction amongst those who received leaflets.

Few patients taking ß-adrenoceptor antagonists or bronchodilators expressed any dissatisfaction with their most recent consultation but 25 patients prescribed NSAIDs were dissatisfied. The nature of the complaints made by patients who received leaflets were significantly different from those made by those in the control group. The comments were coded into three broad areas (1) dissatisfaction with the doctors behaviour (eg not enough information provided); (2) dissatisfaction with the doctors technical competence and, (3) dissatisfaction with administrative issues (eg waiting time at the surgery, availability of the doctor etc). Two-thirds of those who were dissatisfied and did not receive a leaflet were critical of the behaviour of their general practitioners. Amongst those given leaflets, the technical competence of the doctor was more often questioned (Over half (56.3%) of those dissatisfied in this group mentioned this issue) (X^2_3=8.80, $p<0.05$).

Satisfaction scale

Satisfaction with the most recent consultation was measured on a 14 item attitude scale (Oppenheim 1966; Moser and Kalton 1981). The scale had a Likert format : Patients' were asked to give a response to each item, selected from "strongly agree", "agree", "uncertain", "disagree" and "strongly disagree". Positive items were scored from 5 to 1 for "strongly agree" to "strongly disagree", whereas negative items were scored from 1 for "strongly agree" to 5 for "strongly disagree" (Oppenheim 1966). A total score was calculated as the sum of the tab

Table 4.14

Patients' overall satisfaction with their most recent general practitioner consultation
(percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists		Bronchodilators	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Satisfaction with the consultation						
Completely satisfied	116 (50.0)	55 (55.0)	78 (63.9)	59 (59.0)	40 (61.5)	42 (42.0)
Satisfied	96 (41.4)	35 (35.0)	42 (34.4)	34 (34.0)	19 (29.2)	42 (42.0)
Indifferent	4 (1.7)	1 (1.0)	0 (0.0)	0 (0.0)	1 (1.5)	4 (4.0)
Dissatisfied	13 (5.6)	9 (9.0)	1 (0.8)	5 (5.0)	4 (6.2)	10 (10.0)
Completely dissatisfied	3 (1.3)	0 (0.0)	1 (0.8)	2 (2.0)	0 (0.0)	1 (1.0)
Don't know	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.0)

Questions were answered by 100% of the respondents

score for each item.

There were no significant differences in satisfaction with the most recent consultation (as measured on the 14 item attitude scale) between patients who received leaflets about NSAIDs or ß-adrenoceptor antagonists and those who did not ($T=0.01$ and $T=1.49$ respectively). However, the mean satisfaction score obtained for bronchodilator users in the control group (32.6, SD 6.53) was significantly higher than that recorded amongst those who received leaflets (28.6 SD 6.77) ($T=3.36$, $p<0.001$). Factor analysis of the responses to the satisfaction scale suggested that overall satisfaction with the consultation could be broken down into four main factors:

(1) **satisfaction with the doctor** (Items on the scale which contributed to this factor were "The doctor seemed to really understand my problem"; "The consultation with the doctor seemed rushed"; "The doctor seemed too busy to listen to my problem"; and "The doctor I saw last time seemed thorough and competent")

(2) **convenience** ("Taking this medicine is often very inconvenient"; "Far too much time was spent waiting to see the doctor at the surgery"; "The receptionists were courteous and helpful"; "It was difficult to get to see my usual doctor"; "It was easy to make an appointment at the time I wanted")

(3) **information received** ("I'm anxious about possible side-effects with this medicine"; "All my questions about my medicine were answered"; "I would like some more information about my medicine")

(4) **the medicine** ("The medicine I've been given seems to be just right for my problem"; "I expected the doctor to prescribe this type of medicine for me")

Mean satisfaction scores were calculated for each factor for patients who received leaflets and others who did not. These are shown in table 4.15.

4.38 The influence of sex, age and social class on the effects of the leaflets

With the exception of awareness that NSAIDs should be taken with meals an

Table 4.15

Patients' satisfaction with specific aspects of their most recent general practitioner consultation : Mean satisfaction scores (standard deviations are shown in brackets)

Medicine	NSAIDS				ß-adrenoceptor antagonists				Bronchodilators			
Leaflet	Yes		No		Yes		No		Yes		No	
Total number	232		100		122		100		65		100	
Satisfaction with specific aspects of the consultation												
Factor 1 : Doctors' behaviour	6.60	(1.95)	6.72	(2.29)	6.43	(2.00)	7.17 *	(2.95)	7.03	(2.43)	7.64	(2.70)
Factor 2 : Convenience	10.71	(5.36)	10.31	(4.52)	9.92	(5.25)	9.98	(3.68)	10.02	(3.67)	12.91 ***	(6.12)
Factor 3 : Information provision	7.26	(2.37)	7.86	(2.56)	6.95	(2.16)	8.20 **	(2.99)	7.12	(2.44)	8.69 ***	(2.61)
Factor 4 : The medicine	5.72	(1.76)	5.16 *	(1.82)	4.50	(1.54)	4.29	(1.78)	4.30	(1.53)	4.47	(1.68)

*** p<0.001, ** p<0.01, * p<0.05 . Questions were answered by between 68-86% of respondents. Missing values were excluded. Factor 1 had a range of between 1-20, factor 2 between 1-25, factor 3 between 1-15, and factor 4 ranged from 1-10. A low mean score is suggestive of a high level of satisfaction.

item which significantly more women than men were aware of irrespective of whether or not they received a leaflet), the demographic characteristics of the patients did not appear to confound the results of thus study. Significant improvements in the knowledge and satisfaction items tested were associated with the leaflets regardless of a patients' sex, age and social class. These findings are summarised in table 4.16.

4.39 The leaflets

Not all patients who should have received a leaflet in this study remembered receiving one. Altogether 202 (87%) NSAID takers remembered receiving a leaflet as did 108 (89%) of the ß-adrenoceptor antagonist takers. However, only 39 of the patients using bronchodilators (60%) claimed to have received a leaflet.

Three hundred and forty of the 349 patients who remembered receiving a leaflet said they had read it (Table 4.17). However, the three leaflets were used in different ways. Of those who read a leaflet, nine out of ten NSAID and ß-adrenoceptor antagonist takers claimed to have read it all the way through, but only just over three-quarters of those receiving the leaflet on bronchodilators had read it thoroughly. Almost all the patients who read a leaflet about NSAIDs read it before they took any of the tablets. Slightly fewer patients (85%) read the leaflet for ß-adrenoceptor antagonists before they took any tablets, but 27% of those who remembered reading the leaflet about bronchodilators had only referred to it after they had started using the inhaler. Furthermore, 154 (76.2%) NSAID and 89 (82.4%) ß-adrenoceptor antagonist patients said they had kept their leaflet, whereas only 26 (66.7%) bronchodilator takers claimed to have kept it.

Patients reaction to leaflets

Five hundred and seventy-eight patients (80%) thought it would be a good idea to be given a leaflet with their medicine, whether or not they received one in

Table 4.16

Summary of the effects of demographic group on knowledge and satisfaction

Factor	Leaflet (Yes)	Sex (Female)	Age (55+)	Social class (non-manual)	Model X^2	Model df
NSAIDS						
Correct dosage	2.17 *	2.19	2.14	2.15	294	(296)
Medicine and meals	1.82 *	1.15	2.51	1.27	349	(294)
Side effects	4.28 ***	4.35	2.85	4.10	356	(294)
Satisfaction	6.68 ***	4.87	4.88	6.53	347	(294)
ß-adrenoceptor antagonists						
Correct dosage	2.90 *	4.72	0.82	1.11	75	(195)
Side effects	2.51 *	5.17	2.99	2.04	189	(197)
Satisfaction	4.92 ***	4.37	5.03	2.74	235	(197)
Bronchodilators						
Correct dosage	2.52 *	4.10	0.93	3.98	168	(137)
Side effects	3.20 **	4.04	8.02	6.91	141	(140)
Satisfaction	3.16 **	2.65	2.50	2.80	180	(140)

* $p<0.05$, ** $p<0.01$, *** $p<0.001$

All figures are for the odds ratio which is quoted relative to the factor given. An odds ratio >1 implies a positive association between the factor and outcome, whereas an odds ratio <1 implies an association in the other direction. If the odds ratio is zero there is no association. Odds ratios are quoted for receiving a leaflet relative to no leaflet, for females relative to males, for the 55+ age group relative to the <55 age group and for the non-manual class relative to the manual class.

Table 4.17

Patients' use of, and opinions about, leaflets **(percentages are shown in brackets)**

Medicine	NSAIDS	ß-adrenoceptor antagonists	Bronchodilators
Total number	232	122	65
Remembered receiving leaflet	202 (87.1)	108 (88.5)	39 (60.0)
Read leaflet	197 (97.5)	106 (98.2)	37 (94.9)
Kept leaflet	154 (76.2)	89 (82.4)	26 (66.7)
Found leaflet helpful	178 (90.4)	96 (90.6)	26 (70.3)
Found leaflet worrying	55 (27.9)	14 (13.2)	4 (10.8)
Opinion about providing leaflets			
(i) Good idea	204 (87.9)	101 (82.8)	58 (89.2)
(ii) Bad idea	12 (5.2)	11 (9.0)	5 (7.7)
(iii) Unsure	16 (6.9)	10 (8.2)	2 (3.1)

Missing values were excluded from the percentages

this study. Of those who read a leaflet about NSAIDs or ß-adrenoceptor antagonists, 274 (91%) said they found it helpful. Indeed, 120 (44%) of these patients claimed the leaflet had been very helpful. One of these patients made the following comment:

"I had a blood pressure check with my doctor. It was then he gave me the leaflet about ß-blockers. Previously he had been very upset with me because I just stopped taking Atenolol. I now know this was a dangerous thing to do."

However, only five patients (14%) rated the leaflet about bronchodilators as very helpful and ten (27%) said it had not been at all helpful to them. "I received a leaflet, read it and threw it away. If there's any information I require I ask the doctor".

Of those who read a leaflet, 10.8% of bronchodilator patients and 13.2% of the ß-adrenoceptor antagonist takers found it "worrying". The number of patients worried by the NSAID leaflet was higher, with 55 patients (27.9%) who read it claiming it caused them anxiety about their treatment. Forty-one of these patients said they were worried about the side-effects listed on the leaflet. Patients who found this leaflet worrying were not significantly different in age, sex or social class from those who were not worried by the leaflet. However, there was a tendency for the leaflet to cause concern more often amongst patients who had no previous experience of the medicine ($X^2_1=1.13$, $p=0.29$).

4.4 DISCUSSION

The advantages and disadvantages of the design of the study and the implications are discussed in chapter 8.

Although the medicines chosen for this part of the study are all commonly prescribed in general practice, there are differences in their prescription rates. This was reflected in the relative ease of recruitment of patients taking the three medicines during the survey period. Whilst adequate numbers of patients on NSAIDs and ß-adrenoceptor antagonists were recruited in both the leaflet and the control towns, the target of 100 bronchodilator users was not reached in the leaflet towns. This may have been due in part to many prescriptions for inhalers being issued on a repeat basis, without a visit to the doctor. But the recruitment of patients for all three medicines was poor in the towns where leaflets were issued by general practitioners. Possible reasons for this are discussed in chapter 7.

The survey elicited a good response from patients with four out of every five recruited agreeing to be interviewed. The response rate was better than that reported by Ridout, Waters and George whose investigation of knowledge and attitudes to medicines in the Southampton community achieved a 60% response (Ridout et al 1986). This may be due in part to the collection of data in the present study by personal interview, a procedure which often produces a better response than a postal questionnaire (Oppenheim 1966; Moser and Kalton 1981). In addition, the involvement of patients, all of who had recently received a prescribed medicine, might have boosted the response. It has been noted also that general practitioner recruitment in surveys can improve response rates (Smith et al 1985). Whereas for NSAIDs takers and bronchodilators users, there were no significant differences in the response rates between those recruited in the leaflet and control towns, a better response from ß-adrenoceptor antagonist takers was elicited in the leaflet towns. Because of this, selection bias in favour

of "co-operative patients" cannot be ruled out in this group. The existence, extent and implications of this possible source of bias are discussed in chapter 7.

The excess of women and those over 65 years in the sample was expected, since both groups consult their general practitioners more often and are prescribed more medicines than others in the general population (Dunnell and Cartwright 1972; Ridout et al 1986; Svarstad et al 1987; Cartwright and Smith 1988). The likelihood that a sample drawn from residents of small, rural Hampshire towns would be biased in favour of the non-manual social classes was also recognised, but the class distribution of the respondents was found to be representative of that for south-east England (Office of Population Censuses and Surveys 1981). No significant differences in the demographic characteristics were found between patients who received a leaflet about ß-adrenoceptor antagonists and others who did not, but there were some differences between patients who received leaflets about NSAIDs or bronchodilators and the control groups who were not given any written information. Patients prescribed bronchodilators were significantly younger in the control town than those who received leaflets. An above average rate of childhood asthma is suspected in the control town (Charlton et al 1983; Burney 1987). A tendency for patients who received leaflets about NSAIDs, particularly from their general practitioners, to be drawn from the "upper" social classes was also detected. An excess of patients drawn from social class III (non-manual and manual combined) and a deficiency of those drawn from social classes IV and V was found amongst those who received leaflets about NSAIDs. Since written information may have been more effective amongst well educated patients (Gatherer et al 1979), it is possible that the effects of the NSAID leaflet have been overestimated in this study. However, this is unlikely because trends in favour of the leaflets were still apparent when comparisons were made within each sex, age and social class group. In addition, there was no evidence that patients who read their leaflet were more likely to be female rather than male, to be any particular age or to come from a particular social class group. The overall effectiveness of the leaflet about NSAIDs may have been enhanced

however, because only a small proportion of the patients prescribed NSAIDs had received their medicine previously (compared with the other two medicines). Although it might have been better to limit the interviews to patients who were new to the medicine, this was not done for two reasons. Firstly, it was necessary to include patients who were already taking the medicines in order to recruit an adequate number of patients during the 10 week survey period and secondly, it is likely that both continuing and new patients will receive leaflets if they are to be introduced.

Improvements in patients' knowledge about their medicines were recorded amongst those who received leaflets. All three leaflets were associated with a greater awareness of how to use the medicine correctly, a finding supported by studies conducted in the USA (Morris and Halperin 1979; Gotsch and Liguori 1982; Wiederholt and Kotzan 1983) and pilot studies conducted in the UK (George et al 1983; Gibbs et al 1987). The most marked improvement was the increased awareness of the side-effects amongst patients who received leaflets. However, despite this improvement, the number of patients who could name any side-effects of their medicine remained low at around 30%. It is possible that although patients may read and consider the side-effects of their medicine when they receive a leaflet, these items may not be retained in memory, particularly if a course of treatment remains problem free. Evidence that leaflets were kept by many of the patients suggests that a ready source of reference would be available to enable identification of suspected side-effects should they occur.

For some items, knowledge was found to be high whether or not a leaflet was received. Almost all patients interviewed were aware of the purpose for which the medicine was prescribed, a finding which is in agreement with those studies which have shown that patients remember diagnostic information given in verbal consultations (Ley and Spelman 1965; Ley et al 1976b; Tuckett et al 1985). Awareness of the dosage instructions was also high. Despite this, more patients who received leaflets knew when to take their medicines. This suggests that the

leaflets, which did not contain advice about dosage, successfully drew patients attention to the instructions printed on the medicine bottle itself.

The only item of knowledge found not to be improved by the leaflets was the name of the medicine. This finding was in contrast to previous improvements associated with leaflets about penicillins and NSAIDs (George et al 1983). The lack of influence in the present studies may be because the leaflets distributed were of a "generic" nature and as such gave information about the group of medicines rather than the specific product prescribed. Although space was left for the product name to be inserted by the doctor or pharmacist, it is likely that this was not filled in on every occasion. Evidence that product specific leaflets might be more effective comes from the widespread ability of the patients prescribed bronchodilators to name their inhaler. Most bronchodilators come with a manufacturers instruction leaflet in the box with the inhaler.

There was little evidence from the present study that information about side-effects encourages people to imagine those side-effects. Patients who received leaflets actually reported experiencing fewer of the listed side-effects than did the controls who were given no additional information. There was also no evidence of an increase in general health problems amongst those who received leaflets. These results confirm the findings of earlier studies (Myers and Calvert 1976,1984; George et al 1983).

Amongst NSAID takers who reported any of the symptoms listed as side-effects, those who received leaflets were more likely to identify their problems as potential adverse reactions to their medicine than the patients in the control group. Whilst heightened recognition of side-effects may enable patients to take appropriate action swiftly to minimise their risk of harm, the number of patients who experienced a potential side-effect and who followed the advice given on the leaflets (to stop the medicine or tell the doctor) was too small to draw any conclusions from the present study.

Although some of the problems reported were clearly connected with the treatment, for example the stomach discomfort reported by over a quarter of NSAID takers, the majority of symptoms were of a general nature, unlikely to be caused by the medicine. But the apparent tendency for unrelated problems to be connected with the medicine by patients who received leaflets points to an enhanced sensitivity amongst patients who received leaflets. This finding, which has been reported by others (Morris and Gagliardi 1977; Morris and Kanouse 1982) suggests that informed patients may pay more attention to any symptoms experienced whilst taking their medicines.

The widespread awareness that medicines should be kept out of reach of children may be connected with the increased use of warnings on medicine bottles (the warning "Keep out of reach of children" is a legal requirement on all dispensed medicines) (British National Formulary 1988). Despite this, tablets were not stored out of reach in about half of the homes visited. In most cases, the patients did not perceive their tablets as a safety risk because no small children lived in, or regularly visited, the household. NSAIDs and ß-adrenoceptor antagonists were most frequently kept in the kitchen where they were visible and therefore not forgotten. Inhalers were usually carried about the person in case of need. The high levels of awareness of what to do with unused medicines was in contrast with that recorded for NSAIDs in a previous study (George et al 1983). It is possible that this apparently recent improvement in public awareness may in part be due to recent "DUMP" campaigns run in community pharmacies to encourage the return of unused medicines for disposal (Anonymous 1978a). Although there was little difference in awareness of correct methods of disposal of medicines between those who received leaflets and others who did not, the finding that some patients who received leaflets claimed to be discouraged from hoarding old medicines is encouraging.

In contrast to the improvements in knowledge about medicines amongst patients who received leaflets, there was little change in medicine taking behaviour. As

in previous studies, a wide range of compliance rates were obtained and most non-compliance consisted of patients taking less medicine than they had been prescribed (Sackett and Haynes 1976) . But for around one tenth of patients whose NSAIDs or ß-adrenoceptor antagonist tablets were counted, overconsumption of medicine was suspected. Moreover, one in five bronchodilator users claimed to exceed the recommended dose regularly. In the light of reports of sudden death and collapse from overdose of bronchodilators (Conolly et al 1973), this practice is cause for concern.

The measurement of patient compliance used in this study may, however, be inadequate for several reasons. Firstly, the tablet count itself is widely recognised to be an unreliable measure of compliance which obscures the true pattern of medicine taking behaviour (Gordis et al 1969). Secondly, since tablet counts could only be conducted when the patients made their medicines available to the interviewers (in two-thirds of the interviews with people prescribed NSAIDs or ß-adrenoceptor antagonists), and since there were problems obtaining a valid start date for the tablets in many instances, the true pattern of compliance might be further obscured. Thirdly, although there is some evidence that patients own accounts of their medicine taking behaviour can be as reliable as tablet counts (Gordis 1979) this was not substantiated by this study or by others (Morgan and Watkins 1988). Patients frequently claimed to take their tablets regularly but only about half were classified as "compliant" from the tablet counts. Finally, even when a valid measure of compliance was obtained the definition of what constitutes "good compliance" remains arbitrary one. Administration of the tablets in the exact manner prescribed may not always be necessary to obtain the desired clinical effect (Burley and Inman 1988).

Despite these difficulties it would seem that, for NSAIDs and ß-adrenoceptor antagonists, patients were only slightly more likely to comply with medicine taking instructions if they received a leaflet. This is in contrast to the improved compliance reported in association with leaflets for short-term antibiotic therapy

(George et al 1983; Dodds 1986), but in agreement with studies of leaflets provided with long term treatment for hypertension (Sackett et al 1975) or warfarin therapy (Clark and Bayley 1972). Although many patients with long-term illnesses would welcome additional written information, and would obtain benefit in terms of improved awareness of their treatment, receiving a leaflet does not appear to improve compliance. Indeed, ignorance was clearly not the only reason for non-compliance in the present study. Two-thirds of the patients who, on their own admission, did not take their medicine as directed by their doctor had chosen not to do so. Many factors have been found to influence patient compliance and it cannot be assumed that all patients will behave in the same way (Haynes et al 1979). An information leaflet can be seen as just one of many influences on medicine taking when this is a central part of everyday life (Becker and Maiman 1975; Stimson and Webb 1975; Mechanic 1978; Conrad 1985; Calnan 1987).

The finding that more NSAID takers decided to stop their medicine prematurely if they received a leaflet, (especially those who had never had this treatment before) reflected their concern that the treatment may be unnecessary, or not worth taking the risk. Reservations about overprescription and inappropriate prescription of NSAIDs have been expressed recently within the medical profession (eg Steele et al 1987) and by the media.

Significant improvements in satisfaction with the information received were recorded amongst those who received leaflets. This was despite very high overall levels of patients' satisfaction being recorded, as has often been found to be the case in general practice surveys (Cartwright and Anderson 1981). However, the improved levels of satisfaction were not accompanied by changes in medicine taking behaviour despite there being evidence from several studies that satisfied patients are more likely to comply (Davis 1968; Korsch et al 1968; Waitzkin and Stoeckle 1972; Stimson 1974; Becker and Maiman 1975; Kincey et al 1975; Hayes-Bautista 1976; Hulka et al 1976; Larsen and Rootman 1976; Ley 1982).

One possible explanation for this concerns the nature of satisfaction itself. In contrast to the substantial improvements in satisfaction with information amongst those who received leaflets, the situation for satisfaction with the medicine, information received about the illness and satisfaction with the consultation was less clear cut.

Global measures of patient satisfaction have, however, been criticised for their insensitivity because respondents frequently reply in a stereotyped socially acceptable manner and only infrequently express negative attitudes (Oppenheim 1966). By contrast, the satisfaction scale is likely to be more sensitive to actual differences in satisfaction than measures of general attitudes (Stiles et al 1978). Since patients continually reappraise their consultations and symptoms (Stimson and Webb 1975; Locker and Dunt 1978), their views at a particular point in time were uncovered by referring in the interviews to a specific consultation. Moreover, by investigating the different facets known to influence satisfaction using a series of statements, the scale enabled a more comprehensive picture of opinion to be developed.

Patients who received leaflets were not more satisfied with their most recent consultation (as measured by the 14 item satisfaction scale) than those who received no written information. However, the findings that those who received leaflets appeared more favourably disposed towards their doctor but were more ready to criticise the medicine they had received, offer support for the results obtained by the global assessments of satisfaction. But the satisfaction scale, in common with other scales used to measure attitude, remains only a crude instrument for several reasons. Firstly, although use of an existing scale (Wolf et al 1978) increases the validity and reliability of the measure, the modifications have not been tested. As it stands, the scale can be said to have "face validity" and "content validity" since the central attitudinal dimensions known to influence satisfaction with care (the doctors behaviour, his or her professional competence and the availability and convenience of care) (Hulka et al 1970; Ware and

Snyder 1975; Dimatteo and DiNicola 1982) are covered. However, as yet, there appears to be no absolute way to measure validity (Oppenheim 1966). Secondly, Likert scales have been criticised for their lack of reproducibility, since the same total score can be obtained in many different ways. Moreover, the assumption that each of the items making up the composite score is of equal importance to the patient may be invalid. Finally, the scale itself rests on the assumption that positive attitudes are a legitimate indicator of satisfaction with care which, although it seems likely, is disputable. It may be that greater improvements in patients' satisfaction with the communication exchange between doctor and patient may be needed, particularly before any changes in medicine taking behaviour follow for medicines prescribed on a long-term basis. Support for this suggestion comes from several studies which have found that it is only in combination with verbal counselling that the best effects of written information can be realised (Richards 1975; Gatherer et al 1979; Mullen and Green 1984).

The level of satisfaction with the information received about the medicine was found to be lowest amongst patients prescribed bronchodilators. Three explanations for this seem possible. Firstly, the leaflet may be inadequate. In the present study, many patients requested information about the condition of asthma itself, an area not covered in the leaflet. This interest has been confirmed recently by Partridge (1986). Secondly, these patients already received a manufacturers leaflet with their medicine and this may have diminished the impact of further written information. Finally, the patients interviewed about bronchodilators were younger than for the other two groups of medicines. The young have been found to expect more from health care than older people (Cartwright and Anderson 1981; Fitzpatrick et al 1984).

An important finding was that the effects of the leaflets on knowledge and satisfaction were not confounded by sex, age or social class. Although there were differences in the level of knowledge recorded amongst the under 55 and the 55 and over age groups, there was little evidence from the logit analysis that

older patients did not benefit from receiving leaflets, as has sometimes been suggested (Dodds and King 1989). In addition, leaflets were associated with improvements in satisfaction within each age group, and the belief that younger people tend to be more dissatisfied in general was not confirmed (Cartwright and Anderson 1981; Fitzpatrick et al 1984).

There was no evidence that patients from the manual social classes failed to benefit from receiving the leaflets, despite reservations about the usefulness of written communication amongst the less well educated (Gatherer et al 1979). The finding that knowledge levels were generally lower in this group of patients confirms the need for more information to be supplied to them as well as to those from the non-manual classes. Furthermore, the benefits of leaflets were not confined to newcomers to the treatment, or to females who, despite the widespread view that women know more about health matters (Cartwright and Anderson 1988), did not know more about their medicines than the men in the present study.

However, the logit analysis may have been inadequate for three reasons. Firstly, small numbers limited the investigation of the very elderly, as well as testing higher order interactions (eg age x sex). It is possible that the lack of significant findings was due to the small numbers in each sub-group. Secondly, the analysis forced responses into dichotomous categories (eg correct/ incorrect; satisfied/ dissatisfied). Thirdly, it was only possible to examine a handful of knowledge and satisfaction outcomes. A larger study would be needed to explore these issues further.

Almost all patients who received a leaflet claimed to have read it. There was no evidence that sex, age, or social class influenced whether the leaflet was read. Although almost all patients liked the leaflets, and despite extensive pilot testing prior to the main study, several points about the ß-adrenoceptor antagonist leaflet were spontaneously raised by patients who received them. Seven patients

thought this leaflet should have included a warning to expect cold hands and feet, and three patients felt the possibility of impotence should have been discussed. In addition, there were several requests for clarification of why it might be bad to stop taking ß-adrenoceptor antagonists suddenly. One comment was typical "I'm addicted to this I suppose?" These points should be taken into account in the design of future leaflets which give information about ß-adrenoceptor antagonists.

Not everyone who should have been given a leaflet remembered receiving one. It is impossible to tell whether these people had simply forgotten about the leaflet or whether they had really not received one. Of slight concern is the finding that some patients (especially those prescribed NSAIDs for the first time) were alarmed by the side-effects listed on the leaflet. Although almost all patients in this study thought the introduction of leaflets would be a good idea (Fisher et al 1982), this finding highlights the need to expand the range of patients and leaflets evaluated.

CHAPTER 5

MAIN STUDY (II):
PENICILLINS, DIURETICS and BENZODIAZEPINES

CHAPTER 5

5.1 INTRODUCTION

In the previous chapter, prescription information leaflets giving information about non steroidal anti-inflammatory drugs (NSAIDs), ß-adrenoceptor antagonists and inhaled bronchodilators were evaluated. These leaflets were associated with improvements in patients' knowledge about their treatment. In particular, marked improvements in awareness of the side-effects were recorded without producing spurious side-effects by suggestion. Furthermore, although the leaflets did not appear to influence patients' compliance, substantial improvements in patients' satisfaction with the information they received were reported amongst those who were given leaflets.

This chapter extends the range of drug groups and conditions studied, by evaluating the effects of leaflets giving information about three further medicines: penicillins (frequently prescribed in general practice for short term acute infections), diuretics of the loop or benzothiazide type (which are commonly used to relieve oedema and to reduce blood pressure), and benzodiazepines (the minor tranquillisers). The effects of these leaflets on patients' knowledge, behaviour and satisfaction are evaluated when issued in general practice by community pharmacists. A leaflet giving information about penicillins was designed and tested in the pilot study. The leaflets about diuretics and benzodiazepines were developed in the same way as outlined in chapters 3 and 4.

5.2 METHODS

The study design was based on that described in chapter 4. The remaining two of the eight small Hampshire towns identified as suitable were selected for the

present study. Town G (population 10,068) was assigned to be the experimental town, where leaflets were issued by community pharmacists. The second town, Town H, (population 11,100) acted as a control town, where no leaflets were distributed. The survey ran for 10 weeks in each town. It was conducted between April and June 1987 in town G and in town H from August to October of the same year.

The survey procedure has been outlined in detail in chapter 4. As previously, patients who received a consultation prescription for a study drug during the survey period were included. Data on patients' knowledge about their medicine, medicine taking behaviour, satisfaction and opinions about information provision were collected by the two interviewers during structured interviews conducted in the patients' homes.

Data were analysed using the SPSS-X statistical package. Associations were tested using the Chi-squared statistic (with Yates correction for 2 x 2 tables). In addition, the GLIM statistical package (Baker and Nelder 1978) was used to apply logit modelling techniques (Cox 1970; Gilbert 1981) to investigate the effects of receiving a leaflet, sex, age, and social class on knowledge and satisfaction.

5.3 RESULTS

5.31 The leaflets

The leaflets are shown in figures 5.1-5.3

5.32 Sample Characteristics

Response from general practitioners and pharmacists

All the 19 general practitioners approached initially agreed to take part in the survey. However, one of the pharmacies in each town declined to participate because they were too busy at the time of the survey. In town G, the pharmacy concerned had only a very small proportion of the trade, but the non-cooperative pharmacy in town H was part of a large chain with an estimated 40% of the prescriptions issued by the local doctors filled there.

One of the two group general practices in town H withdrew from the survey at the end of week five. One of the doctors in this practice raised an objection to the questioning of his patients on their level of satisfaction with their general practitioner. After some discussion, the other members of the practice decided to support their colleague and stopped entering patients into the study.

Response from patients

The overall patient response rate to interview was 84% (Table 5.1). A total of 499 patients were interviewed, 252 in leaflet towns and 247 in the control town. One hundred and eighty-three patients had been prescribed a penicillin, 189 a diuretic and 127 a benzodiazepine. Of these, 83 penicillin takers, 99 patients prescribed diuretics and 70 patients prescribed benzodiazepines were given leaflets. The number of patients recruited in the control town H was lower than expected, particularly those taking benzodiazepines.

Figure 5.1

PIL giving information about Penicillins

What you should know about Penicillins.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____
This is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Things to remember about Penicillin.

1 **Do not take Penicillin** if you are allergic to it.

2 **Look at the label** on your Penicillin. It will tell you when to take it.

3 **Keep taking your Penicillin** until it is finished. **Don't stop** just because you feel better.

4 **Penicillin sometimes causes problems**
You can find these listed on the back of this leaflet. ✽

5 Keep your Penicillin **out of reach of children.**

You will find more about Penicillin on the back of this leaflet.

Your medicine is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Before taking your medicine

- Has anyone ever told you you are allergic to Penicillin? If so, tell your doctor or pharmacist. You can be given another medicine instead of Penicillin.

Taking your medicine

- You must take your medicine regularly. The label will tell you when to take your medicine. It will also tell you how much to take. *Ask your doctor or pharmacist if you are not sure.*
- This medicine works best swallowed with water when your stomach is empty. This is 1 hour before a meal or 2 hours after a meal. But sometimes your doctor will tell you to take it at other times.
- If the medicine is for a baby the best time to give it is between feeds.
- Shake liquid medicine before you take a dose.
- Keep taking your medicine until it is finished. Don't stop just because you feel better. The medicine may not have killed all the germs. If you stop too soon the infection may start up again.
- If you forget to take a dose take another as soon as you remember. Then go on as before.

✻ After taking your medicine

A few people can be upset by this medicine. They have frequent loose bowel motions or feel like being sick.
If you suffer from either of these very badly or you vomit the medicine tell your doctor.
Tell your doctor if you START suffering from any of the following:

- Rashes, itching, or any other skin trouble.
- Wheezing.
- Pain in your joints for the first time.

Tell your doctor about any other unusual problems as soon as you can.

Storing your medicine

- Keep liquid Penicillin in the refrigerator but **not** in the freezer compartment. Liquid Penicillin lasts only a few days even in the refrigerator. The label will tell you how long. Don't take the medicine after this date.
- Keep your medicine in a safe place where children cannot reach it. Your medicine could harm them.
- If your doctor decides to stop the treatment, return any left-over medicine to the pharmacist or flush it down the toilet. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Figure 5.2

PIL giving information about Diuretics

What you should know about Diuretics

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____

This is one in a group of medicines called Diuretics. Diuretics are "water tablets" which help your body get rid of excess water and salt. They bring down swollen ankles and improve shortness of breath. They also help reduce high blood pressure.

Things to remember about Diuretics

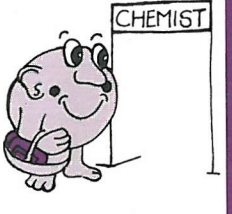
1 **Make sure it is safe for you** to take Diuretics *(see the back of this leaflet).*♦

2 **Look at the label** on your medicine. It will tell you when to take it.

3 **Diuretics sometimes cause problems.** You can find these listed on the back of this leaflet.*

4 Keep your medicine **out of reach of children.**

5 **Remember to return any unused Diuretics** to your pharmacist or flush them down the toilet.



You will find more about Diuretics on the back of this leaflet.

Your medicine is a Diuretic. Diuretics are "water tablets" which help your body get rid of excess water and salt. They bring down swollen ankles and improve shortness of breath. They also help reduce high blood pressure.

♦ Before taking your medicine

- Are you taking any of the following medicines:
  - Other water tablets?
  - Medicine for heart trouble eg. digoxin?
  - Insulin or tablets for diabetes?
  - Lithium?
- Have you ever had a rash after taking water tablets or Sulphonamides?
- Do you get gout?
- Are you pregnant?
- Are you breast feeding?

If the answer is YES to any of these questions tell your dotor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, ask your doctor or pharmacist.
- Take your tablets or capsules with a glass of water or milk.
- Keep taking your medicine until your doctor tells you to stop. Don't stop just because you feel better. If you stop the tablets your condition may get worse.
- If you forget to take a dose, take another as soon as you remember. Then go on as before.

✻ After taking your medicine

Most people benefit from taking this medicine but it can cause side-effects.
If you get any of the following, tell your doctor:

- Dizziness or lightheadedness
- Feeling extremely thirsty.
- Muscle pains or cramps.
- Skin trouble such as rash or itching for the first time.

You may lose potassium from your body while you are taking water tablets. You may be given tablets or sachets or told to eat plenty of foods rich in potassium, such as bananas, oranges and fruit juices.
Your doctor will tell you about this.

Storing your medicine

- Keep your medicine in a safe place out of reach of children. Your medicine could harm them.
- Return any left-over medicine to the pharmacist or flush it down the toilet. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptons are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Figure 5.3

PIL giving information about Benzodiazepines

What you should know about Benzodiazepines

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____
Your medicine is one in a group of medicines called Benzodiazepines. These medicines calm anxious or worried people and help them to sleep. They also relax muscle spasms.

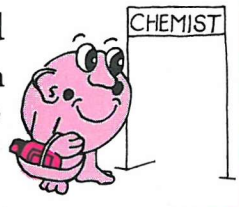
Things to remember about Benzodiazepines

1 **Make sure it is safe for you** to take Benzodiazepines *(see the back of this leaflet).*♦

2 **Look at the label** on your tablets. It will tell you when to take them.

3 **Benzodiazepines can cause problems.** You can find these listed on the back of this leaflet. ✱

4 Keep your tablets **out of reach of children.**



5 **Remember to return any unused tablets** to the Pharmacist or flush them down the toilet unless your doctor has told you to keep them.

You will find more about Benzodiazepines on the back of this leaflet.

Your medicine is one in a group of medicines called Benzodiazepines. These medicines calm anxious or worried people and help them to sleep. They also relax muscle spasms.

♦ Before taking your medicine

- Do you suffer from chronic bronchitis or lung problems?
- Are you on other medicines for nerves or epileptic fits or to help you sleep?
- Are you pregnant?
- Are you breast feeding?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, ask your doctor or pharmacist.
- To help you sleep take your tablets ½ hour before you go to bed.
- Take your tablets or capsules with a glass of water.
- If you forget to take a dose take another as soon as you remember. Then go on as before. Don't take a double dose next time.
- If you take an overdose by accident contact your nearest hospital casualty department or tell your doctor immediately.

✱ After taking your medicine

A few people can be upset by this medicine. If you get any of the following, tell your doctor.

- Seeing things hazy or blurred
- Dizziness, unsteadiness or not walking straight
- Feeling more depressed than usual
- Skin trouble such as rash or itching for the first time.

Your tablets may make you feel drowsy during the day. Don't drive a car or work a machine while you are on these tablets.

Don't drink alcohol while you are on these tablets. The two together will make you very drowsy and this could be dangerous.

Stopping your medicine

- Have you been taking these tablets for 3 months or more? If you have make sure you talk to your doctor about it. He may want to stop your tablets.
- If your doctor decides to stop your tablets, he will reduce your dose slowly over several weeks. Your body may need time to adjust so don't stop taking your tablets suddenly.
- When you stop the tablets you may feel sick, anxious and shaky and find it hard getting to sleep. If this happens to you take another tablet as soon as possible. Tell your doctor about it next time.

Storing your medicine

- Keep your tablets in a safe place where children cannot reach them. Your tablets could harm them.
- If your doctor decides to stop the treatment, return any left-over tablets to the pharmacist or flush them down the toilet. Only keep them if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptons are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Table 5.1

Number of patients interviewed in the study towns (percentages are shown in brackets)

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Number of patients interviewed	83 (82.0)	100 (86.0)	99 (85.0)	90 (90.0)	70 (80.0)	57 (80.0)

Demographic characteristics

Demographic characteristics of patients interviewed in this study are shown in Table 5.2. Seventy-five percent of the respondents were women. The mean age of patients interviewed about a diuretic or a benzodiazepine was 68 years, whereas for penicillins it was 42 years. Forty-one percent of the prescriptions for penicillins were for children under the age of 16 and in most of these cases, the mother of the child was interviewed. More patients were interviewed from the non-manual social classes (classes I, II and IIINM made up 54%) than from the manual social classes (40% from classes IIIM, IV and V) as classified according to the Registrar General's Classification of Occupations (Office of Population Censuses and Surveys 1980) but 6% of respondents were unclassifiable using this method. No significant differences in sex, age or social class distribution were found between those who received a leaflet and others who did not for any of the three groups of medicines.

Over three-quarters (76.4%) of the patients interviewed about benzodiazepines had taken their medicine before. This figure increased to 85.2% of penicillin takers and 89.9% of those prescribed diuretics. The proportion who had taken the medicine before was not significantly different amongst those who received a leaflet and others who did not.

The non-respondents

Ninety-four (16%) patients approached either refused to be interviewed or could not be contacted after three visits to their home. Around three-quarters of these patients declined to participate and the remaining quarter could not be contacted. The ratio of males to females amongst the non-respondents was not significantly different from those who agreed to be interviewed.

5.33 Patients' knowledge

Patients who received leaflets were better informed about their medicines than those who did not (Table 5.3).

Table 5.2

Demographic characteristics of the patients interviewed **(percentages are shown in brackets)**

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Sex						
Male	20 (24.1)	19 (19.0)	36 (36.4)	29 (32.2)	16 (22.9)	10 (17.5)
Female	#63(75.9)	81 (81.0)	63 (63.6)	61 (67.8)	54 (77.1)	47 (82.5)
Age (years)						
16-24	7 (8.4)	5 (5.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)
25-34	32 (38.6)	35 (35.0)	2 (2.0)	2 (2.2)	1 (1.4)	1 (1.8)
35-44	16 (19.3)	26 (26.0)	1 (1.0)	2 (2.2)	5 (7.1)	2 (3.5)
45-54	5 (6.0)	10 (10.0)	6 (6.1)	3 (3.3)	7 (10.0)	11 (19.3)
55-64	8 (9.6)	10 (10.0)	22 (22.2)	17(18.9)	11 (15.7)	13 (22.8)
65-74	8 (9.6)	10 (10.0)	32 (32.3)	30(33.3)	22 (31.4)	20 (35.1)
75 and over	7 (8.4)	4 (4.0)	36 (36.4)	36(40.0)	23 (32.9)	10 (17.5)

Table 5.2 (continued)

Medicine	Penicillins		Diuretics		Diazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Social Class						
I professional	7 (8.4)	12 (12.0)	12 (12.1)	10 (11.1)	14 (20.0)	6 (10.5)
II intermediate	20 (24.1)	24 (24.0)	28 (28.3)	24 (26.7)	17 (24.3)	21 (36.8)
IIIN skilled non-manual	13 (15.7)	19 (19.0)	15 (15.2)	14 (15.6)	5 (7.1)	6 (10.5)
IIIM skilled manual	25 (30.1)	33 (33.0)	14 (14.1)	22 (24.4)	14 (20.0)	14 (24.6)
IV semi-skilled	5 (6.0)	9 (9.0)	13 (13.1)	9 (10.0)	10 (14.3)	8 (14.0)
V unskilled	4 (4.8)	3 (3.0)	6 (6.1)	6 (6.7)	3 (4.3)	0 (0.0)
Unclassifiable	9 (10.8)	0 (0.0)	11 (11.1)	5 (5.6)	7 (10.0)	2 (3.5)

Includes mothers of children prescribed penicillins

Table 5.3

Patients' knowledge about their medicine **(numbers are those giving correct answers [percentages are shown in brackets])**

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Name of medicine	69 (83.1)	92 (92.0)	64 (64.6)	63 (70.0)	40 (58.0)	30 (52.6)
Purposes of therapy	83(100.0)	99 (99.0)	90 (90.9)	81 (90.0)	68 (98.6)	53 (93.0)
When to take it	75 (91.5)	90 (90.0)	90 (90.9)	76 (85.4)	49 (77.8)	34 (59.6) *
Take with fluid	48 (58.5)	57 (57.0)	91 (91.9)	83 (94.3)	57 (90.5)	46 (80.7)
Take on an empty stomach	69 (84.1) ***	59 (59.0)	-	-	-	-
What to do if dose is missed	71 (86.6) ***	58 (58.0)	64 (64.6)	49 (55.7)	†12 (24.5)	13 (26.0)
Storage out of reach of children	73 (89.0) **	71 (71.0)	95 (96.0) **	71 (80.7)	58 (92.1)	43 (76.8)

Table 5.3 (continued)

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Safe method of disposal	66 (80.5)	79 (79.0)	81 (81.8)	63 (71.6)	49 (77.7)	44 (77.2)
Aware not to share medicines	77 (93.9)	96 (96.0)	96 (97.0)	80 (89.9)	60 (95.2)	45 (78.9) *

* $p<0.05$, ** $p<0.01$, *** $p<0.001$
Questions were answered by 90-100% of respondents except †, 'what to do if a dose of diazepine is missed'.
Missing values were excluded from the percentages.

How to take the medicine

More patients who received a leaflet were aware of how to take their medicine correctly. Eighty-four percent of penicillin takers who received a leaflet knew their medicine should be taken on a empty stomach compared with 59% in the control group ($X^2_1=12.47$, $p<0.001$). More of these patients were also aware of what to do if a dose was missed ($X^2_1=15.83$, $p<0.001$) and the trend was in the same direction for patients taking diuretics ($X^2_1=1.21$, $p=0.27$). In addition, over three-quarters of the benzodiazepine takers who received leaflets knew when to take their tablets compared with 60% of the control group ($X^2_1=3.81$, $p<0.05$). However, the purpose for which the therapy had been prescribed was known by nine out of ten respondents whether or not a leaflet was received. A similar proportion of diuretics and benzodiazepine takers were aware of the correct dosage instructions for their medicines.

Safe storage and disposal

Over three-quarters of those questioned were aware of safe methods of storing and disposing of medicines. Despite this high level of awareness, significantly more people who received leaflets knew this was an important consideration (penicillins $X^2_1=7.80$, $p<0.01$: diuretics $X^2_1=9.43$, $p<0.01$: benzodiazepines $X^2_1=4.27$, $p<0.05$). Knowledge of the potential dangers of sharing prescribed medicines with family or friends was also found to be widespread. Nevertheless, significantly more benzodiazepine takers were aware of the dangers of sharing tablets with family or friends if they received a leaflet (96% cf 79%, $X^2_1=4.82$, $p<0.05$).

Knowledge of side-effects

Awareness of the side-effects of all three medicines was significantly higher among patients who were given leaflets (Table 5.4). Significantly more people interviewed about penicillins knew that this medicine can sometimes cause rash ($X^2_1=11.03$, $p<0.001$), wheezing ($X^2_1=4.20$, $p<0.05$) and pains in the joints ($X^2_1=5.45$, $p<0.05$) if they received a leaflet. More patients prescribed diuretics

Table 5.4

Patients' knowledge of the side effects of their medicine **(percentages are shown in brackets)**

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Aware of any side effects	51 (61.4)	35 (35.0) ***	28 (28.3)	7 (7.8) ***	22 (31.4)	8 (14.0) *
Aware of individual side effects						
Sickness	12 (14.5)	9 (9.0)	Dizziness	10 (10.1) 1 (1.1) *	Blurred Vision	3 (4.3) 0 (0.0)
Bowel problems	16 (19.3)	15 (15.0)	Rash	6 (6.1) 1 (1.1)	Dizziness	7 (10.1) 0 (0.0) *
Rash	40 (48.2)	23 (23.0) ***	Feeling very thirsty	10 (10.1) 1 (1.1)	Increased depression	4 (5.8) 0 (0.0)

Table 5.4 (continued)

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Wheezing	5 (6.0)	0 (0.0) *	Muscle cramp 4 (4.0)	0 (0.0)	Rash 3 (4.3)	0 (0.0)
Pains in the joints	6 (7.2)	0 (0.0) *			Drowsiness 14 (20.3)	8 (14.0)

* $p<0.05$, *** $p<0.001$
Questions were answered by 100% of respondents

or benzodiazepines who received leaflets were aware that their therapy sometimes caused dizziness (X^2_1=5.32, p<0.05 and X^2_1=3.89, p<0.05, respectively). Over 60% of the people who received leaflets about penicillins were able to name at least one side-effect of their medicine. But, awareness of the side-effects of the other two medicines remained low at less than one third, even amongst those who received leaflets.

Trends in favour of the leaflets were found for all of the knowledge items tested except for the name of the medicine. Although this item was known by almost all those interviewed about penicillins, only two-thirds of those taking diuretics and about half of the patients prescribed benzodiazepines could name their medicine. Slightly more of the patients taking penicillins and diuretics could name their medicine if they did not receive a leaflet.

5.34 "Side-effects" experienced

Side-effects listed in the leaflets

Around 60% of the patients prescribed penicillins or benzodiazepines claimed to have experienced at least one of the side-effects listed on the leaflet since starting their medicine (Table 5.5). The figure was slightly lower amongst the diuretic takers with 41% experiencing any of the problems listed. For penicillins, the most common problem was wheezing reported by 24% of the respondents, followed by rash, reported by 18%. The most common problems reported by patients prescribed benzodiazepines were dizziness, drowsiness and depression. Dizziness was experienced by over 20% of the diuretic takers and 19% of these patients reported experiencing a rash after starting their tablets. With the exception of rashes, which were reported by significantly more diuretic takers who received leaflets (X^2_1=4.87, p<0.05), there was little evidence of increased reporting of the side-effects amongst penicillin and diuretic patients who received leaflets. However, there was some evidence of increased reporting of the side-effects listed on the benzodiazepine leaflet. Three of the five "side effects" listed

Table 5.5

Patients' experience of 'side effects' listed in the leaflets (percentages are shown in brackets)

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Experience of any of the side effects listed	55 (66.3)	52 (52.0)	44 (44.4)	33 (36.7)	42 (60.0)	32 (56.1)
Experience of individual side effects						
Sickness	12 (14.6)	20 (20.0)	Dizziness	23 (23.2)	25 (28.7)	Blurred vision	10 (16.4)	11 (19.6)
Bowel problems	17 (20.7)	17 (17.0)	Rash	25 (25.3)	10 (11.5) *	Dizziness	19 (31.1)	12 (21.4)
Rash	16 (19.5)	12 (12.0)	Feeling very thirsty	0 (0.0)	1 (1.1)	Increased depression	21 (34.4)	9 (16.1) *
Wheezing	19 (23.2)	25 (25.0)	Muscle cramp	3 (3.0)	0 (0.0)	Rash	14 (23.0)	7 (12.5)
Pains in the joints	18 (22.0)	16 (16.0)				Drowsiness	16 (26.2)	15 (26.8)

* $p<0.05$ Questions were answered by 100% of respondents

on the benzodiazepine leaflet were reported more frequently by patients who received leaflets. Significantly more benzodiazepine takers who received a leaflet reported experiencing depression (X^2_1=4.24, p<0.05).

Other health problems

There were few differences amongst the penicillin and diuretic takers in the pattern of health problems which were not mentioned in the leaflets (Table 5.6). An exception to this was headaches, which were reported more frequently by diuretic takers who had received a leaflet (X^2_1=7.12, p<0.01). By contrast, there was a tendency for almost all of the health problems mentioned by benzodiazepine takers to be reported more frequently by those who received leaflets, but this trend did not attain statistical significance. One exception to this tendency were reports of nervousness, which were made twice as frequently by benzodiazepine takers who did not receive a leaflet (X^2_1=3.16, p=0.08).

Were all the problems connected with the medicine?

Nearly one quarter of the penicillin takers who had bowel problems or who experienced drowsiness thought this was caused by their medicine. This proportion remained constant whether or not a leaflet was received. Similarly, around 20% of those who experienced drowsiness whilst on benzodiazepines blamed their tablets. However, patients connected very few of the other problems reported with any of these treatments.

A total of twelve patients who experienced side-effects stopped their tablets. Five of these patients had been prescribed penicillin, three were taking a diuretic and four were on benzodiazepines. Only 6 of these patients reported their suspected side-effect to their doctor.

5.35 Storage and disposal of medicines

The most common place for storage of penicillins was the kitchen (Figure 5.4). This was also the case for diuretics, although the bedroom was favoured by 30% of these patients. The bedroom was the most popular place for storage of

Table 5.6

Other health problems reported by patients since starting the medicine **(percentages are shown in brackets)**

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Health problems reported						
Blurred vision	4 (4.9)	5 (5.0)	11 (11.1)	11 (12.6)	-	-
Wheezing	-	-	50 (50.5)	35 (40.2)	19 (31.1)	11 (19.6)
Dizziness	7 (8.5)	9 (9.0)	-	-	-	-
Sickness	-	-	14 (14.1)	8 (9.2)	12 (19.7)	7 (12.5)
Stomach discomfort	10 (12.2)	16 (16.0)	22 (22.2)	21 (24.1)	13 (21.3)	12 (21.4)
Joint pain	-	-	61 (61.6)	50 (57.5)	34 (55.7)	28 (50.0)
Cold extremities	5 (6.1)	4 (4.0)	30 (30.3)	21 (24.1)	14 (23.0)	11 (19.6)
Depression	6 (7.3)	3 (3.0)	17 (17.2)	12 (13.8)	-	-

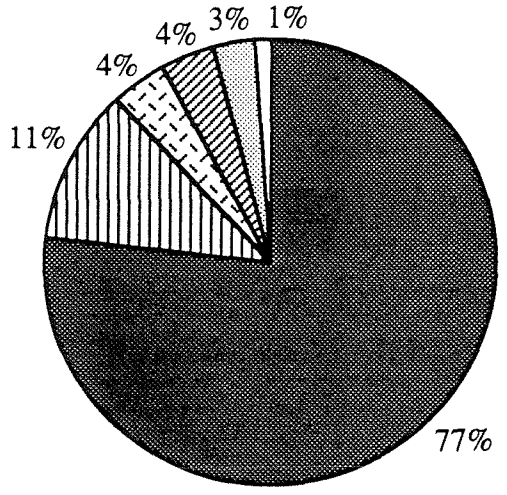
Table 5.6 (continued)

Medicine		Penicillins		Diuretics		Benzodiazepines	
Leaflet		Yes	No	Yes	No	Yes	No
	Ringing in ears	10 (12.2)	12 (12.0)	15 (15.2)	13 (14.9)	9 (14.8)	3 (5.4)
	Drowsiness	14 (17.1)	16 (16.0)	16 (16.2)	20 (23.0)	-	-
	Nervousness	4 (4.9)	1 (1.0)	14 (14.1)	8 (9.2)	10 (16.4)	18 (32.1)
	Headaches	18 (22.0)	14 (14.0)	25 (25.3)	8 (9.2) **	22 (36.1)	15 (26.8)
	Bowel complaints	-	-	14 (14.1)	11 (12.6)	14 (23.0)	10 (17.9)
	Tarry stools	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Others	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

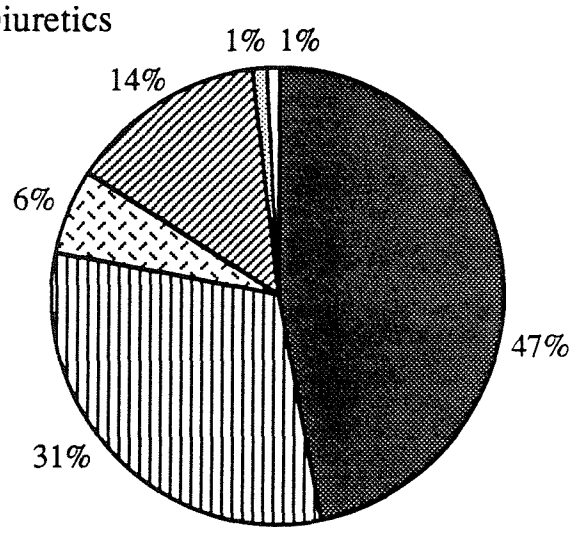
** $p<0.01$

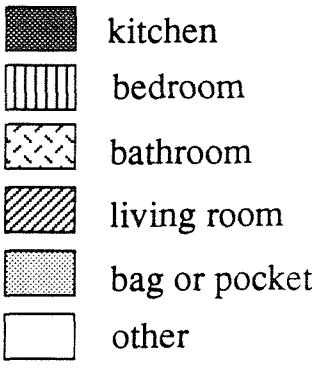
Figure 5.4
Place of storage of the medicines

(a) Penicillins

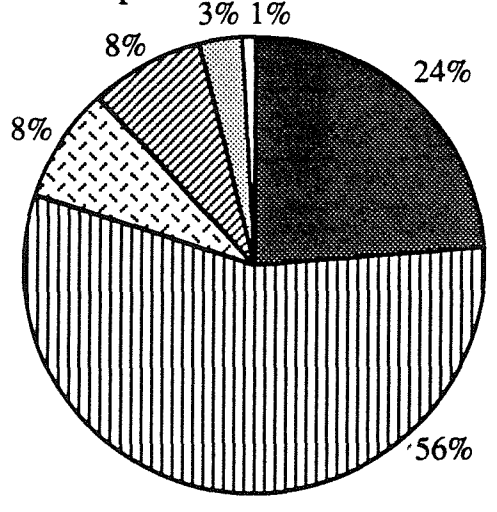


(b) Diuretics





(c) Benzodiazepines



benzodiazepine tablets. Over three-quarters of the respondents were aware of the need to store medicines out of reach of children. However, on inspection the interviewers found that only about one third of patients taking diuretics or benzodiazepines took this precaution. These tablets were not more likely to be stored out of reach in households where children lived or visited regularly.

The majority of the penicillin takers had finished their course of medicine by the time of their interview, making direct observation of storage place impossible. However, only half of those interviewed said they had kept their penicillin out of reach of children, irrespective of whether children lived in or regularly visited the home (Figure 5.5). Significantly more people claimed to have kept penicillin out of reach if they received a leaflet ($X^2_1=5.44$, $p<0.05$).

Figure 5.6 shows what the respondents said they would do with any left over medicine. There were no significant differences between the answers given by those who received leaflets and others who did not.

5.36 Patient Compliance

Medicine taking

The interviewers were able to confirm that all the people questioned about penicillins or diuretics had recently been prescribed a study drug. For almost all of those prescribed penicillin this was the only prescribed medicine they were currently taking. However, over half of the diuretics takers were taking two or more drugs prescribed by their doctor. Nine of the respondents who had been prescribed benzodiazepine tablets did not confirm this during the interview or show the tablets to the interviewers.

Tablet counts

Tablet counts were conducted during 65% of the interviews with patients prescribed diuretics and 63% of interviews about benzodiazepines when tablets

Figure 5.5
Storage of medicine out of reach of children

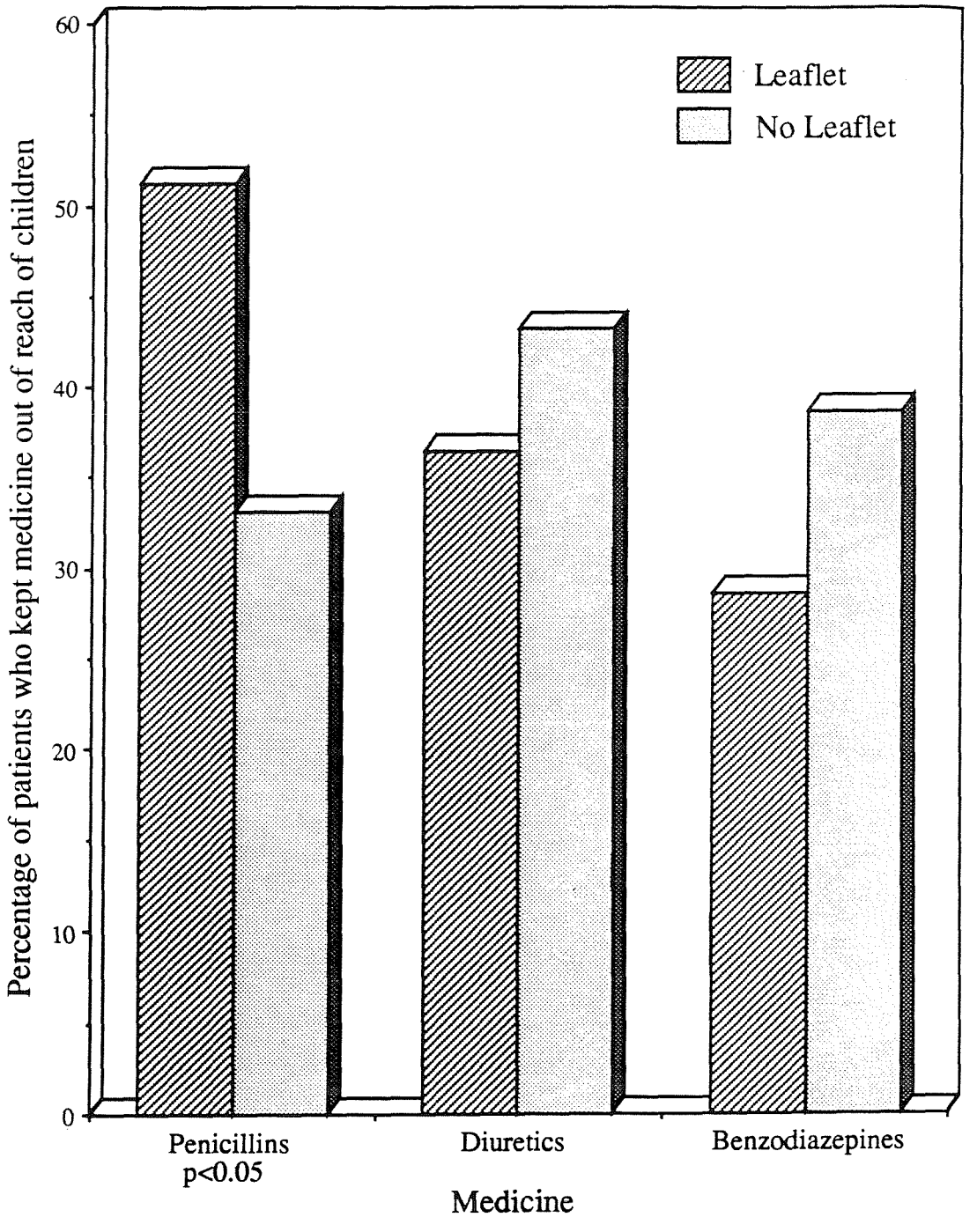
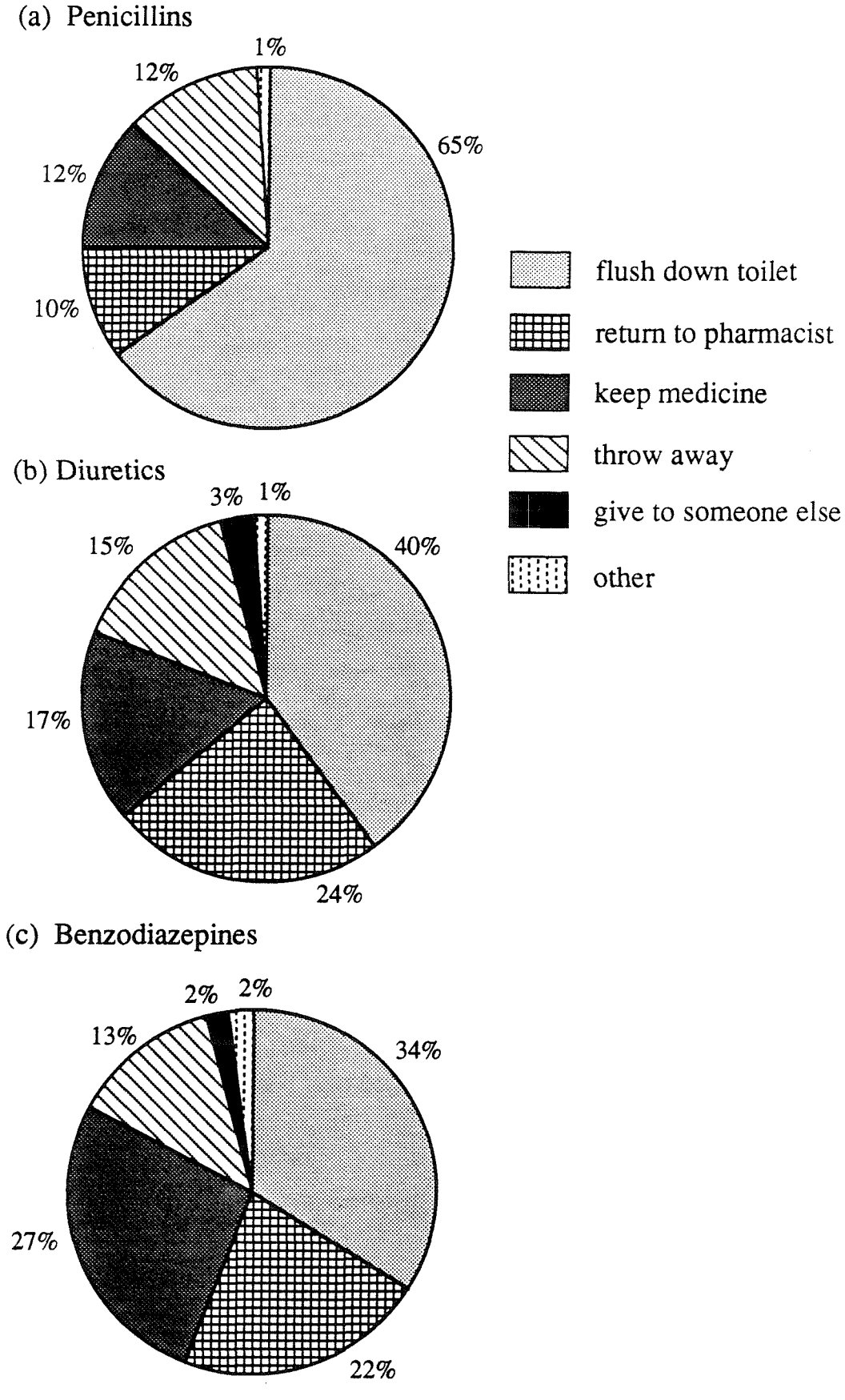


Figure 5.6
Method of disposal of leftover medicines



were made available for counting. Since four out of every five penicillins takers had finished their course by the time of interview, tablet counts or medicine estimations were only conducted during 18% of these interviews. Compliance rates for diuretics and benzodiazepines were calculated from the tablet counts as described in chapter 4.

The distribution of the compliance rates obtained are shown in figures 5.7 and 5.8. The rates were found to vary markedly with a range of 0-442%. There were no significant differences in the compliance rates recorded amongst those who received leaflets and others who did not (For diuretics $X^2_2=0.19$; for benzodiazepines $X^2_2=0.55$). Just over half the compliance rates calculated for diuretics takers were in the range arbitrarily defined as acceptable (80-120%), a quarter were "under-compliant" (under 80%) and a quarter were "over-compliant" (over 120%) (Table 5.7). Two of the diuretic takers seemed to have been taking three times as many tablets as prescribed, and a further patient appeared to be exceeding the dose by four times the amount prescribed. By contrast, under compliance was more common amongst the benzodiazepine takers. The proportion of these patients classified as "compliant" was lower than for the diuretics takers, with just over 40% falling in this range. Nevertheless, 16% of the benzodiazepine tablet counts gave compliance rates in excess of 120%.

The pattern of compliance

The pattern of medicine taking as reported by the respondents on the day prior to interview is shown in table 5.8. For all three medicines, there were no significant differences in self reported compliance between those who received leaflets and others who did not. Around 85% of the patients taking penicillin and diuretics claimed to have taken their tablets exactly as directed on the day prior to their interview, or on the last day they took the medicine. This proportion was lower amongst benzodiazepine takers (60% agreement). Few penicillin and diuretic takers claimed to be taking too much or too little

Figure 5.7

Distribution of compliance rates calculated from Diuretics tablet counts

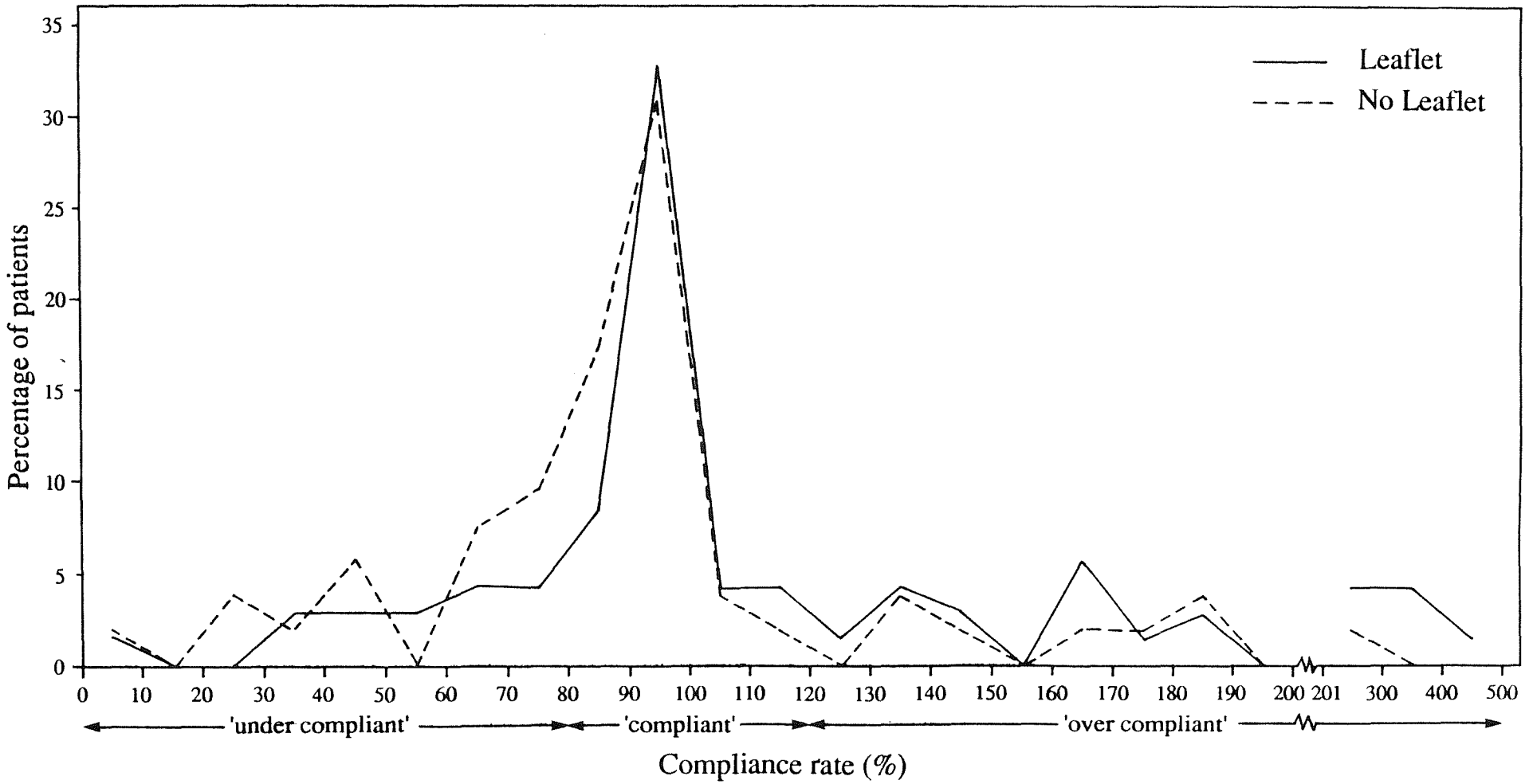
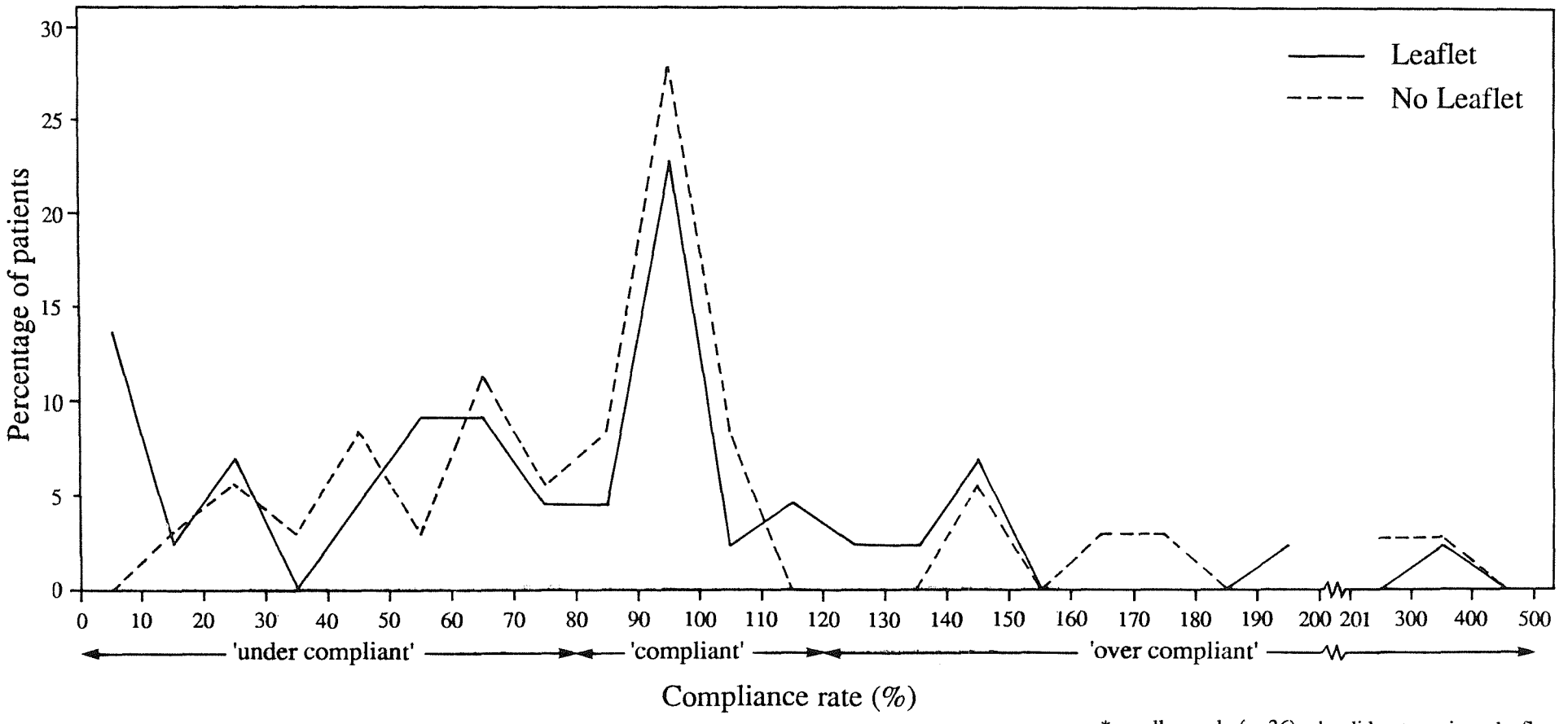


Figure 5.8
Distribution of compliance rates calculated from Benzodiazepines tablet counts*



* small sample (n=36) who did not receive a leaflet

Table 5.7

Compliance rates calculated from tablet counts **(percentages are shown in brackets)**

Medicine	Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No
Total number	70	52	44	36
Under 80% compliance	14 (20.0)	15 (28.8)	21 (47.7)	13 (36.1)
80-120% compliance	36 (51.4)	29 (55.8)	16 (36.4)	17 (47.2)
Over 120% compliance	20 (28.6)	8 (15.6)	7 (15.9)	6 (16.7)

Table 5.8

Patients' reports of medicine taking yesterday as compared with instructions on the label (numbers are those giving correct answers [percentages are shown in brackets])

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Taken as directed	70 (85.4)	82 (82.0)	89 (89.9)	75 (84.3)	39 (61.9)	33 (57.9)
Dose reduced	7 (8.5)	8 (8.0)	4 (4.0)	8 (9.0)	16 (25.4)	11 (19.3)
Dose increased	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.1)	5 (7.9)	4 (7.0)
Spacing of doses error	5 (6.1)	6 (6.0)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)
Regimen totally altered	0 (0.0)	4 (4.0)	1 (1.0)	1 (1.1)	1 (1.6)	1 (1.8)
Unable to remember	0 (0.0)	0 (0.0)	4 (4.0)	3 (3.4)	2 (3.2)	8 (14.0)

Questions were answered by 93-100% of respondents. Missing values were excluded from the percentages.

medicine. However, just over one fifth of the benzodiazepine takers claimed they were taking fewer tablets than prescribed, whereas 7% admitted to taking more than the prescribed dose yesterday.

Did patients know if their medicine taking regimens were correct?

Over three-quarters of the patients were sure they were following the dosage instructions for their medicine correctly (Table 5.9). A slightly larger proportion of patients were sure about this if they had received a leaflet, but this trend was not statistically significant (diuretics $X^2_3=1.82$; benzodiazepines $X^2_3=1.88$). Amongst those where discrepancies between the dose they were taking and the dosage advised on the label were discovered, 26 (44.8%) were under the impression they were following the dosage regimen correctly. The remainder were aware they were not using their medicine exactly in the way the doctor had advised. There was no evidence that this was influenced by receiving a leaflet.

Stopping the medicine

The number of patients who had either stopped or not started their medicine by the time of their interview is shown in table 5.10. Nine out of every ten patients prescribed penicillins had stopped their medicine by the time of interview. By contrast, only 3% of diuretic takers and 16% of benzodiazepine takers had stopped their tablets. There was no evidence that receipt of a leaflet influenced whether treatment was discontinued for these two medicines. However, 13 (20.6%) patients on benzodiazepines had stopped taking them if they had received a leaflet compared with only three patients (5.3%) who stopped in the control group ($X^2_1=4.86$, $p<0.05$). Of the patients who received a leaflet about benzodiazepines and discontinued the treatment, only one patient claimed to have stopped the tablets because the leaflet made her anxious about potential side-effects. Six patients said they had stopped because they felt better, two had experienced side-effects and one patient felt the tablets were inappropriate for her problem "The leaflet says its a sleeping pill- I need pain killers". The remaining three patients expressed concern about addiction.

Table 5.9

Patients' self reported compliance (percentages are shown in brackets)

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Following the dosage instructions						
Completely	62 (75.6)	68 (68.0)	89 (89.9)	73 (82.0)	51 (81.0)	39 (68.4)
Mostly	17 (20.7)	31 (31.0)	7 (7.1)	16 (18.0)	10 (15.9)	14 (24.6)
Not at all	3 (3.7)	0 (0.0)	3 (3.0)	0 (0.0)	0 (0.0)	3 (5.3)
Uncertain	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	2 (3.2)	1 (1.8)

Missing values were excluded from the percentages

Table 5.10

Number of patients who had stopped or did not start taking their medicine **(percentages are shown in brackets)**

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Stopped the medicine	77 (93.9)	88 (88.0)	2 (2.0)	3 (3.4)	13 (20.6) *	3 (5.3)
Not starting the medicine	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.1)	6 (8.6) *	0 (0.0)

* $p<0.05$ Missing values were excluded from the percentages

A comment from one of the patients was typical. "No one told me to stop - I just didn't want to become addicted." Seven patients who stopped their tablets had been prescribed benzodiazepines as hypnotics whereas the indication was anxiety for the remaining six. Eleven of the patients were women, their ages ranged from 22 to 78 years, they were drawn from a mixture of social classes and six had never taken benzodazepines before.

Not starting the medicine

Only eight patients interviewed did not start their medicine at all. Six of these had been prescribed benzodiazepines and had received a leaflet ($X^2_1=4.27$, $p<0.05$). All of these patients had been prescribed benzodiazepines as hypnotics and two of the six cited the leaflet as the main reason for deciding not to take the tablets. The other four did not agree that benzodiazepines were the right medicine for their problem. One said "You can get addicted! I didn't need it!". Another patient commented that she "..decided not to take them right now (but I've kept them in case I really need them again). After all, if you start to take them you'll have to keep on with them, won't you?".

5.37 Patients' Satisfaction

Satisfaction with information received about medicine

Patients who received leaflets about diuretics and benzodiazepines were more satisfied with the information they received than those who were not given a leaflet ($X^2_4=9.11$, $p<0.05$ and $X^2_4=7.40$, $p=0.06$ respectively) (Table 5.11). These trends were apparent despite the fact that four out of five of the respondents were either satisfied or completely satisfied with the information they had been given. The main difference between patients who received leaflets and those in the control groups who did not was in the number claiming complete satisfaction with the information received about their medicine. More people were completely satisfied if they received a leaflet. Around half of the diuretic and benzodiazepine takers who received leaflet were completely

Table 5. 11

Patients' satisfaction with information received **(percentages are shown in brackets)**

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Satisfaction with information						
Completely satisfied	17 (20.5)	19 (19.0)	47 (47.5)	32 (36.0)	35 (50.7)	17 (29.8)
Satisfied	44 (53.0)	65 (65.0)	32 (32.3)	45 (50.6)	20 (29.6)	29 (50.9)
Indifferent	12 (14.5)	8 (8.0)	12 (12.1)	8 (9.0)	8 (11.6)	5 (8.8)
Dissatisfied	7 (8.4)	8 (8.0)	7 (7.1)	2 (2.2)	5 (7.2)	4 (7.0)
Completely dissatisfied	2 (2.4)	0 (0.0)	0 (0.0)	1 (1.1) *	1 (1.4)	1 (1.8)
Don't know	1 (1.2)	0 (0.0)	1 (1.0)	1 (1.1)	0 (0.0)	1 (1.8)

* $p<0.05$

Questions were answered by 100% of the respondents

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

satisfied compared with about one third of the control groups.

In contrast to these results, there was little difference in the level of satisfaction reported amongst those who received leaflets about penicillins and others who did not (X^2_1=5.30, p=0.26). Moreover, the level of satisfaction was lower than that reported for the other two medicines. Only one fifth of those questioned about penicillins said they were completely satisfied.

Satisfaction with information received about the illness

Over two-thirds of the respondents claimed to have received all of the information they wanted about their illness (Table 5.12). This did not appear to be influenced by receipt of a leaflet.

Satisfaction with the medicine

Around 80% of the respondents were either satisfied or completely satisfied with the medicine they had been prescribed (Table 5.13). There was little evidence that those who received leaflets were more satisfied with their medicine than those who did not receive additional written information. Moreover, only 10 (14.5%) patients who received a leaflet on benzodiazepines were completely satisfied with their medicine compared with 23 (40.4%) in the control group (X^2_1 test for trend=7.84, p<0.01).

Satisfaction with the consultation

Because of the objections and withdrawal of one general practice from the study, the satisfaction scale was dropped from the interviews in town H. The results presented are therefore confined to those obtained from the global satisfaction measure. Nine out of every ten patients were either satisfied or completely satisfied with their most recent general practitioner consultation (Table 5.14). There was little evidence to suggest higher levels of satisfaction amongst those who received leaflets. In fact, a trend in the opposite direction was apparent.

Table 5.12

Information received about illness **(percentages are shown in brackets)**

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Information received about illness						
All of	52 (65.0)	62 (63.3)	70 (70.7)	62 (72.9)	48 (69.6)	41 (74.5)
Some of	22 (27.5)	28 (28.6)	20 (20.2)	15 (17.6)	16 (23.2)	7 (12.7)
None of	6 (7.5)	8 (8.2)	9 (9.1)	8 (9.4)	5 (7.2)	7 (12.7)

Missing values were excluded from the percentages

The table shows the responses to the question, 'Did you get all of, some of, or none of the information you wanted about your illness?'

Table 5.13

Patients' satisfaction with the medicine itself (percentages are shown in brackets)

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Satisfaction with the medicine						
Completely satisfied	21 (25.3)	31 (31.0)	27 (27.3)	31 (34.4)	10 (14.5)	23 (40.4)
Satisfied	48 (57.8)	57 (57.0)	54 (54.5)	46 (51.1)	40 (58.0)	26 (45.6)
Indifferent	6 (7.2)	4 (4.0)	8 (8.1)	6 (6.7)	3 (4.3)	1 (1.8)
Dissatisfied	4 (4.8)	7 (7.0)	7 (7.1)	6 (6.7)	13 (18.8)	7 (12.3)
Completely dissatisfied	2 (2.4)	1 (1.0)	0 (0.0)	0 (0.0)	3 (4.3)	0 (0.0) **
Don't know	2 (2.4)	0 (0.0)	3 (3.0)	1 (1.1)	0 (0.0)	0 (0.0)

** $p<0.01$
Missing values were excluded from the percentages

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

Table 5.14

Patients' overall satisfaction with their most recent general practitioner consultation
(percentages are shown in brackets)

Medicine	Penicillins		Diuretics		Benzodiazepines	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Satisfaction with the consultation						
Completely satisfied	36 (43.4)	54 (54.0)	55 (55.6)	58 (64.4)	33 (47.1)	31 (54.4)
Satisfied	39 (47.0)	43 (43.0)	37 (37.4)	26 (28.9)	33 (47.1)	21 (36.8)
Indifferent	1 (1.2)	0 (0.0)	2 (2.0)	2 (2.2)	3 (4.3)	0 (0.0)
Dissatisfied	6 (7.2)	3 (3.0)	5 (5.1)	2 (2.2)	1 (1.4)	3 (3.5)
Completely dissatisfied	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	0 (0.0)	1 (1.8)
Don't know	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.1)	0 (0.0)	2 (3.5)

Missing values were excluded from the percentages

Few patients expressed any dissatisfaction with their doctor.

5.38 The impact of sex, age and social class

There was little evidence from the logit analysis that the demographic characteristics of the patients confounded the results of this study. With the exception of pencillins (where receipt of a leaflet did not appear to enhance awareness of the dosage instructions or result in higher levels of satisfaction) significant improvements in the knowledge and satisfaction items tested were associated with the leaflets regardless of a patients' sex, age or social class (Table 5.15).

5.39 Use made and opinions of the leaflets

Not all patients who should have received a leaflet in this study remembered receiving one. Seventy-five (90%) patients taking penicillin remembered receiving one. However, the number remembering receiving leaflets on the other two medicines was much lower. Fifty-seven (58%) of the diuretic takers and only 33 (47%) patients taking benzodiazepines claimed to have received a leaflet.

Table 5.16 illustrates the use made of the leaflets by patients who remembered receiving them. One hundred and fifty-eight of the 165 patients who remembered receiving a leaflet said they had read it. The majority of patients who read the leaflet claimed to have read it all the way through before taking any medicine. But, whereas three-quarters of diuretics takers and two-thirds of those on benzodiazepines said they had kept their leaflet, the leaflet about penicillin was kept by only half of those who received it.

Patients' reaction to the leaflets

One hundred and fifty-one (83%) people interviewed about penicillin or diuretics thought it would be a good idea to be given a leaflet with their medicine, whether or not they remembered receiving one in this study. Moreover, 139

Table 5.15

Summary of the effects of demographic group on knowledge and satisfaction

Factor	Leaflet (Yes)	Sex (Female)	Age (55+)	Social class (non-manual)	Model X^2	Model df
Penicillins						
Correct dosage	1.19	0.96	2.19	0.75	93	(158)
Medicine and meals	2.21 ***	2.25	2.10	2.12	190	(158)
Side effects	3.27 ***	3.30	8.22	5.26	216	(159)
Satisfaction	0.94	0.85	0.56	1.80	163	(159)
Diuretics						
Correct dosage	2.15 *	1.54	1.82	2.09	78	(157)
Side effects	7.90 ***	13.81	5.75	6.25	125	(158)
Satisfaction	1.96 *	1.24	1.34	0.96	210	(157)
Benzodiazepines						
Correct dosage	5.55 **	9.44	5.50	2.79	109	(94)
Side effects	3.01 *	4.21	2.40	1.88	107	(101)
Satisfaction	2.72 *	3.03	3.72	2.67	134	(100)

* $p<0.05$, ** $p<0.01$, *** $p<0.001$

All figures are for the odds ratio which is quoted relative to the factor given. An odds ratio >1 implies a positive association between the factor and outcome, whereas an odds ratio <1 implies an association in the other direction. If the odds ratio is zero there is no association. Odds ratios are quoted for receiving a leaflet relative to no leaflet, for females relative to males, for the 55+ age group relative to the <55 age group and for the non-manual class relative to the manual class.

Table 5.16

Patients' use of, and opinions about, leaflets **(percentages are shown in brackets)**

Medicine	Penicillins	Diuretics	Benzodiazepines
Total number	83	99	70
Remembered receiving leaflet	75 (90.0)	57 (58.0)	33 (47.0)
Read leaflet	72 (96.0)	55 (96.5)	31 (94.0)
Kept leaflet	37 (49.3)	42 (73.7)	20 (60.6)
Found leaflet helpful	67 (93.1)	45 (81.8)	27 (87.1)
Found leaflet worrying	6 (8.3)	7 (12.7)	10 (32.3)
Opinion about providing leaflets			
(i) Good idea	79 (95.2)	72 (72.7)	45 (64.3)
(ii) Bad idea	4 (4.8)	18 (18.2)	14 (20.0)
(iii) Unsure	0 (0.0)	9 (9.1)	11 (15.7)

Missing values were excluded from the percentages

(88%) respondents who read a leaflet said they found it either quite or very helpful. However, one third of benzodiazepine takers who should have received leaflets either thought they were a bad idea, or were unsure about this.

Of those who read a leaflet, 8.3% of those interviewed about penicillin and 12.7% of diuretic takers found it "worrying". The number of patients worried by the leaflet which gave information about benzodiazepines was higher, with 10 patients (32.3%) who read it claiming it caused anxiety about their treatment. However, only three of these patients said they were worried about the side-effects listed on the leaflet. The others were worried about the possibility of addiction. One patient admitted that, "everything makes me anxious". Patients who found the leaflet worrying were not significantly different in age, social class or extent of previous experience of benzodiazepines from those who were not worried by the leaflet, but only one of the patients who found the leaflet worrying was male. Despite the anxiety caused, eight out of the ten patients thought it was a good idea to be given a leaflet with their tablets. One comment was typical - "The leaflet was a very, very good idea. It helped me decide what to do".

5.4 DISCUSSION

The high response rate from patients (84%) achieved in this study was comparable with that obtained in the survey reported in the previous chapter. Furthermore, there were no significant differences between the response rates achieved in the two towns. Whereas the refusal of the small pharmacy in town G to participate was probably of little consequence, it is possible that the exclusion of the larger pharmacy in town H led to some bias in the sample. However, this is unlikely because patients collecting prescriptions from the Boots chain (the pharmacy which agreed to take part in town H) have not been found to differ significantly from those who take their prescriptions to other community pharmacies (Busson and Dunn 1986). Although the numbers recruited were not adversely affected by the non-cooperative pharmacies, the premature withdrawal from the study of one of the participating practices in town H resulted in a lower than expected patient recruitment in the control town. Despite this, the numbers recruited and interviewed during the first five weeks together with the further patients entered from the remaining practice meant that, with the possible exception of benzodiazepine patients, the numbers were adequate for analysis.

As expected, women, the elderly and the non-manual social classes were disproportionately represented amongst the respondents, but the class distribution was found to be representative of that for south-east England (Office of Population Censuses and Surveys 1981). The excess of female respondents was further increased because the sample included mothers of children prescribed penicillins. Nevertheless, the similarity of the demographic characteristics of those who received leaflets and others who did not enabled comparison to be made between the two groups.

This study has extended the range of drug groups for which PILs have been produced. Moreover, several of the benefits previously found to be associated

with PILs have been confirmed. The findings that patients who received leaflets knew more about their medicines, particularly the potential side-effects, were more satisfied with the information received, but not more compliant, are consistent with those reported for patients who received leaflets about NSAIDs, ß-adrenoceptor antagonists and inhaled bronchodilators (chapter 4).

Some findings were inconsistent with those previously reported. Whereas there was little evidence that the greater knowledge which accompanied the receipt of a leaflet encouraged the reporting of side-effects by suggestion for five of the six leaflets, the leaflet giving information about benzodiazepines did appear to have caused "spurious" side-effects. Three of the five side-effects mentioned on this leaflet were reported more frequently by patients who received a leaflet. About 80% of those affected were women and three-quarters of them had taken benzodiazepines before.

In contrast to the previous study, patients who received leaflets were not more likely to connect general symptoms with their medicine than those in the control group. Although headaches were reported significantly more frequently amongst diuretic takers in the "leaflet" town, none of the 25 patients affected thought they were caused by the diuretic. Indeed, concurrent medicines (indomethacin, nifedipine and transcutaneous glyeryl trinitrate) were a likely cause in 3 patients and several others were long term migraine sufferers.

In the light of concern about the over-prescription of diuretics, particularly amongst the elderly (Bullpitt and Dollery 1973; Peach and Charlton 1986; Anonymous 1988; MacLennan 1988), the finding that some patients may be taking up to four times the prescribed dose of diuretics is cause for concern. The compliance rates calculated from the tablet counts provided little evidence that the leaflets encouraged patients to take their medicines correctly. However, compliance could not be assessed in several interviews with patients prescribed benzodiazepines, because they were reluctant to admit to taking benzodiazepine

tablets. It has been suggested that this type of treatment is perceived by many as a sign of weakness (Manheimer et al 1973; Gabe and Lipshitz-Phillips 1982) and this may explain their reluctance to discuss this treatment.

The fact that no objective assessment of compliance was possible during the majority of the interviews with penicillin takers was a weakness of the present study. Previous studies have found that compliance with short term treatment can be improved by leaflets (George et al 1983; Dodds 1986). Several comments made during the interviews in the present study suggested that although the message about completing a course of antibiotics appeared to have been received, not everyone felt it was necessary to do as they were told. "Everyone knows you are supposed to take penicillin until it's finished but no one does. Why should you if you's better? Just smile and say "Yes doctor".

In contrast to the results for the other five leaflets, the leaflet giving information about penicillins was not associated with improved satisfaction with the information received. One possible explanation was the widespread perception amongst patients that they were already well informed about this familiar treatment. Indeed, there was some evidence that patients knew more about penicillins than any of the other drug groups studied. Despite considerable scepticism expressed about the usefulness of further information, significant improvements in knowledge about penicillins were recorded amongst patients who received leaflets. However, the level of satisfaction amongst penicillin takers in this study was lower than that reported previously (George et al 1983) but similar to that recorded during the preliminary study reported in chapter 3 (Gibbs et al 1987). This may reflect real changes in the level of satisfaction over recent years, particularly amongst the young (Fitzpatrick et al 1984). Two-thirds of those interviewed about penicillins were under 45 years old.

The finding that the effects of the leaflets on knowledge and satisfaction did not appear to be confounded by sex, age or social class is consistent with the results

reported in the chapter 4. However, it is not possible to extrapolate with confidence from the small number of patients in each of the sub-groups in either of these studies. A larger study is needed to further investigate the influence of these variables.

Although the benefits associated with previous leaflets have been largely confirmed, the impact of the three leaflets evaluated in the present study was more modest. Several explanations seem possible. Firstly, only about half of the patients taking diuretics or benzodiazepines who should have received a leaflet claimed to have been given one with their tablets. As before, it is impossible to tell whether these people had simply forgotten about the leaflet or whether they had not received one. Nevertheless, it is likely that the effects of these two leaflets have been underestimated in this study for this reason. Secondly, the leaflets themselves may be inadequate. The statement on the leaflet about benzodiazepines which advised "If you forget to take a dose, take another as soon as you remember" was confusing and open to misinterpretation by the three quarters of patients taking benzodiazepines as hypnotics. In addition, more information about alternative methods to reduce anxiety or relieve sleeplessness would be useful in view of current concern about the over use of benzodiazepines. Finally, there may be inadequacies in the study design itself. The prevalence of rash in town G was unexpectedly high amongst patients prescribed all of the study drugs. Furthermore, the reasons for a lower level of satisfaction with consultations in town G compared with town H are unclear.

This chapter has extended the study of the effects of leaflets by broadening the range of medicines studied. Benefits, in terms of improved knowledge and satisfaction, have now been associated with leaflets for six groups of medicines: NSAIDs, ß-adrenoceptor antagonists, inhaled bronchodilators, penicillins, diuretics, and benzodiazepines. It remains unclear, however, whether these initial benefits will be stable over time.

CHAPTER 6

FOLLOW-UP STUDY

CHAPTER 6

6.1 INTRODUCTION

In the preceding chapters, the development and evaluation of simple, easy to read leaflets which inform patients about a range of therapies has been described. Unlike most previous studies, which have focused on a limited range of medicines (mainly those prescribed for acute conditions), the therapeutic groups examined in the present studies included several which are commonly prescribed on a long term basis for chronic conditions.

Little is known about the long term effects of written information. Initial improvements in patients' knowledge about their medicines and satisfaction with the information received have been demonstrated when Prescription Information Leaflets are issued in a general practice setting (chapters 4 and 5). However, it is unclear whether these initial benefits will be stable over time. In addition, it is not known whether the patients continue to make use of the leaflets over a longer period.

This chapter describes a follow-up of patients prescribed NSAIDs and ß-adrenoceptor antagonists 12 months after they received their original prescription. The longer-term effects of the leaflets on patients' knowledge and satisfaction with their medicines were investigated.

6.2 METHODS

6.21 The leaflets

The leaflets giving information about NSAIDs and ß-adrenoceptor antagonists are shown in figures 4.3 and 4.4 (chapter 4).

6.22 Study design

After an initial pilot investigation in towns A an B, a follow-up study was conducted in towns C, D, E and F 1 year after the original interview survey had taken place. Leaflets were originally issued in towns C, D and F whereas town E was a control town where no leaflets were issued. Further details about these towns and the main survey procedure are given in chapter 4.

General practitioners were asked at the time of the original interview survey, and again one month before the proposed start of the follow-up in their town, for consent for their patients to be included in a study to assess the longer-term effects of information leaflets. Patients who were prescribed either an NSAID or a ß-adrenoceptor antagonist in the study towns 12 months previously were included in the follow-up study. People who declined an interview in the main study or who requested not to take part in any further studies were excluded from the sample.

A list of patients who were eligible for inclusion was prepared and sent to each practice prior to commencement of the follow up survey. A check was made to ascertain that all the patients listed were still alive and registered with the practice. An amended list was passed to each of the general practitioners concerned for their approval. General practitioners were asked to retain as many of the names on the list as possible but, where exclusions were necessary reasons were requested. The final list was checked by the practice receptionist to ensure the patients' contact address was correct.

The pilot study was conducted between September and December 1986 in towns A and B. The follow-up study commenced in March 1987 in town C. In town D, the study started in July 1987, in town E in November 1987 and in town F the study started in March 1988. A maximum period of three months was allowed in each town for the follow up study and data received after this time were excluded from the analysis.

6.23 Data collection

Data were collected using a structured postal questionnaire. A covering letter requesting further help with the research was sent to each patient with a copy of the questionnaire (Appendix 2). As previously, patients were not informed of the true nature of the study, only that, "You may know that the University of Southampton is conducting a survey of people's views about prescribed medicines. You may remember helping us with part of this survey last year". Throughout the follow up study period, general practitioners were requested not to discuss the nature of the survey with their patients or provide any more verbal information than was their usual practice.

Patients were asked to fill in the questionnaire, answering as many questions as they could, even if they were not taking medicines at the moment. Assurance that any answers given on the questionnaire would be confidential and the doctor would not be reading them was given in the covering letter. Completed questionnaires were returned to the University using the "freepost" envelope provided. If no reply was received from the patient within 1 month of issue, a reminder was posted, together with another copy of the questionnaire.

The questionnaire

The questions were made up of a mixture of closed, pre-coded questions and open ended questions, which were piloted on patients recruited in towns A and B. The questions were designed to collect similar information to that recorded in the original interview study. Patients' knowledge about the medicine and satisfaction, both with the information received and with the medicine prescribed 12 months previously, was assessed. In addition, patients were asked whether they were still taking the original medicine. Finally, the number of people who had kept their leaflets over the 12 month period was investigated. Attempts were made to keep the questionnaire short and to present the questions in a logical sequence. In addition, simple language was used and the questionnaire conformed to the principles for good design enumerated in chapter 2.

No assessment of compliance was made in the follow-up study and hypothetical questions about other aspects of behaviour were avoided. Furthermore, the assessment of patients' satisfaction with their most recent consultation was not repeated. The name of the medicine prescribed 12 months previously was inserted at the top of each page of the questionnaire to serve as a reminder to the respondent.

6.24 Data analysis

The questionnaires were logged in on return and the answers coded using a standard coding sheet drawn up after the pilot study. A 100% check of the coding was conducted. The data were double punched onto magnetic tape by a commercial punching agency (Data Speed Ltd, Southampton) and transferred to the University of Southampton IBM 3090 mainframe computer, where they were combined with the data collected in the main study (chapter 4).

Analysis was conducted using the SPSS-X statistical package. Frequencies and cross tabulations of the variables were produced as described in chapter 4. Throughout the analysis patients intended to receive leaflets were assumed to have done so. Associations were tested using the Chi-squared statistic (with Yates correction for 2 x 2 tables). The satisfaction data were ranked from "completely satisfied" to "completely dissatisfied" and a chi-squared test for trend performed. Data from the original study were compared with those obtained in the follow up using McNemar's test for correlated proportions in a 2 X 2 table (Everitt 1977), a test more appropriate than the chi-squared test for assessing the difference between correlated (rather than independent) samples. The 5% level ($p<0.05$) was considered significant throughout.

6.3 RESULTS

6.31 Sample Characteristics

Response from general practitioners

All 51 general practitioners approached agreed for their patients to be included in the follow-up study. Four hundred and sixty-four (84%) of the NSAID and ß-adrenoceptor antagonists takers originally interviewed were included in the follow-up study. The remaining 90 patients were excluded from the second study by their general practitioner. Seventy-nine of these patients had either moved or died and five were excluded because they were considered too ill. No reasons were given for the exclusion of the other six.

Response from patients

A total of three hundred and sixty-eight questionnaires were returned by patients, of which 10 forms were blank. Three hundred and fifty-eight questionnaires were analysed, giving an overall response rate of 77% (Table 6.1). Two hundred and eight patients had been prescribed an NSAID twelve months previously and 150 a ß-adrenoceptor antagonist. Of these, 145 NSAID patients and 74 patients prescribed a ß-adrenoceptor antagonist were originally given leaflets. There were no significant differences in the response rate to the postal questionnaire from those who originally received leaflets and others who did not for either medicine.

Demographic characteristics of the respondents

The demographic characteristics of the respondents are shown in Table 6.2. The age, sex and social class distribution of those who responded to the follow-up questionnaire did not differ significantly from the patients who were not involved in the follow up-study. Patients who received a leaflet with an NSAID or a ß-adrenoceptor antagonist about 1 year previously were found not to differ significantly in age or sex distribution from those who did not get one. An

Table 6.1

Number of questionnaires returned in the follow up study (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Leaflet	Yes	No	Yes	No
Total number of questionnaires sent	196	81	96	91
Number of questionnaires returned	145 (74.0)	63 (77.8)	74 (77.1)	76 (83.5)

Table 6.2

Demographic characteristics of the respondents in the follow up study (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Leaflets	Yes	No	Yes	No
Total number of questionnaires returned	145	63	74	76
Sex				
Male	50 (34.5)	17 (27.0)	28 (37.8)	35 (46.1)
Female	95 (65.5)	46 (73.0)	46 (62.2)	41 (53.9)
Age (years)				
16-24	8 (5.5)	2 (3.2)	1 (1.4)	0 (0.0)
25-34	15 (10.3)	3 (4.8)	2 (2.7)	4 (5.3)
35-44	20 (13.8)	9 (14.3)	3 (4.1)	3 (3.9)
45-54	24 (16.6)	9 (14.3)	17 (23.0)	14 (18.4)
55-64	32 (22.1)	17 (27.0)	21 (28.4)	20 (26.3)
65-74	24 (16.6)	11 (17.5)	23 (31.1)	24 (31.6)
75 and over	22 (15.2)	12 (19.0)	7 (9.5)	11 (14.5)

Table 6.2 (continued)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Leaflet	Yes	No	Yes	No
Social class				
I professional	10 (7.1)	2 (3.4)	6 (8.2)	2 (2.8)
II intermediate	35 (25.0)	20 (33.9)	12 (16.4)	29 (40.3)
IIIN skilled non-manual	32 (22.9)	7 (11.9)	20 (27.4)	11 (15.3)
IIIM skilled manual	44 (31.4)	13 (22.0)	25 (34.2)	19 (26.4)
IV semi-skilled	13 (9.3)	14 (23.7)	7 (9.6)	10 (13.9)
V unskilled	6 (4.3)	3 (5.1)	3 (4.1)	1 (1.4)
		*		*
U Unclassifiable	5 (3.4)	4 (6.3)	1 (1.4)	4 (5.3)

* $p<0.05$
Data were available for 100% of the respondents

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

excess of social class III was still present amongst NSAID patients who received leaflets, with more social class IV and V respondents in the control group (X^2_5=10.01, p<0.05). A similar excess of social class III was present amongst respondents who originally received a leaflet about ß-adrenoceptor antagonists, but with more social class II respondents in the control group (X^2_5=14.00, p<0.05).

6.32 Medicine taking

Thirty three NSAID takers and 11 of those on ß-adrenoceptor antagonists said that they did not remember being prescribed the medicine in question 12 months previously. Because of this, no useful data could be obtained from these patients who have therefore been excluded from further analysis. One hundred and seventy-five NSAID patients and 139 ß-adrenoceptor antagonist patients remembered being prescribed the "original" medicine. Of these 122 (69.7%) should have received the NSAID leaflet and 70 (50.4%) that giving information about ß-adrenoceptor antagonists.

Four out of every five patients "originally" prescribed a ß-adrenoceptor antagonist were still taking it 12 months later (Table 6.3). By contrast, around two-thirds of those previously on NSAIDs had stopped their tablets over the 12 month period. For the most part, these patients had stopped their treatment because they felt better or had finished the prescribed course of tablets. Twenty-three patients stopped the tablets because they were not working. However, significantly more patients had stopped their NSAIDs if they originally received a leaflet (X^2_1=23.63, p<0.001). Fourteen of the fifteen patients who stopped because of suspected side-effects were in the leaflet group. Other reasons given for stopping the tablets included "I was worried about taking tablets for any length of time", "I waited to see if my specialist said they were OK, but he didn't!" and "reflexology and manipulation alleviated the problem".

Table 6.3

Medicine taking in the 12 month study period **(percentages are shown in brackets)**

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Leaflets	Yes	No	Yes	No
Total number of questionnaires returned	145	63	74	76
Number of patients who remembered being prescribed the medicine 12 months ago	122 (84.1)	53 (84.1)	70 (94.6)	69 (90.8)
Stopped the medicine in 12 month period	92 (74.4) ***	19 (35.8)	11 (15.7)	17 (24.6)

*** $p<0.001$

Patients who did not remember receiving the medicine 12 months ago and missing values were excluded from the percentages.

6.33 Patients' knowledge

Patients who originally received leaflets were found to be more knowledgeable about their medicine than those who did not (Table 6.4). Moreover, the difference was apparent regardless of whether the patients were still taking the medicine. NSAID patients who received a leaflet were still more aware of what to do if a dose was missed than those who did not get one 12 months previously, and this difference reached statistical significance ($X^2_1=3.83$, $p<0.05$). The trend was in the same direction for those originally given leaflets about ß-adrenoceptor antagonists. Three-quarters of these patients were aware of what to do if a dose was missed compared with just over two-thirds of those in the control group ($X^2_1=0.24$, $p=0.62$). Of the ß-adrenoceptor antagonist patients who originally received leaflets, 92.4% knew they should take their tablets with fluid compared with 78.5% in the control group ($X^2_1=4.08$, $p<0.05$). Patients who received leaflets were more aware also of the need to take NSAIDs with food and of safe methods to dispose of unused medicine, but these trends did not attain statistical significance.

In general, the level of awareness about both medicines appeared to have fallen slightly over the 12 month period. The fall was most marked amongst those who originally received leaflets. Eighteen NSAID takers originally in the PIL group and who were previously aware that NSAIDs should be taken with food, were now unable to answer this question correctly (McNemars $X^2_1=5.04$, $p<0.05$). By contrast, the slight "decrease" in knowledge in the control group did not reach statistical significance (McNemars $X^2_1=0.07$). Similar falls were apparent amongst the respondents knowledge of what to do if a dose of NSAIDs was missed and their awareness of the need to keep both types of medicine out of reach of children. Nevertheless, knowledge of some items appeared to improve over the 12 month period. More of the respondents to the follow-up questionnaire were aware of safe methods of disposal of medicines than in the original interview study. The "improvement" was most marked amongst those who originally received leaflets. In addition, awareness of what to do if a dose

Table 6.4

Patients' knowledge about their medicine prescribed 12 months earlier (Numbers are those giving correct answers [percentages are shown in brackets])

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Leaflets	Yes	No	Yes	No
Total number who remembered medicine	122	53	70	69
Take with fluid	89 (91.8)	45 (95.7)	61 (92.4)	51 (78.5) *
Take with food	┼64 (71.1)	29 (65.9)	-	-
What to do if dose is missed	#49(53.3)	14 (33.3) *	46 (74.2)	39 (68.4)
Storage out of reach of children	102 (83.6)	44 (83.0)	59 (84.3)	54 (78.3)
Safe method of disposal	119 (97.5)	44 (83.0)	67 (95.7)	58 (84.1)
Aware not to share medicines	107 (99.1)	47(100.0)	67(100.0)	64 (98.5)

* $p<0.05$ Questions were answered by 80-100% of the respondents (with the exception of ┼ 'take with food' [74% response), and # 'what to do if a dose is missed [75% response], amongst NSAID patients who received leaflets). Missing values were excluded from the percentages, but the table includes patients who stopped their tablets during the 12 month period.

of ß-adrenoceptor antagonists was missed was higher in the follow-up study than previously reported irrespective of whether or not a leaflet was originally received.

Knowledge of side-effects

More patients who received leaflets were aware of the side-effects of their "original" medicine (Table 6.5). Almost twice as many NSAID patients who originally received leaflets could name at least one side-effect, but the difference did not quite reach statistical significance ($X^2_1=3.46$, $p=0.07$). Awareness of the side-effects of ß-adrenoceptor antagonists was also higher amongst patients who had received a leaflet 12 months previously ($X^2_1=5.47$, $p<0.05$). The number of patients who knew at least one side-effect of their medicine did not differ significantly from that obtained 12 months previously. However, awareness of each individual side-effect of NSAIDs fell over the 12 month period, especially amongst those who were originally given leaflets. However, significantly more NSAID takers who received leaflets knew there were some potential side-effects associated with their medicine, but were unable to remember the exact symptoms to look out for. By contrast, there was no significant "decrease" in awareness of side-effects amongst ß-adrenoceptor antagonist takers over the 12 month period.

6.34 "Side-effects" experienced

Twenty-seven (20.6%) patients originally prescribed ß-adrenoceptor antagonists who had experienced one or more potential side-effects during the past year thought their problems had been caused by the medicine (Table 6.6). Thirteen of these patients had received leaflets whereas 14 were in the control group. Similarly, during the past 12 months 30 (20.4%) of the NSAID patients who gave an answer to this question claimed to have experienced one or more side-effects. However, in this case 26 of these patients had received leaflets whereas only 4 were in the control group ($X^2_1=4.65$, $p<0.05$). Thirteen of the patients who originally received a leaflet about NSAIDs and who had experienced

Table 6.5

Patients' knowledge of the side effects of their medicine prescribed 12 months earlier (percentages are shown in brackets)

Medicine		NSAIDS			ß-adrenoceptor antagonists	
Leaflet		Yes	No		Yes	No
Total number who remembered medicine		122	53		70	69
Aware of any side effects		45 (43.7)	12 (26.1)		24 (36.4)	10 (16.4) *
Aware of individual side effects						
	Stomach discomfort	27 (22.1)	10 (18.9)	Dizziness	7 (10.0)	3 (30.0)
	Ringing in ears	1 (0.8)	0 (0.0)	Wheezing	4 (5.7)	0 (0.0)
	Dizziness	7 (5.7)	0 (0.0)	Rash	4 (5.7)	0 (0.0)
	Rash	4 (3.3)	1 (1.9)	Slow pulse	2 (2.9)	1 (10.0)
	Wheezing	2 (1.6)	0 (0.0)			
	Tarry stools	3 (2.5)	1 (1.9)	Sleeplessness or vivid dreams	7 (10.0)	0 (0.0)
	Can't remember	9 (7.4)	1 (1.9) *	Can't remember	11 (15.7)	6 (60.0)

* $p<0.05$ Missing values were excluded from the percentages

Table 6.6

Health problems experienced over the 12 month period and thought by the patient to be caused by the medicine (percentages are shown in brackets)

Medicine		NSAIDS			ß-adrenoceptor antagonists	
Leaflet		Yes	No		Yes	No
Total number who remembered the medicine		122	53		70	69
Had any of the side effects listed		26 (24.1)	4 (10.0) *		13 (19.7)	14 (21.5)
Had individual side effects listed in the leaflets						
	Stomach discomfort	13	1	Dizziness	2	4
	Ringing in ears	4	2	Wheezing	3	5
	Dizziness	5	3	Rash	1	0
	Rash	2	0	Slow pulse	0	0
	Wheezing	2	0			
	Tarry stools	0	0	Sleeplessness or vivid dreams	7	5

* $p<0.05$ Missing values were excluded from the percentages

stomach discomfort associated this problem with their tables compared with only one patient in the control group.

A variety of health problems not listed on the leaflets were thought by some to have been side-effects of their treatment. There were no significant differences in the type of symptoms mentioned by those who received leaflets and others who did not. Five patients originally prescribed NSAIDs who had experienced sickness over the past 12 months blamed the tablets; two patients thought their drowsiness was a side-effect and a further two thought the tablets had brought on bowel problems. Other symptoms thought by individual patients to have been caused by NSAIDs included dry eyes, palpitations, nervousness, water retention, pains in the chest, weight gain and a "drunk feeling". Cold extremities, a potential side-effect not listed on the ß-adrenoceptor antagonist leaflet, was thought by 6 patients to have been caused by their tablets. A further 6 complained that these tablets had brought on drowsiness and lethargy whilst two thought the treatment was responsible for a loss in libido. Other symptoms experienced by ß-adrenoceptor takers and thought by individual patients to have been caused by the tablets included sickness, bowel problems, weight gain, night cramps, stuffy nose, excess sweating and "a tight feeling".

6.35 Patients' satisfaction

Satisfaction with the information received about the medicine

The number of patients claiming to be completely satisfied with the information they received about their medicine was lower than that reported in the initial survey for both types of medicine (Table 6.7). Despite this, patients who originally received leaflets about ß-adrenoceptor antagonists were still more satisfied with the information received than those who were not given a leaflet 12 months previously. Ninety-four percent of the patients given a leaflet about ß-adrenoceptor antagonists claimed to be either completely satisfied or satisfied with the information received compared with 74% of the controls (X^2_1 test for

Table 6.7

Patients' satisfaction with the information received and with the medicine prescribed 12 months earlier
(percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists			NSAIDS		ß-adrenoceptor antagonists	
Leaflet	Yes	No	Yes	No		Yes	No	Yes	No
Total number who remembered medicine	122	53	70	69		122	53	70	69
Satisfaction with information received					Satisfaction with the medicine				
Completely satisfied	43 (42.6)	18 (40.0)	28 (43.1)	24 (39.3)	Completely satisfied	33 (33.3)	22 (46.8)	36 (53.7)	31(48.4)
Satisfied	45 (44.6)	17 (37.8)	33 (50.8)	21 (34.4)	Satisfied	34 (34.3)	18 (38.3)	27 (40.3)	24(37.5)
Indifferent	9 (8.9)	5 (11.1)	1 (1.5)	5 (8.2)	Indifferent	13 (13.1)	3 (6.4)	2 (3.0)	3 (4.7)
Dissatisfied	4 (4.0)	3 (6.7)	3 (4.6)	9 (14.8)	Dissatisfied	14 (14.1)	3 (6.4)	1 (1.5)	5 (7.8)
Completely dissatisfied	0 (0.0)	2 (4.4)	0 (0.0)	2 (3.3)	Completely dissatisfied	5 (5.1)	1 (2.1)	1 (1.5)	1 (1.6)
				**					

** p<0.01 Questions were answered by 80-100% of the respondents. Missing values were excluded from the percentages.

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

trend=4.88, P<0.05). However, there was no significant difference in the level of satisfaction with information recorded amongst NSAID takers who received leaflets and others who did not: 87% in the leaflet group were either satisfied or completely satisfied with the information received compared with 78% of the control group (X^2_1 test for trend=2.40, P=0.2).

Satisfaction with the medicine

Patients who received a ß-adrenoceptor antagonist leaflet were still slightly more satisfied 12 months later with the medicine "originally" prescribed than those who were not given a leaflet, but this trend did not reach statistical significance (X^2_1 test for trend 1.70, p=0.2). By contrast, patients who originally received an NSAID leaflet were significantly less satisfied with the medicine they received 12 months previously (X^2_1 test for trend=4.80, p<0.05). Despite this, the level of satisfaction with both medicines was higher than that recorded at the time of the original survey, especially in the control groups.

6.36 Use made of the leaflets

Sixty-three percent of the respondents who should have received a leaflet remembered receiving one 12 months previously. Thirty-two patients originally prescribed a ß-adrenoceptor antagonist (69.6%) had kept their leaflet compared with only 29 (39.2%) patients prescribed an NSAID. The proportion was higher amongst NSAID patients who were still taking their medicine : 17 of these patients (56.5%) had kept the leaflet.

6.4 DISCUSSION

The follow-up study achieved a good response rate. As is often found when data are collected using a postal questionnaire (Moser and Kalton 1981), the response rate was lower than that obtained in the main study (chapter 4), where the data were collected by personal interviewing. Nevertheless, around three-quarters of the patients approached responded to the follow-up study, a better response rate than was achieved in a postal survey of Southampton residents (Ridout et al 1986). Use of a reminder to those who did not reply within the first month succeeded in improving the response to the follow-up questionnaire. But because the quality of returns often diminishes with successive mailings (Moser and Kalton 1981), this procedure was used only once. Although the majority of patients included took part in the study, some patients were lost to follow-up altogether (notably those who had died or moved away from the practice over the 12 month period). In common with other cohort studies, this remains a potential source of bias.

No significant differences were found between the response rates from patients who originally received leaflets and others who did not. Whilst the sex and age distribution of the respondents did not differ significantly between the "leafleted" groups and their respective controls, the tendency noted in the original survey for more respondents who received leaflets to be drawn from social class III (non-manual and manual combined) was still clear. The implications of this finding were discussed in chapter 4. The possibility that social class differences may be a reflection of a selection bias in the issuing of leaflets, notably by general practitioners, is discussed in chapter 7.

Whereas ß-adrenoceptor antagonists are commonly prescribed on a continuous basis for hypertension or angina, NSAIDs can be used both in the treatment of mild or intermittent pain and for continuous regular pain associated with inflammation (British National Formulary 1990). The finding that the majority

of those originally prescribed ß-adrenoceptor antagonists were still taking them 12 months later, but that many patients originally on NSAIDs had stopped their tablets, reflects these different uses. In addition, a series of different NSAIDs may be tried over the course of a patients' illness in order to maximise the therapeutic effect and minimise the side-effects (Steele et al 1987). This may be one reason for the inability of some patients to remember the particular NSAID they had been prescribed 12 months previously.

Many of the initial "improvements" in knowledge and satisfaction amongst patients who received leaflets were still apparent 1 year later. However, the effect of the leaflet appeared to diminish over time, even amongst those still taking their original medicine. Especially marked was the reduction in awareness of the side-effects of the medicine. Several explanations seem possible. Firstly, this "reduction" may be due in part to the differences between the methods used to assess knowledge in the two studies. Whereas in the original survey patients knowledge of the side-effects of their medicines was assessed using a modified form of aided recall, in the follow-up study knowledge was assessed by free recall only. Free recall has been found to produce a poorer response than probed or aided recall (Ley 1988). Secondly, patients still taking their tablets after 12 months are likely to be those who have not experienced any problems and, although they may have read about the potential problems when first given a leaflet, may not have committed them to memory. Finally, written information may be seen as a reference material as well as a text to be learned (Hermann et al 1978). The fact that leaflets were kept by many patients for up to 12 months suggests that the patients in the present study may have been using the leaflets in this way.

Since no previous studies which have investigated the longer-term effects of prescription information leaflets have been traced, the results of this study are of particular importance. However, the study itself is limited in several ways. Firstly, only two drug therapeutic groups (NSAIDs and ß-adrenocepor

antagonists) were studied. It may not therefore be possible to extrapolate the long term effects of the two leaflets to a broader range of drug groups. Patients using bronchodilators were not followed-up because, although medicines from this group are frequently used to treat long term chronic conditions (eg asthma), the number of patients originally receiving leaflets in this group was inadequate. In addition, the age distribution of the patients in the experimental and control towns was significantly different.

A second limitation arises from the design of the study. It is possible that the original interview may have influenced patients' knowledge and satisfaction with their medicines. The "improvement" in knowledge recorded amongst the controls may be due, in part, to the original interview. In addition, a detailed interview may have assisted assimilation of the contents of a leaflet into long term memory. An attempt was made to control for the initial interview by following up patients who were included in the original study but were not contacted the first time around. Of the 20 patients in this category who responded to the questionnaire, only 14 remembered receiving the medicine in question 12 months earlier. Although the responses given by these patients on the questionnaires appeared to be consistent with those offered by the other respondents, the numbers were too small to draw any conclusions.

Thirdly, the data obtained from the follow-up postal questionnaire may not be comparable with those obtained during structured interviews. Whereas interviewers can observe the respondent, obtain a rapport and probe each answer to ensure full understanding, the returns to a postal questionnaire are final and the questions may be answered in any order (which may influence the answers given). Moreover, forms completed at home may be the work of many hands, not necessarily those of the intended respondent. By contrast, the information provided on self administered questionnaires may have been more thoroughly considered by the respondent (Oppenheim 1966). One explanation for the lower level of satisfaction obtained in the follow-up study might be that

respondents were more prepared to make critical comments and give less socially acceptable responses on a postal questionnaire than in a face to face interview (Moser and Kalton 1981).

Finally, although some patients retain their leaflets as a possible source of future reference, others do not. For that reason, the availability of repeat information with further prescriptions might be advantageous. However, this point has not been addressed in the current studies. The issues surrounding leaflet distribution are discussed in the next chapter.

CHAPTER 7

WHO SHOULD DISTRIBUTE THE LEAFLETS?

CHAPTER 7

7.1 INTRODUCTION

In the studies reported in previous chapters, benefits have been associated with the issue of prescription information leaflets. These benefits, which have been demonstrated both in the short term and after a period of 12 months, include improved knowledge (particularly of the side-effects of medicines) and improved satisfaction with the information received. However, the optimum method for distribution of the leaflets has not been determined. Debate has focused on whether leaflets about medicines should be distributed by general practitioners or by pharmacists when the medicine is dispensed. Those who argue that information should originate from the general practitioner have emphasised the ultimate responsibility doctors have to provide information about the medicines they prescribe (Drury 1984). Pharmacists, on the other hand, are well qualified to provide information about medicines and there have been recent moves towards the widening of the pharmacists role to include counselling (Committee of Inquiry 1986).

Throughout the debate, the important question of whether doctors and pharmacists will remember to issue leaflets has been neglected. There is some evidence that general practitioners do not make full use of the health education leaflets currently available to them (O'Hanrahan et al 1980; Sloan 1984; Fowler 1985; Clayton 1986)[1]. Some evidence from the United States suggests that pharmacists may also fail to issue information leaflets; 61% of pharmacists did not spontaneously issue a leaflet with oestrogen products, despite this being required by the Food and Drug Administration (Morris et al 1980).

The effect the source might have on the impact of leaflets has also received little attention. Since general practitioners have been shown to have high credibility as information providers (Tuckett et al 1985) and new beliefs are more readily

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[1] *Reasons given for not providing patients with literature include forgetting to issue a leaflet, lack of time during the consultation, or sceptism about the usefulness of the "plethora of leaflets exhorting people to change their behaviour" (Fowler 1985).*

accepted from trusted sources (Mathews 1983), it has been suggested that leaflets issued by general practitioners might have a greater impact on patients than those issued at the pharmacy. Further, it may be too late for some patients to make a fully informed choice if leaflets are dispensed at the same time as the medicine, and there is some concern that information leaflets from pharmacists may cause confusion if the advice conflicts with that given by the doctor (Hermann 1980). An American study found that leaflets distributed by the provider resulted in higher knowledge levels and greater satisfaction than those distributed at the pharmacy in the bag with the medicine (De Tullio et al 1986). No studies have been traced which have investigated the extent to which the source of a prescription information leaflet might influence its impact in this country.

This chapter examines the use made of the leaflets by general practitioners and pharmacists in the studies reported in previous chapters. In addition, the effects of leaflets issued by pharmacists and general practitioners on patients' knowledge and satisfaction are compared.

7.2 METHODS

The original study design enabled the merits and disadvantages of pharmacist and general practitioner leaflet distribution to be compared. For a detailed description of the design of the study, the reader is referred back to chapter 4.

7.21 The use made of leaflets by general practitioners and pharmacists

In order to determine whether all the patients who were eligible to receive a leaflet actually got one, the number of leaflets issued during the study period in each town was examined. In addition, an audit was conducted in the pharmacies in town C. During one week of the survey period, all of the prescriptions presented at the three pharmacies in this town were examined.

The demographic characteristics of the patients who received leaflets from general practitioners and pharmacists were compared. The records kept by general practitioners and pharmacists of eligible patients who were not given leaflets, and the reasons for their exclusion, were also examined. Further information on the distribution of the leaflets was provided by the patients; each was asked whether or not they had received a leaflet.

7.22 The effect of the source of the leaflet on its impact

The effect of the source of the leaflet was evaluated amongst patients who received leaflets about NSAIDs or ß-adrenoceptor antagonists either from pharmacists in town C, or from general practitioners in towns D and F. Data from interviews with patients prescribed bronchodilators in these towns were not included in this part of the study since only 15 of these leaflets were distributed by general practitioners. Levels of knowledge and satisfaction recorded amongst the patients who received leaflets from general practitioners and pharmacists were compared.

7.23 Data Analysis

Information obtained from patients who received leaflets from pharmacists was compared with that from patients who were given leaflets by general practitioners. The data, coded and transferred to the University of Southampton IBM 3090 mainframe computer, were analysed using the SPSS-X statistical package. Throughout the analysis patients intended to receive leaflets were assumed to have done so. Associations were tested using the Chi-squared statistic (with Yates correction for 2 x 2 tables). Where significant X^2 values were produced for contingency tables with more than 2 rows or 2 columns, the cells were partitioned in order to determine whether non-independence of the two variables occurred throughout or in a specific part of the table (Everitt 1977). The satisfaction data were ranked from "completely satisfied" to "completely dissatisfied" and a chi-squared test for trend performed (Everitt 1977).

7.3 RESULTS

7.31 Use made of leaflets by general practitioners and pharmacists

The number of patients who received leaflets giving information about NSAIDs or ß-adrenoceptor antagonists from either a general practitioner or a pharmacist is shown in table 7.1. The number of ß-adrenoceptor antagonist leaflets distributed by general practitioners and pharmacists was similar. However, pharmacists distributed almost twice as many NSAID leaflets as the doctors. The general practitioners in towns D and F distributed only 15 leaflets for bronchodilators and these are excluded from the table.

From the audit of one weeks prescriptions presented at the pharmacies in town C, it was estimated that the pharmacists issued leaflets to one fifth of the patients eligible to receive them. Direct audit of the frequency with which general practitioners used the leaflets was not possible[1]. However, evidence from the preliminary study suggests that doctors often did not remember to issue leaflets (Figure 3.7 chapter 3). Moreover, marked differences were apparent between the general practitioners in the number of leaflets issued (Figure 3.8). Whilst most of the doctors clearly experienced difficulties, one doctor in each town appeared to find it easy to remember to issue the leaflets. Nevertheless, even these "super-doctors" issued, on average, only 5 leaflets per week.

Which patients received leaflets?

Slightly more patients (93%) remembered receiving a leaflet if it was issued by their general practitioner compared with the pharmacist (84%), but this difference did not attain statistical significance.

The demographic characteristics of the patients who received NSAID or ß-adrenoceptor antagonist leaflets from pharmacists or general practitioners are shown in table 7.2. There was a tendency for general practitioners to distribute leaflets to older patients for both medicines (NSAIDs $X^2_4=11.37$, $p<0.05$; ß

Table 7.1

General practitioner and pharmacist leaflet distribution : number of patients interviewed in the study towns (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Number of patients interviewed	150 (87.0)	82 (83.0)	60 (83.0)	62 (88.0)

Table 7.2

Demographic characteristics of patients receiving leaflets from pharmacists and from general practitioners (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Total number	150	82	60	62
Sex				
Male	54 (36.0)	27 (32.9)	23(38.3)	22 (35.5)
Female	96 (64.0)	55 (67.1)	37(61.7)	40 (64.5)
Age (years)				
16-24	11 (7.3)	1 (1.3)	1 (1.7)	0 (0.0)
25-34	21 (14.0)	3 (3.8)	1 (1.7)	1 (1.6)
35-44	27 (18.0)	15 (18.8)	5 (8.3)	2 (3.2)
45-54	23 (15.3)	11 (13.8)	15(25.0)	9 (14.5)
55-64	25 (16.7)	16 (20.0)	17(28.3)	17 (27.4)
65-74	22 (14.7)	21 (26.3)	15(25.0)	25 (40.3)
75 and over	21 (14.0)	13 (16.3)	6(10.0)	8 (12.9)

*

Table 7.2 (continued)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Social Class				
I professional	13 (8.7)	4 (4.9)	7(11.7)	3 (4.8)
II intermediate	29 (19.3)	30 (36.6)	16(26.7)	13 (21.0)
IIIN skilled non-manual	33 (22.6)	15 (18.3)	14(23.3)	14 (22.6)
IIIM skilled manual	48 (32.0)	15 (18.3)	12(20.0)	22 (33.5)
IV semi-skilled	20 (13.3)	7 (8.5)	8(13.3)	5 (8.1)
V unskilled	5 (3.3)	2 (2.4)	2 (3.3)	4 (6.5)
Unclassifiable	2 (1.3)	9 (11.0)	1 (1.7)	1 (1.6)
		***		

* $p<0.05$, *** $p<0.001$ Missing values were excluded from the percentages

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

-adrenoceptor antagonists $X^2_4=8.79$, $p=0.1$ respectively). In addition, more of the patients who received a leaflet about NSAIDs from their doctor were drawn from the higher social classes (NSAIDs $X^2_5=23.86$, $p<0.001$). There were no significant differences in the demographic characteristics between patients who received leaflets in towns D and F, the two "general practitioner distribution" towns. For the most part, general practitioners and pharmacists failed to keep a record of the demographic characteristics of patients excluded from the study.

7.32 The effect of the source of the leaflet on its impact

Data from 354 interview schedules were examined for this part of the study. Two hundred and ten interviews with patients from town C (where leaflets were distributed by pharmacists) were included and in towns D and F (where leaflets were issued by general practitioners) 144 schedules were examined. One hundred and fifty NSAID takers received leaflets from their pharmacist whereas 82 received them from their general practitioner. Of the patients prescribed ß-adrenoceptor antagonists, 60 were given leaflets by a pharmacist and 62 received them from their general practitioner.

Patients' knowledge

Patients who were given a leaflet by a pharmacist knew more about their medicine than those who received a leaflet from their general practitioner (Table 7.3). Significantly more NSAID takers who received a leaflet from a pharmacist were aware of the correct dosage instructions ($X^2_1=6.72$, $p<0.01$), the need to take their medicine with food ($X^2_1=4.98$, $p<0.05$) and the dangers of sharing tablets with family or friends ($X^2_1=3.95$, $p<0.05$). The trend was in the same direction for the other items of knowledge assessed, with the exception of knowledge of the name of the medicine and awareness that the tablets should be kept out of childrens' reach.

By contrast, "improvements" in knowledge amongst patients given leaflets about ß-adrenoceptor antagonists by pharmacists did not achieve statistical significance

Table 7.3

Patients' knowledge about their medicine after receiving a leaflet from the pharmacist or from their general practitioner
(Numbers are those giving correct answers [percentages are shown in brackets])

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Total number	150	82	60	62
Name of medicine	77 (51.3)	49 (59.8)	46(76.7)	43 (69.4)
Purposes of therapy	148 (98.7)	80 (97.6)	58(96.7)	57 (91.9)
When to take it	122 (85.9)	61 (79.2) **	56(93.3)	61 (98.4)
Take with fluid	128 (90.1)	74 (96.1)	57(95.0)	62 (100.0)
Take with food	118 (83.1)	59 (76.6) *	-	-
What to do if dose is missed	87 (62.1)	39 (50.6)	35(58.3)	41 (66.1)

Table 7.3 (continued)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Storage out of reach of children	128 (90.1)	72 (93.5)	55(93.2)	55 (88.7)
Safe method of disposal	128 (90.1)	68 (88.3)	44(73.3)	49 (79.0)
Aware not to share medicines	137 (96.5)	67 (87.0) *	59(98.3)	61 (98.4)

* $p<0.05$, ** $p<0.01$ Missing values were excluded from the percentages

and some trends were in the other direction. (Slightly more patients were aware of the correct dosage instructions of this medicine, that tablets should be swallowed with fluid and what to do if a dose was missed if they received a leaflet from their general practitioner).

Knowledge of side-effects

More patients who received a leaflet from a pharmacist were aware of the side-effects of their medicine (Table 7.4). This trend was most marked amongst ß-adrenoceptor antagonist takers. Just over a quarter of the patients who received a leaflet from a pharmacist were aware that this type of medicine sometimes causes dizziness compared with only four (6.5%) of those who were given a leaflet by their doctor (X^2_1=6,83, $p<0.01$). Similarly, 9 patients (15%) knew wheezing was a potential side-effect if their leaflet came from a pharmacist compared with only 1 patient (1.6%) in the general practitioner leaflet distribution group (X^2_1=5.16, $p<0.05$). With the exception of rash, the trend was in the same direction for the other side-effects mentioned on both of these leaflets.

Patients' satisfaction

More patients were completely satisfied with the information they received about their medicine if they were given a leaflet at the pharmacy (Table 7.5). For both medicines, these findings were statistically significant (NSAIDs X^2_1 test for trend=31.89, $p<0.001$; ß-adrenoceptor antagonists X^2_1 test for trend=4.29, $p<0.05$).

Patients' reactions to the leaflets

Table 7.6 shows patients reaction to the leaflets. There was little difference in the number of patients who claimed to have read or kept the leaflet between the two groups. However, more patients who received a leaflet from the pharmacist were worried by it. This was particularly marked amongst patients prescribed ß-adrenoceptor antagonists, 12 (25%) of whom found the leaflet tab

Table 7.4.

Patients' knowledge of the side effects of their medicine : those who received leaflets from pharmacists compared with others who received leaflets from general practitioners (percentages are shown in brackets)

Medicine	NSAIDS			ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.		Pharmacist	G.P.
Total number	150	82		60	62
Aware of any side effects	70 (46.7)	29(35.7)		25 (41.7)	12 (19.4) *
Aware of individual side effects					
Stomach discomfort	55 (38.7)	21(27.3)	Dizziness	17 (28.3)	4 (6.5) **
Ringing in ears	18 (12.7)	3 (3.9)	Wheezing	9 (15.0)	1 (1.6) *
Dizziness	26 (18.3)	12(15.6)	Rash	6 (10.0)	3 (4.8)
Rash	7 (4.9)	6 (7.8)	Slow pulse	4 (6.6)	0 (0.0)

Table 7.4 (continued)

Medicine	NSAIDS			ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.		Pharmacist	G.P.
Wheezing	7 (4.9)	2 (2.6)	Sleeplessness or vivid dreams	12 (20.0)	2 (3.2)
Tarry stools	19 (13.4)	4 (5.2)			

* $p<0.05$, ** $p<0.01$

Questions were answered by 100% of respondents

Table 7.5

Satisfaction with information received about the medicine amongst patients who received leaflets from either a pharmacist or a general practitioner (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Total number	150	82	60	62
Satisfaction with information				
Completely satisfied	129 (86.0)	42 (51.2)	49 (81.7)	42 (67.7)
Satisfied	17 (11.3)	34 (41.5)	11 (18.3)	17 (27.4)
Indifferent	2 (1.3)	3 (3.7)	0 (0.0)	3 (4.8)
Dissatisfied	0 (0.0)	2 (2.4)	0 (0.0)	0 (0.0)
Completely dissatisfied	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	***		*	
Don't know	2 (1.3)	1 (1.2)	0 (0.0)	0 (0.0)

* $p<0.05$, *** $p<0.001$ Questions were answered by 100% of the respondents

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

Table 7.6

Patients' use of, and reaction to, the leaflets they received from either the pharmacist or their general practitioner (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Total number	150	82	60	62
Remembered receiving leaflet	127 (84.7)	75 (91.5)	50 (83.3)	58 (93.5)
Read leaflet	123 (96.8)	58 (77.3)	48 (96.0)	58 (100.0)
Kept leaflet	96 (75.6)	74 (98.7)	40 (80.0)	49 (84.5)
Found leaflet worrying	40 (32.5)	15 (20.3)	12 (25.0) **	2 (3.4)

** $p<0.01$ Missing values were excluded from the percentages

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

worrying when it came from a pharmacist compared with only 2 (3.4%) who expressed anxiety when it came from their general practitioners (X^2_1=8.84, p<0.01). Nevertheless, all but one of these patients thought the leaflet was a good idea.

Main sources of information about the medicine

Patients' main sources of information about NSAIDs and ß-adrenoceptor antagonists are shown in figures 7.1 and 7.2. Almost half of the patients who received a leaflet on NSAIDs cited the PIL as their main source of information about their treatment, as did over one third of those who received a leaflet on ß-adrenoceptor antagonists. Whilst the general practitioner remained a popular source of information, only around a half of those interviewed cited the doctor as their main source of information, even amongst the patients in the control group. One patient in the control town was very sure that the doctor was his main source of information; "I am satisfied with my GP (Dr. B) as I have regular checks and consultations with him and therefore complete faith in him follows. I have not had any precise information about the tablets **but** with faith in my doctor and my own feelings I have never needed to question this". By contrast, another patient in the same town said she "..had to telephone the chemist to find out information". However, under 5% of the patients in this study cited the pharmacist as their main information source about medicines.

Some of the patients implied they had heard about the side-effects of their tablets from other patients. "A friend with a similar complaint to mine is on the same tablets and she said she suffers from dizziness". Finally, a substantial minority of patients in the control town said they had not had any information about their medicine. One patient had solved the problem: "I have not been given any information by my general practitioners or the consultant. I found some information in my sister's copy of Mims".

Figure 7.1
Patients' main sources of information about NSAIDs

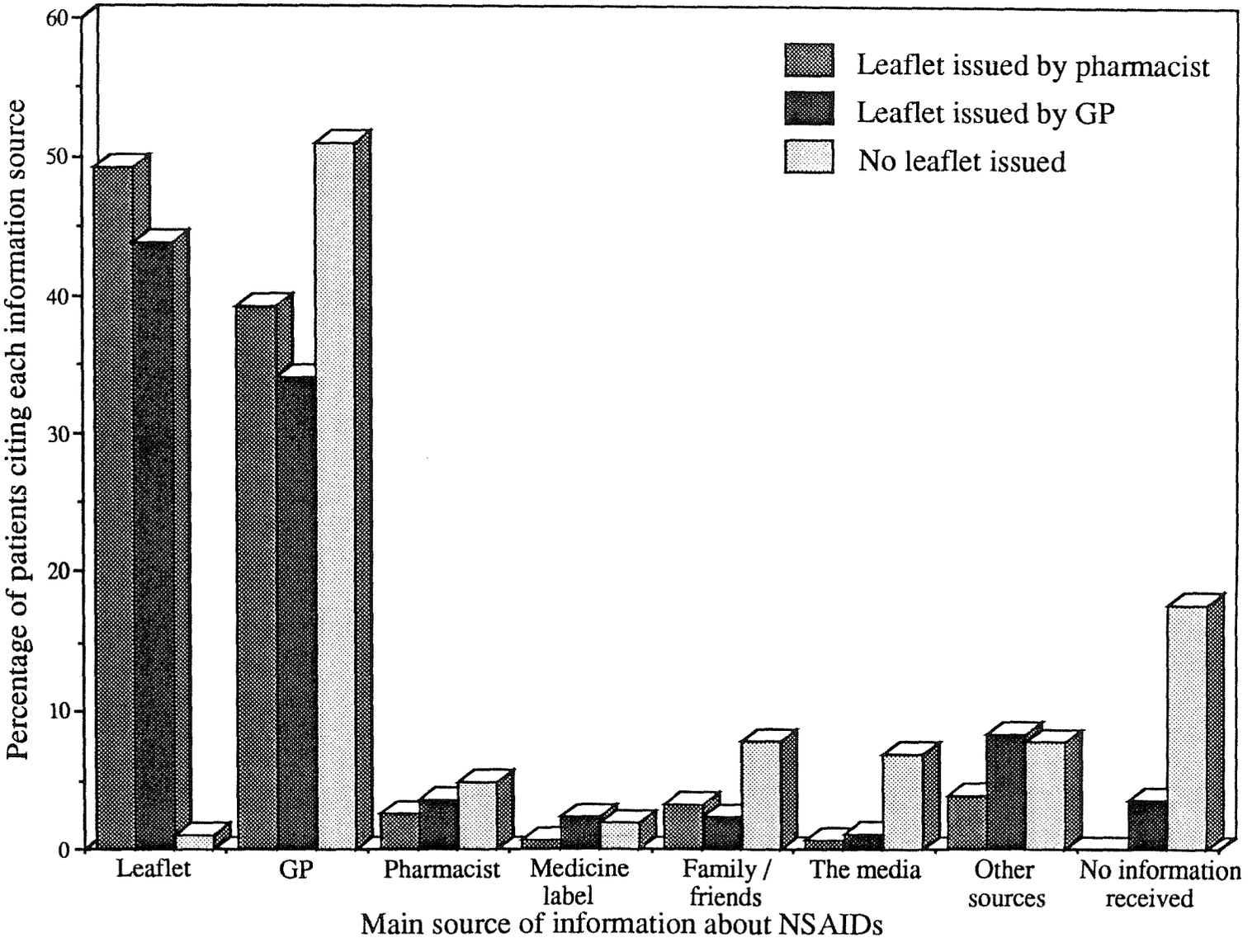
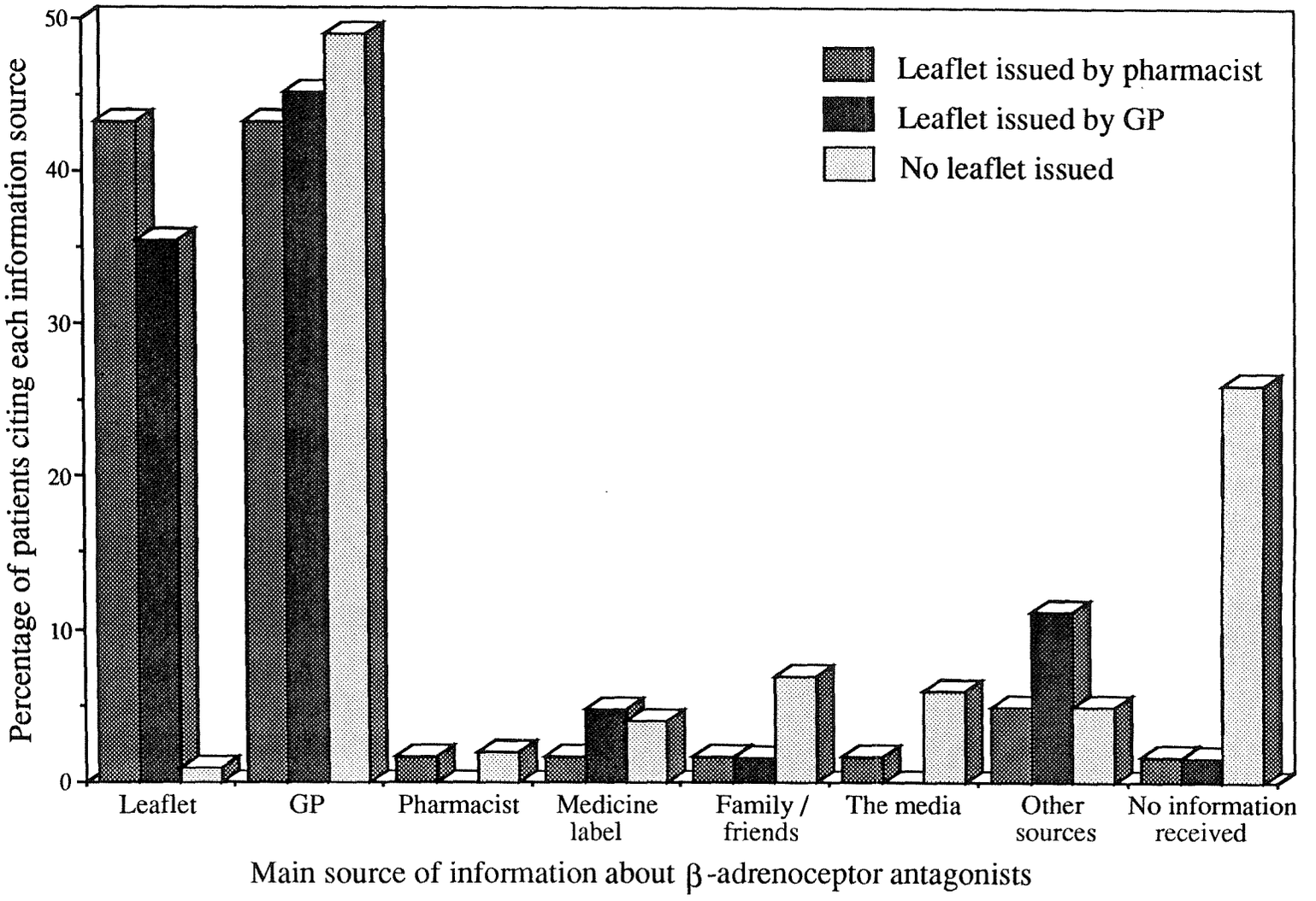


Figure 7.2
Patients' main sources of information about β-adrenoceptor antagonists



Would patients prefer leaflets to be issued by general practitioners or by pharmacists?

Patients' preferred source of leaflet is shown in table 7.7. A third of the patients did not mind whether a leaflet was issued by their doctor or by a pharmacist. Patients' preferences were strongly associated with their own experience. Almost half of those taking NSAIDs and around one third of the ß-adrenoceptor antagonist takers who had received a leaflet from a pharmacist thought leaflets should be issued in this way. By contrast, only a very few patients who had experienced general practitioner leaflet distribution were in favour of pharmacist leaflet distribution.

Table 7.7

Patients' preferred source of leaflet (percentages are shown in brackets)

Medicine	NSAIDS		ß-adrenoceptor antagonists	
Source of leaflet	Pharmacist	G.P.	Pharmacist	G.P.
Total number	150	82	60	62
Preferred source of leaflet				
Pharmacist	70 (46.7)	2 (2.4)	19 (31.7)	1 (1.6)
General practitioner	47 (31.3)	38 (46.3)	27 (45.0)	37 (59.7)
Either pharmacist or general practitioner	33 (22.0) ***	42 (51.2)	14 (23.3) ***	24 (38.7)

*** $p<0.001$ Missing values were excluded from the percentages

The asterisks (*) indicating significance levels refer to the totality of the data and not just the bottom line

7.4 DISCUSSION

In these studies neither the general practitioners nor the pharmacists issued leaflets to all of the patients who should have received them. Altogether, 70 general practitioners and 8 pharmacists were asked to give prescription information leaflets to patients in 6 towns (combined population of approximately 90,000) over a total survey period of 64 weeks. Only 845 leaflets were issued: that is approximately 13 leaflets per week. This was despite the six drug groups chosen being commonly prescribed in general practice.

The difficulties general practitioners experienced remembering to issue leaflets in the preliminary study were repeated. Only 15 leaflets for bronchodilators were issued by general practitioners in towns D and F over a period of 20 weeks. By contrast, 100 patients using these drugs were recruited in under 10 weeks in the control town, where no leaflets were issued. Even allowing for differences in the prevalence of asthma, the general practitioners must have failed to provide leaflets for many eligible patients. Similarly, the doctors distributed only just over half the number of NSAIDs leaflets issued by the pharmacists. Research on other aspects of general practitioner behaviour suggests that whilst there is interest in written material for patients (Tapper-Jones et al 1987), doctors may be unreliable when asked to perform routine tasks of this nature (Reynolds 1978; Acheson 1986). Not only did the general practitioners frequently appear to forget, but also to select the patients to whom they distributed the leaflets: doctors tended to distribute leaflets to older patients and, for NSAIDs, to those from a higher social class.

Pharmacists issued more leaflets than general practitioners. Nevertheless, it was clear from the audit of prescriptions that they were also an unreliable source of prescription information leaflets. For every patient who was given a leaflet by a pharmacist, there were four who did not get the information they should have received. For the most part, pharmacists and general practitioners forgot to

issue the leaflets.

In an American study reported by De Tullio et al (1986), provider-dispensed patient information leaflets resulted in higher levels of drug knowledge and greater satisfaction with knowledge than a pharmacy-dispensed leaflet. By contrast, patients' knowledge about their medicine and satisfaction with the information received were higher in the present study amongst those who received leaflets from pharmacists. There are several possible explanations for the greater impact of pharmacist distributed leaflets in this study. First, the issuing of a leaflet on top of previous verbal advice provided by the general practitioner may have enhanced the effect. It is generally recognised that written information has a greater impact when combined with verbal reinforcement, and that leaflets are best used to reinforce and amplify verbal consultation (Gatherer et al 1979; Mullen and Green 1984). Second, despite instructions for leaflets to be included in the bag with the medicine (the situation described by De Tullio et al 1986), it is possible that some pharmacists may have gone through the leaflet with patients. There was evidence from leaflet supplies in the pharmacies that keen pharmacists were giving out leaflets to patients who were not in the study. Third, the pharmacists distributed leaflets to a broader cross section of patients.

The patients' own experience of receiving a leaflet from a pharmacist or from the general practitioner strongly influenced his or her preference for one supplier or the other. Whereas only a tiny minority of patients given leaflets by their general practitioners favoured pharmacist leaflet distribution, there was considerable support for this method amongst patients who had themselves been in receipt of a leaflet from a pharmacist. Nevertheless, around half of the ß-adrenoceptor antagonist takers said they would prefer any leaflet about treatment to come from their doctor. This view was reflected by the patients who were worried by this leaflet when it came from a pharmacist. Several complained that the leaflet came "out of the blue" and that no discussion of the benefits and possible disadvantages of ß-adrenoceptor antagonists had taken

place with their doctor.

One third of the patients, however, did not mind whether their leaflet came from a pharmacist or the general practitioner so long as they got one. This finding is in agreement with an American survey of patient information about medicines, where respondents placed great importance on the pharmacist as well as the physician as preferred sources of drug information (Joubert and Lasagna 1975a), and a Norwegian survey, where one fifth of the hypertensive patients questioned preferred also to receive information from both the doctor and the pharmacist (Bakaas and Helgeland 1980). The leaflet was clearly perceived to be an important source of information about the prescribed medicine whether it was issued by a pharmacist or by a general practitioner.

In conclusion, the problems general practitioners and pharmacists experienced in issuing the leaflets emphasise the need for other more reliable methods of distribution to be considered. One solution might be to include the leaflet within the pack with the medicine.

CHAPTER 8

GENERAL DISCUSSION

CHAPTER 8

8.1 GENERAL DISCUSSION

There were four general aims of this research, all of which have been met. The first aim was to develop a format for prescription information leaflets which provided the different levels of information required by patients. A two-sided "details plus summary" design was developed (Chapter 3). This design was evaluated positively by patients and offered advantages over an alternative one-sided "details only" format.

Prescription information leaflets were produced for a range of medicines which are commonly prescribed in general practice. Thus, leaflets have been produced for non-steroidal anti-inflammatory drugs (NSAIDs), ß-adrenoceptor antagonists, inhaled bronchodilators, oral penicillins, diuretics and benzodiazepines. These drugs are taken by a wide variety of patients for a range of illnesses, including chronic conditions. Since, until recently, few patient-oriented leaflets have been available in this country, the present studies have extended the range of drugs for which patient information is now available.

The second aim of these studies was to evaluate the effects of prescription information leaflets in the setting of general practice. Specifically, the benefits and disadvantages of the 6 leaflets were evaluated in controlled trials described in chapters 4 and 5. In these, 671 patients received leaflets and a further 547 received no written information. One of the specific aims of these studies was to determine the effects of leaflets on patients' knowledge about their medicines. All 6 leaflets were associated with greater knowledge among patients who received them, a finding which adds further support to previous studies (Sackett et al 1975; Ellis et al 1979; Gotsch and Ligouri 1982; Ley and Morris 1984; Mullen et al 1985; Johnson et al 1986; Ley 1988). Knowledge of the side-effects was enhanced to a greater extent than the other items and, with the exception of benzodiazepines,

there was little evidence this knowledge produced spurious side-effects. These results add to the evidence from other studies which have failed to find a link between the reported incidence of side-effects and the provision of drug information (Myers and Calvert 1973; 1976; 1978; 1984; George et al 1983; Johnson et al 1986). It therefore seems unlikely that providing patients with written details of the common side effects of their medicines will encourage them to experience the symptoms about which they have read.

Too few patients experienced side-effects in the present studies for conclusions to be draw about whether or not leaflets encourage patients to stop their tablets and report to the doctors. However, more recent evidence suggests this may be an additional benefit of leaflets. Thus, Regner et al (1987) reported that a printed leaflet for digoxin enabled patients to decide to take the appropriate course of action if side-effects occurred. In another study, patients were given a leaflet by pharmacists which encouraged them to report any adverse reaction to their doctors. Reports of adverse reactions rose over the two-month study period (Campbell and Howie 1988). It appears that patients are able to discriminate adverse drug reactions from other symptoms to a significant degree (Solovitz et al 1987).

The leaflets tested in these studies gave information about a wide range of commonly prescribed medicines including drugs usually prescribed on a short-term basis (penicillins), medicines more often prescribed for long-term chronic conditions (ß-adrenoceptor antagonists, inhaled bronchodilators and diuretics) and other which are used both intermittently and on a long-term basis (NSAIDs and benzodiazepines). One of the aims of this research was to see if leaflets can improve patients' compliance with the dosage instructions. There was little evidence that any of the leaflets tested were associated with changes in medicine taking behaviour. These findings concur with many previous failed attempts to improve compliance with treatment for chronic conditions by the use of written information (eg Sackett et al 1975; George et al 1983). Leaflets have been found to encourage patients to take antibiotics correctly (George et al 1983; Dodds 1986)

but the design of the present studies involved a delay in obtaining consent from both the general practitioner and the patient. This meant that most penicillin patients had finished their short course medicine by the time they were visited and so no objective measurement of compliance was possible.

Previous research has concluded that written patient information is often more effective in terms of changing attitudes and behaviour when it is combined with verbal advice (Gatherer et al 1979; Haynes et al 1987; Leventhal and Cameron 1987; Smith et al 1987; Hunt and Martin 1988). It should be noted that the present study was not designed specifically to test this, but that the general practitioners and pharmacists who took part were encouraged to provide as much verbal information as was their normal practice. The finding that patient compliance was, for the most part, unaffected by leaflets issued in this context has several implications. Firstly, the assumption which underlies many previous studies, namely that telling patients what to do means they will follow the instructions is clearly simplistic. While ignorance of the correct dosage instructions may contribute to non-compliance, other factors may be more important. This has implications for the traditional doctor-patient relationship where the patient was seen as a passive receiver of care (Parsons 1951; Szasz and Hollender 1956). Second, we may need to rethink the type of information which will help patients to take their drugs as prescribed and understand the rationale behind their therapy. For instance, it is known that patients want information about their medical condition as well its treatment (Bakaas and Helgeland 1980; Fitzpatrick et al 1984; Ley 1988).

A further aim of these studies was to establish whether the use of leaflets improved satisfaction with the information received and with treatment in general. The most striking finding was the highly significant improvement in satisfaction with information received, particularly among those patients given PILs for NSAIDs and ß-adrenoceptor antagonists. However, similar trends were seen for inhaled bronchodilators, diuretics and benzodiazepines (but not for pencillins). From this and other studies it appears that patients are more satisfied if they feel

the information provided is important for them (De Tullio et al 1986). In the present study many of the penicillin takers felt that they were already well informed about their treatment. This finding tends to emphasise the need for patients to be consulted before the contents of leaflets are finalised.

The marked improvements in satisfaction with the information received are all the more impressive when viewed against the background of high overall levels of satisfaction (as are often found in general practice surveys) (Cartwright and Anderson 1981). Several explanations for the improvement seem possible. First, the leaflets tested in these studies were for the most part meeting patients' drug information needs or expectations. The finding that many patients found the leaflets helpful and evaluated them positively offers support to this explanation. Second, patients who received leaflets may have perceived they were receiving more attention (and therefore better care) than those who did not get written information. Third, it is possible that patients who received leaflets actually received more verbal information from doctors and pharmacists, and that this contributed to their overall satisfaction level. It was not within the scope of the present study to measure this variable, but there is a need for further research to explore the effect of written drug information on communication between doctors, pharmacists and patients.

Since others have reported links between satisfaction and compliance (Korsch et al 1968; Kincey et al 1975; Ley 1982; Smith et al 1987), it might be predicted that improved compliance should follow. But this was not the case in the present studies. Furthermore, the leaflets were not associated with improvements in other aspects of satisfaction, such as the medicine itself or with the consultation. Thus, even well designed leaflets about medicines cannot be expected to compensate for inadequate communication in other areas of medical practice. Nevertheless, the patients' subjective assessment of his treatment, and the adequacy or otherwise of the information provided about it, are increasingly being viewed as important outcomes in their own right (Fitzpatrick et al 1984).

In this context it is interesting to note that the majority of patients appreciated being given information about side-effects even though some found this worrying. For the most part, patients did not discontinue their treatment because they were anxious. Similar findings have been reported by Fleckenstein et al (1976) who identified a group of women who were worried about the possible deleterious effects oral contraceptives might be having on their health, but continued to take them. However, a significant minority of patients prescribed NSAIDs or benzodiazepines decided either not to start or to discontinue the treatment after receiving a leaflet. In the light of current controversy about over-prescribing from both of these drug groups (Somerville et al 1986; Steele et al 1987; Isacson et al 1988; Hawkey 1990) this may reflect patients feeling that the treatment was unnecessary. There was little evidence that the patients who discontinued treatment were giving up important therapy, although this possibly cannot be ruled out completely. It is also possible that patient information about the risks of therapy may ultimately affect the prescribing practices of the doctor. But patients' decisions clearly depend on how risk is interpreted. There is evidence that the way in which information is presented influences the way a risk is perceived (Fischoff et al 1981; Slovic et al 1981; Slovic et al 1989) but it is unclear at present how best to present such information.

Despite some patients being worried by the leaflets, they were widely read and evaluated positively by the majority who received them. Since one of the specific aims of the evaluation was to determine the effect of demographic variables on the impact of the leaflets, these findings are important. In addition, the data from the logit analysis appeared to suggest that the benefits of the leaflets extend to both sexes, all age groups and to those from the manual as well as the non-manual social classes. These findings have been confirmed recently in a larger nationwide survey of the effects of PILs (Gibbs et al 1990). There appears to be little evidence to support the reservations that have been expressed about the level of interest in written information amongst the elderly (Dodds and King 1989) or the usefulness of leaflets amongst the less well educated (Gatherer et al 1979).

The third general aim of this research was to investigate the long term effects of the leaflets on patients knowledge and satisfaction. This was met by the follow-up study reported in chapter 6. Whilst patients who originally received a leaflet about NSAIDs or ß-adrenoceptor antagonists were significantly better informed and more satisfied than those who were not given a leaflet 12 months previously, the level of knowledge and satisfaction had decreased over time. But many patients who were still taking their original medicine had kept their leaflet. These findings suggest that the leaflets were perceived as a reference material, to be consulted if and when the need arose (in the event of a suspected side-effect, for example), rather than as a text to be learned and retained in memory. In the light of these findings, it might not always be necessary the a doctor or pharmacist to re-issue an information leaflet with each repeat prescription. However, since only patients prescribed two of the drug therapeutic groups were followed over a 12 month period, it may not be possible to extrapolate these findings to a broader range of drug groups.

The final aim of these studies was to assess the feasibility of leaflet distribution by either general practitioners or pharmacists and to compare the effects of leaflets issued from these two sources. These issues were addressed in chapter 7. Although the debate about the desirability of prescription information continues, all the general practitioners and pharmacists who took part in the present studies welcomed the leaflets. For the most part, professional opinion is now in favour of providing patients with written drug information (George 1987). Indeed, the British Medical Association has recently published its own guide for patients on medicines (British Medical Association 1988) and drug information is increasingly available at pharmacies (Axon et al 1989). Moreover, plans for patient-oriented leaflets have been announced by the Association of the British Pharmaceutical Industry (1987), and there are moves to harmonise the information provided for patients about drugs throughout Europe (Anonymous 1989; Bogaert et al 1989; Anonymous 1990).

The general practitioners and the pharmacists who participated in the present studies frequently forgot to issue prescription information leaflets. There was also some evidence that some general practitioners were selecting "suitable" patients to receive leaflets, that is from the non-manual social classes and the older age groups. Since the doctors and pharmacists who took part were professionals with an expressed interest in providing information for patients, the experience of the present study suggests that less motivated general practitioners and pharmacists might experience more difficulty remembering to issue leaflets. However, it is possible that leaflets would be easier to remember if they became a routine part of care in general practice and community pharmacy, and if doctors and pharmacists were trained to provided them.

Another solution might be to include be an information leaflets in the pack with the medicine. A comparison of the effects of package inserts and prescription information leaflets was beyond the scope of the present study. However, it is possible that some of the benefits of leaflets issued by general practitioners during a consultation or handed out by the pharmacist when the medicine is dispensed may not apply to package inserts. Firstly, patients may receive package inserts without also being given verbal advice from a doctor or pharmacist. Since it is generally recognised that written drug information is best used to reinforce and amplify verbal consultation (Mullen and Green 1984), the impact of package inserts on patients may be reduced. Secondly, it is possible that package inserts may cause patients unnecessary anxiety if the benefits and risks of drug therapy have not been discussed with a doctor or pharmacist. Thirdly, patients may not read inserts which have been folded to fit into packs. One of the facets of the leaflets tested in the present study was that they were mounted on relatively stiff paper; it is not clear how much this factor contributed to the wide readership of PILs. A fourth difference between package inserts and the leaflets was that the leaflets were generic (that is they gave information about a group of related medicines rather than a particular drug). Product specific inserts may confer advantages since it is known that specific information is better absorbed and recalled than more general statements. However, information provided in product

specific inserts produced by the manufacturer may become promotional (Collier 1989). Indeed, a recent survey of leaflets submitted by pharmaceutical manufacturers to the Department of Health for approval revealed that in approximately one third of the leaflets inspected, the name of the medicine was judged as being unduly prominent (Brown 1989).

In the light of the problems experienced by pharmacists and general practitioners in remembering to issue leaflets, putting the information in the pack may be a more reliable way to ensure patients actually get the information, certainly in the short-term. However, the differences between package inserts and the leaflets tested in the present study deserve further research.

8.2 LIMITATIONS OF THE STUDIES

Several criticisms can be levelled at the studies reported in this thesis. Possible shortcomings relate to (i) the leaflets and (ii) the study design

(i) The leaflets

During the study it became apparent that some omissions had been made in the leaflets. For example, the possibility of cold extremities was not mentioned on the leaflet about ß-adrenoceptor antagonists, and neither was impotence. For the most part the omissions were minor. However, the benzodiazepine PIL requires revision to the advice about what to do if a dose is missed, since the existing statements could be confusing, especially when benzodiazepines are being used as hypnotics. In addition, in view of current concern about the over use of benzodiazepines, the leaflet might contain a statement encouraging patients to try alternative methods to reduce anxiety or relieve sleeplessness.

(ii) The study design

One criticism of these studies is that because (for practical reasons) they have been conducted in small towns in the south of England, extrapolation of the results to the rest of the country and to urban communities could be misleading.

However, this is unlikely since the benefits of leaflets have been confirmed recently in the north of England as well as the south and in "medium" sized and "large" towns, as well as their smaller counterparts (Gibbs et al 1990).

Second, women and those over 65 years were over-represented in the sample. These excesses were expected, since both groups consult their general practitioners more often and are prescribed more medicines than others in the general population (Ridout et al 1986; Dunnell and Cartwright 1972; Cartwright and Smith 1988). There was also a slight bias in favour of the non-manual social classes, as would be expected for a sample drawn from residents of small, rural Hampshire towns. In addition, general practitioners tended to select patients from the non-manual social classes for the study, who may have been better equipped to obtain benefit from the leaflet.

A third problem relates to the use of separate experimental and control towns. Differences between the towns may have influenced the effects of the leaflets. In order to minimise these differences, the towns chosen had similar sizes and population profiles, and were all located in the same part of the country (Hampshire). Whilst this problem may have been avoided if a "before and after" design had been employed or if a randomisation of patients into leaflet or no leaflet categories within each town had been conducted, the benefits of adopting a more elaborate design would have been heavily outweighed by several practical problems this would have imposed on the survey. First, the more complicated the design the smaller the numbers of patients in each group (eg Johnson et al 1986). Second, if leaflets were issued during alternate weeks in the same town it would have been very difficult to ensure that leaflets were distributed in the appropriate weeks and withheld in others (George et al 1983). Third, a randomised design would not have prevented contamination of the control group because of exchange of information between patients attending the same practices. Finally, since the general practitioners in the preliminary study experienced difficulty in remembering to issue leaflets at all, complicated procedures might have made the situation even worse. The study design was constrained also by the views of the

Wessex Faculty of the Royal College of General Practitioners, without whose cooperation the project could not have been conducted.

The method adopted in this study made it impossible to conduct the survey "blind". However, this would have been very difficult to achieve even if the study had been truly randomised. In practice, patients who received leaflets frequently revealed this fact to the interviewer early in the visit, despite questions about the leaflet being deliberately placed towards the end of the questionnaire

A fourth criticism of these studies is that it was not possible to assess differences in the behaviour of individual general practitioners, particularly the amount and quality of verbal information they provided. Despite being asked to give no more information than was their usual practice, there was some evidence that extra advice was given. For example, in town C, two patients who shared the same doctor had both been issued with a leaflet for β-adrenoceptor antagonists they had been taking for several months. During the interview, both commented that at their most recent visit the doctor had discussed treatment with them for the very first time. However, a major strength of the study was the context in which the leaflets were evaluated: namely the setting of British general practice.

Finally, there was potential for problems with the follow-up study. Since all patients had received a detailed interview it is possible this may have assisted assimilation of the PIL into long term memory. It would have been interesting to follow-up a further control group of patients who did receive a PIL but did not have an initial interview in order to assess the effects of the leaflet alone.

8.3 CONCLUSIONS

These studies represent the first large-scale systematic examination of prescription information leaflets (PILs) in the setting of British general practice. The production of generic PILs for six commonly prescribed medicines has extended the range of drug groups for which patient information is available in this country. PILs produced in accordance with guidelines for the design of technical information were welcomed by patients. A two-sided "details plus summary" format provided patients with the different levels of information they requested, as well as offering advantages in terms of improved knowledge and satisfaction over a one-sided "details only" version.

Patients who received leaflets were better informed about every item of knowledge tested, except for the name of the medicine. Awareness of the side-effects showed the greatest improvement but there was little evidence that leaflets produced spurious side-effects for five of the six therapeutic groups. Satisfaction with the information received was significantly improved, particularly amongst those who received leaflets for non-steroidal anti-inflammatory drugs and β-adrenoceptor antagonists. These improvements were still apparent 12 months after the original prescription for NSAIDs or β-adrenoceptor antagonists. Improved satisfaction and greater awareness of the side-effects appear to be the major beneficial effects of PILs: the leaflets were not, for the most part, associated with improvements in patients' compliance.

The finding that some patients (especially those prescribed NSAIDs for the first time) were alarmed by the side-effects listed on the leaflet is cause for slight concern. Nevertheless, almost all patients thought the introduction of leaflets would be a good idea. However, since general practitioners and pharmacists often forgot to issue the leaflets in these studies, it is recommended that leaflets be distributed in the pack with the medicine now that patient leaflets are to be provided with prescribed medicines (ABPI 1987).

8.4 OUTCOME OF THESE STUDIES

The studies reported in this thesis have contributed to the development of the Association of the British Pharmaceutical Industry (ABPI) guidelines on the drafting of patient information leaflets. The guidelines are reproduced overleaf.

The ABPI has recommended that patient information leaflets be produced by pharmaceutical manufacturers to be provided in the pack with the medicine as an insert. The form the inserts will take is based largely on the PILs tested in the present studies. Double-sided A5 leaflets are recommended, with a short easy to read summary on the front and a more detail on the reverse. The front of the leaflet is intended to be the easiest to read and to understand, and the guidelines reiterate the need for the most important points about the medicine to be included in this section. The detailed section of the leaflet contains the information suggested for inclusion in the presented studies (what the medicine is for; contraindications; how to take the medicine; common side-effects and what to do about them; advice about storage and disposal).

Some items of information not included in our PILs are suggested for inclusion in the inserts. The guidelines recommend that details about how to recognise whether a medicine is not working and what to do about it should be included, and that the ingredients- both active and inactive-should be listed. Other differences between the inserts and our PILs included: the suggestion that companies might be unspecific in the inserts about what the medicine is for where the indication is cancer, AIDs or another serious illness; the ABPI insert carries no reference to further publications which may be of help to the inquiring reader (the guidelines simply suggest that the procedure to be taken if further information is required should be stated); the inserts will be product specific rather than 'generic'; and finally the leaflets will be distributed in the pack with the medicine rather than issued by the general practitioner or the pharmacist as was the case in the present studies.

PATIENT INFORMATION: ADVICE ON THE DRAFTING OF LEAFLETS

The Association of the British Pharmaceutical Industry

12 Whitehall, London SW1A 2DY

(Reproduced with permission from the ABPI)

PATIENT INFORMATION: ADVICE ON THE DRAFTING OF LEAFLETS

INTRODUCTION

The prime reason for providing information leaflets is to improve patient understanding of the use of their medicines. Such leaflets should be succinct and intelligible. This advice is offered as an aid on how to draw up patient information leaflets. Compliance with this advice is highly recommended based on the research conducted by Professor Charles George at Southampton in this field. This research is well documented and forms the basis of the reasoning behind these guidelines. A high degree of consistency with this guidance is essential in view of possible implication for product liability.

All leaflets must comply with the current EC and UK regulations. The Schedule to the Medicines (Leaflets) Regulations 1977 SI 1055 appear as an Appendix. These guidelines are drafted to be consistent with the Regulations in respect of the content and layout of leaflets and have been the subject of discussions with the DHSS. Members of the Association will note particularly that Regulation 5 makes provision for the approval of the contents of leaflets by the Licensing Authority. Statutory information should not appear in the same sentence as non-statutory information.

There is support for the inclusion of appropriate Patient Information Leaflets in original packs and for their publication. Priority should be given to products already in original packs. For products about to be produced in original packs, leaflets should be included as they are introduced. It is envisaged that for other relevant products, leaflets will have been prepared by the end of 1988. The advice given specifically refers to medicines which are prescribed.

THE LAYOUT OF LEAFLETS

a The leaflets should be of uniform level of detail and layout. This should be A5 size, unless this is impracticable and should use both sides of the leaflet. One side should contain important and immediately relevant information. Supplementary and more detailed information necessary for the patient will normally be accommodated on the reverse side of the leaflet.

b The name of the product should not be unduly prominent or frequent in the text of the leaflet, and the leaflet should not be promotional for the product in nature or intent.

c Selective use of bold text will aid clarity.

d Sub-dividing the information into sections will make the leaflet more 'patient friendly'.

e Short, simple statements should be used as suggested by the Plain English Campaign.

THE CONTENT OF LEAFLETS

All leaflets must be consistent with the Product Licence, and include the name and address of the licence holder, or trading style as per the Product Licence, and the manufacturer where different. Each leaflet should have an identifying reference.

All leaflets should be product specific whether for branded or generic products.

The actual wording used in each of the sections that follows is for illustrative purposes, but is based on the Southampton leaflets.

An illustrative leaflet which incorporates the principal guidelines in this document is appended.

1 The Front of the Leaflet

a This should have a larger type face, and possibly use diagrams.

b It should refer the patient, where appropriate, possibly by the use of symbols, to more detailed information on the back of the leaflet.

c It should be headed up: 'What you should know about (brand name)'

followed by:
'Please read this carefully before you start to take your medicine. This leaflet provides a summary of the information available on your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.'

d It should state 'The name of this medicine is (brand name). It contains (generic name)'.

e This statement should then follow 'This is one in a group of medicines called (the general pharmacological and/or chemical category).'

f A section which should be headed up 'Things to remember about (therapeutic group)' should be followed by a maximum of five simple statements. This section is intended to be the easiest to read and understand, and so care must be taken to include the most important points about the medicine.

eg: This medicine may cause problems. You can find these listed on the back of the leaflet.

Do not take (eg penicillin) if you are allergic to it.

Keep taking your (eg penicillin) until it is finished. Don't stop just because you feel better.

Keep your medicine out of reach of children.

Follow your doctor's directions about when and how to take your medicine.

2 The Back of the Leaflet

a The back of the leaflet should be marked clearly as a continuation page, and again include the name of the medicine. eg: The name of your medicine is (brand name). Its active ingredient is (generic name). A quantitative statement on the strength of the active ingredient must also be made. It may be appropriate for a leaflet including visuals to depict the actual product.

b The general purpose and mode of action of the medicine should be listed. However, in cases where the indication is for cancer, AIDS or other serious illnesses companies may wish to be unspecific as to the nature of the condition being treated.

Where appropriate the clause: 'Doctors sometimes prescribe this medicine for other purposes; consult your doctor for information' should be added.

c Advice to inform the doctor if pregnant should be given at the start of the leaflet under a section 'Before You Take Your Medicine'. This should be stated on all leaflets.

d The leaflet should refer to the dosage instructions given by the doctor, eg: 'Follow your doctor's directions about when and how to take your medicine and look at the label. Your pharmacist may also help if you are not sure'.

e Method of administration should include details of how the medicine should be taken, eg with water, sucked or chewed, etc.

f The times of administration with particular reference to meals should be listed where appropriate. Advice should be given on what to do if a dose is missed; also action to be taken in case of overdosage.

g The duration of the therapy should be detailed as appropriate for the medicine. For example, in the case of antibiotics: 'Keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop the tablets your condition may get worse', or in the case of benzodiazepines a simple statement of 'Have you been taking these tablets for four weeks or more? If you have, make sure you talk to your doctor about it.'

h Important contra-indications and precautions that should be taken during the duration of the therapy should be given. These should include where appropriate the avoidance of driving, use of heavy machinery, the avoidance of alcohol and in the case of photosensitising medicines, the avoidance of strong sunlight. Appendix 4 of the British National Formulary, which lists all mandatory precautionary and advisory labels affixed by the dispensing pharmacist, provides guidance in this respect. Other items under this section should also include concomitant medication, contraceptive pill, pregnancy and breast feeding. Any information which is indicated in the Product Licence as needing to be communicated to the patient must be included.

Clinically significant or potentially dangerous interactions with other medicines or foods should be listed.

i A succinct summary of side effects important and recognisable to the patient and what to do if they should occur should be given:

section 1—those side effects which are well-recognised and about which the patient need not be worried and need only consult the doctor if the symptom becomes troublesome—for example a dry mouth with tricyclic antidepressants.

section 2—those which would be cause for concern and about which the patient should be directed to see his doctor.

A statement should be made, where appropriate, that should the patient experience any other unusual or unexpected symptoms he should see his doctor.

j A statement on how to recognise whether a medicine is not working and what to do about it should be included. This section should be used if and as appropriate to the medicine being discussed in the leaflet. If it is considered that this section is irrelevant it should be left out. On medications which take some time to be effective a statement that: 'This medicine takes some time to work, but if you do not improve after . . . days/weeks you should see your doctor,' should also be included.

k The methods of storage and disposal of medicines should be stated.

This should always include advice such as the following:

'Keep this medicine in a safe place where children cannot reach it. Your medicines could harm them'.

'Keep this medicine in a cool and dry place'.

'If your doctor decides to stop treatment, return any left over medicine to the pharmacist or, in the case of small quantities of tablets or capsules, flush them down the toilet. Only keep them if the doctor tells you to'.

'A reminder: **REMEMBER** this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It many harm them even if their symptoms are the same as yours'.

l Relevant details of formulation should be included particularly the presence or absence of potentially sensitising inactive ingredients as detailed in the report on inactive ingredients produced by the ABPI (compliance with the recommendations of this report should be indicated). This could be included in a section headed 'What's in your medicine?', in which the quantitative statement of active ingredients which is required by statute could also appear.

m The procedure to be taken if further information is required should be stated. A simple statement such as: 'This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information', should be included.

n The leaflet should declare that it has been produced in accordance with guidance issued by the Association of the British Pharmaceutical Industry. It should also state that the information given in it applies only to (Brand name).

o The above information includes that which is required by statute, which should be readily identifiable in the leaflet.

p The leaflet should clearly state the name and address of the company holding the Product Licence.

THE PRODUCTION OF LEAFLETS

a Companies should ensure that the approval of patient information leaflets within the company is in line with the existing company mechanism for the approval of packaging, advertising and/or data sheets. This should always include review by a doctor or pharmacist.

b Companies should be encouraged to liaise with other companies producing leaflets for similar or identical products in order to achieve compatibility of layout and text. Companies should then review any common text to ensure that the details are accurate for their own product.

This is for illustrative purposes only

What you should know about Bloggofen

Please read this carefully before you start to take your medicine. This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is Bloggofen (generic name)
This is one in a group of medicines called Anti-Inflammatory Analgesics. These can relieve pain such as headache, toothache, arthritis and period pain.

Things to remember about Bloggofen

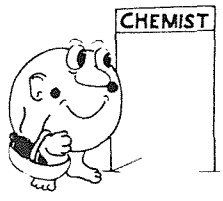
1 Make sure it is safe for you to take Bloggofen *(see the back of this leaflet).* ◆

2 Take your medicine
as directed by your doctor and look at the label on your medicine.

3 Bloggofen sometimes cause problems.
You can find these listed on the back of this leaflet. ★

4 Keep your medicine **out of reach of children.**

5 Remember to return any unused tablets to your pharmacist or flush them down the toilet.



You will find more about Bloggofen on the back of this leaflet. *Reg. No:*

Bloggofen is an Anti-Inflammatory Analgesic. Anti-Inflammatory Analgesics can relieve pain such as headache, toothache, arthritis, and period pain. Doctors sometimes prescribe this medicine for other purposes; consult your doctor for information.

◆ Before taking your medicine

- Are you already taking aspirin or another drug used to treat arthritis?
- Have you had an allergic reaction or wheezing after taking aspirin?
- Have you experienced stomach discomfort, felt like being sick or had heartburn after taking aspirin?
- Have you had a stomach ulcer previously?
- Are you on medicines for thrombosis (eg Warfarin) or gout?
- Are you pregnant?
- Do you suffer from liver or kidney disease?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. You must take it as directed by your doctor. The label will tell you how much to take and how often. If it doesn't or you are not sure, *ask your doctor or pharmacist.*
- Tablets should be swallowed with a glass of water or milk, after meals. The first dose of the day may be taken before breakfast.
- If you forget to take a dose take another as soon as you remember. Then go on as before.
- In the event of an accidental overdose contact your nearest hospital casualty department or tell your doctor immediately.

★ After taking your medicine

This medicine sometimes causes side-effects in some people.
If you get any of the following, stop taking the tablets and tell your doctor.

- Skin troubles such as rash or itching for the first time.
- Wheezing.
- You develop stomach discomfort or heartburn for the first time.
- You vomit blood or pass tarry stools.

Storing your medicine

- Keep your tablets in a safe place where children cannot reach them. Your tablets could harm them.
- If your doctor decides to stop the treatment, return any left over tablets to the pharmacist or flush them down the toilet. Only keep them if your doctor tells you to.

What's in your medicine

- Bloggofen tablets are purple in colour and come in three sizes containing either x mg, y mg, or z mg of approved name(s) of active ingredient(s).
- They contain the following preservatives or other inactive ingredients.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

The Product Licence for Bloggofen is held by (name and address)
The leaflet is produced in accordance with guidance issued by the Association of the British Pharmaceutical Industry. The information in it applies only to Bloggofen.

APPENDIX

SCHEDULE

Regulation 3

Particulars required to be included in leaflets

1. The appropriate non-proprietary name of the proprietary medicinal product (if any) and a proprietary designation.

2. A statement of the appropriate quantitative particulars of the proprietary medicinal product and, where ingredients other than active ingredients are stated, distinguishing between such ingredients as are and such ingredients as are not active ingredients and, where the quantities stated are those from which the product has been prepared, such quantities being preceded by a statement to that effect, except that where any medicinal product or ingredient is identified by reference to a name, or abbreviation of a name, at the head of a monograph in a specified publication and the quantity of that product or ingredient is stated, the requirements of this paragraph shall be regarded as having been complied with.

3. Where any ingredient has an international non-proprietary name, that name, except that particulars of the international non-proprietary name shall not be required to be given where there is an insignificant difference between the spelling of that international non-proprietary name and such name at the head of a monograph or approved synonym or approved name.

4. Directions for use of the proprietary medicinal product.

5. Therapeutic indications for the proprietary medicinal product.

6. Contra-indications, warnings and precautions including any contra-indications, warnings and precautions required to be given by the provisions of any product licence relating to the proprietary medicinal product and thereby required to be addressed to the person to or by whom the product is to be administered.

7. Any special requirements for the handling and storage of the proprietary medicinal product.

8. (*a*) The name and address of the holder of the product licence which relates to the proprietary medicinal product or the business name and address of the part of his business that is responsible for its sale or supply, or

(*b*) where the provisions of the product licence which relates to the proprietary medicinal product or a manufacturer's licence authorising the assembly of the product permit, or where the proprietary medicinal product is assembled by or under the supervision of a pharmacist in accordance with the provisions of section 10(1)(*b*) or 10(6) of the Act, the name and address of a person who sells the proprietary medicinal product by retail or supplies it in circumstances corresponding to retail sale.

9. The name and address of the person who has manufactured the proprietary medicinal product and, if different therefrom, the name and address of the person in the course of whose business the proprietary medicinal product was enclosed in its container, except that such requirement shall be treated as having been complied with if:

(*a*) one person only has manufactured the proprietary medicinal product, or

(*b*) more than one person has manufactured medicinal products of the same description as the proprietary medicinal product and the licensing authority have been notified of the names of the persons who have manufactured medicinal products of the same description and have directed that the name and address of any such person may be omitted.

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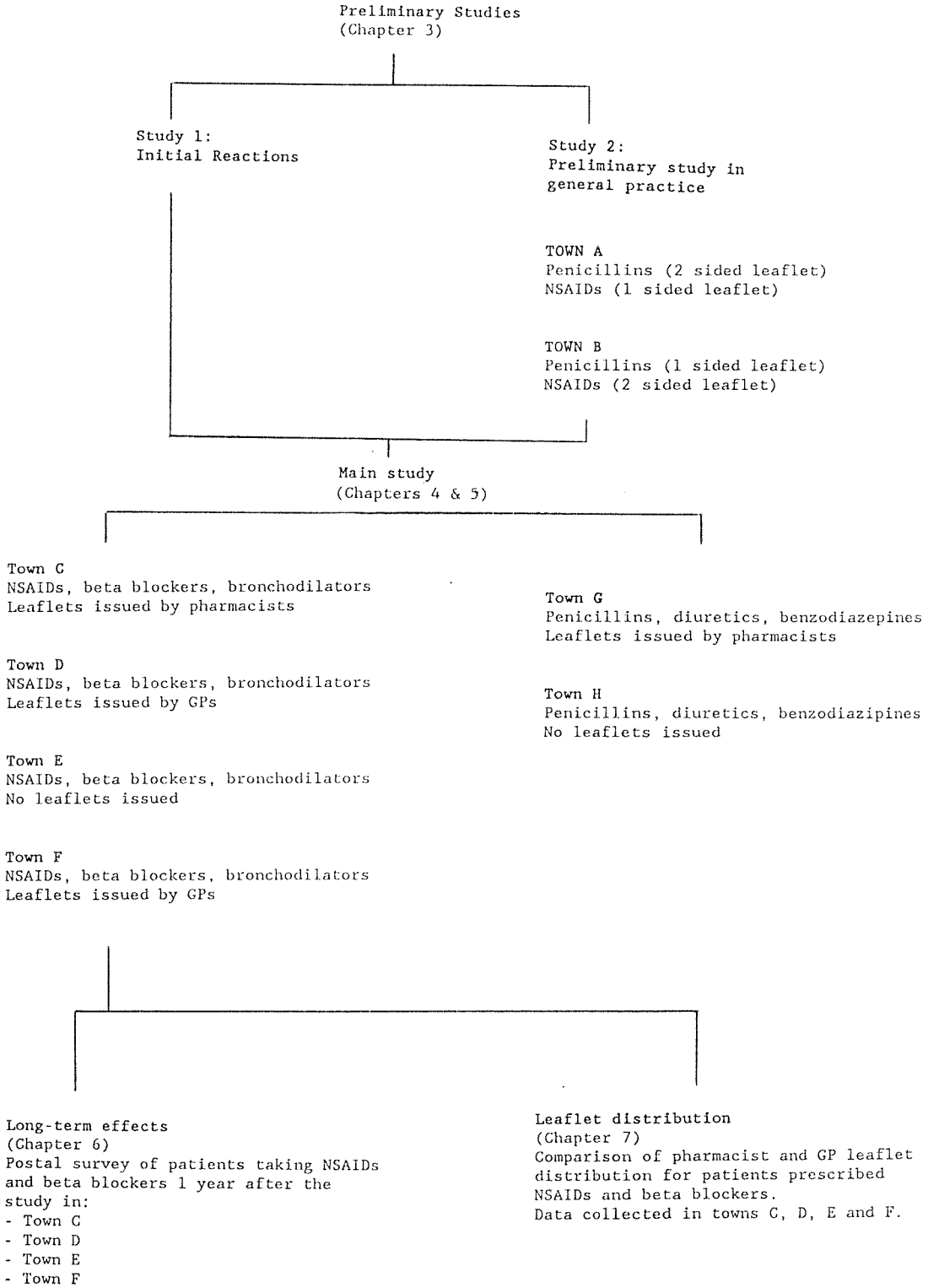
Addendum

Study Design



Addendum

Confidence Intervals

Associations were tested in the studies reported in this thesis using the Chi-squared statistic (with Yates correction for 2x2 tables). The statistical significance of the association was determined and P values were presented. After taking statistical advice, confidence intervals were not calculated.

At the viva voce examination, the examiners were of the opinion that whilst the calculation of confidence intervals was not essential for the interpretation of the results, they would provide the discerning reader with useful additional information about the strength of the reported associations.

This view is in agreement with the recent trend towards the expression of results in the form of confidence intervals rather than hypothesis tests (Gardener and Altman 1989). 95% confidence intervals have therefore been calculated for selected results using the Chi programme (Medical Statistics and Computing, Southampton University). These are presented below:

Table	Medicine	Item	P	Difference in proportions	95%CI
4.3	NSAIDs	Take with food	*	0.12	0.01-0.23
4.4	NSAIDs	Know side-effects	***	0.27	0.18-0.37
4.4	Beta blockers	Know side-effects	***	0.18	0.08-0.29
4.4	Bronchodilators	Know side-effects	**	0.19	0.05-0.33
4.11	NSAIDs	Satisfaction	***	0.38	0.27-0.49
4.11	Beta blockers	Satisfaction	***	0.38	0.26-0.50
4.11	Bronchodilators	Satisfaction	**	0.22	0.06-0.37
5.3	Penicillins	Take on empty stomach	***	0.25	0.13-0.38
5.3	Penicillins	If dose missed	***	0.28	0.16-0.40
5.3	Penicillins	Safe storage	*	0.18	0.07-0.29
5.3	Diuretics	Safe storage	**	0.15	0.06-0.24
5.3	Benzodiazepines	When to take	*	0.18	0.02-0.34
5.3	Benzodiazepines	Sharing medicines	*	0.13	0.02-0.25
5.4	Penicillins	Know side-effects	***	0.26	0.12-0.40
5.4	Diuretics	Know side-effects	***	0.21	0.10-0.31
5.4	Benzodiazepines	Know side-effects	*	0.24	0.05-0.43
7.5	NSAIDs	GPvsPharm satisfaction	***	0.35	0.23-0.47
7.6	Beta blockers	GPvsPharmacist worried	**	0.17	0.06-0.28

Additional Reference

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British Medical Journal: London

APPENDICES

Appendix 1

Interview schedule

ID No. [ ][ ][ ][1]
1 2 3 4

Questionnaire on Medicines

Introduction

My name is ..... and I am a research worker from Southampton University.

I understand that you have visited your doctor recently. He/she may have mentioned that we are conducting a survey of medicines commonly prescribed by doctors.

Would you mind answering a few questions about your medicine? This should not take more than 20 minutes. Thank you.

FOR COMPLETION BEFORE INTERVIEW

Pharmacy [ ][ ] 5 6

FROM PRESCRIPTION

Medicine (record name) .....

PENICILLINS = 1
NSAID = 2
BETA BLOCKERS = 3
BRONCHODILATORS = 4
DIURETICS = 5
BENZODIAZEPINES = 6
CORTICOSTEROID CREAMS = 7

[ ] 7

Dosage .....
.....

Quantity .....

Date of consultation .....
Date dispensed ..... Put days since
Date of interview ..... medicine dispensed in box

[ ][ ] 8 9

Doctor [ ][ ] 10 11

Practice [ ][ ] 12 13

Patient's sex Male = 1 Female = 2 [ ] 14

DATA COLLECTION

Personally conducted = 1
Telephone = 2
Unable to contact = 3
Refusal = 4

[ ] 15

IF REFUSAL, GIVE REASON .....

Interviewers code Sharon = 1 Clare = 2 [ ] 16

SECTION 1: PERSONAL DETAILS

I'd like to start with a few details about yourself.

1.1 Could you tell me your date of birth? Put age in Box

..... N/A = 888

17 18 19

1.2 Are you: Married? = 1
Single? = 2
Widowed? = 3
OR Divorced? = 4
N/A = 8

20

1.3 How old were you when you left full time education?

Put age in Box

..... N/A = 88
D/K = 99

21 22 23

1.4 I'd like to ask you about smoking cigarettes.

Do you smoke now? = 1
Have you given up? = 2
OR Have you never smoked? = 3
N/A = 8
D/K = 9

24

IF GIVEN UP SMOKING

1.5 Did you give up smoking mainly:

For health reasons? = 1
For financial reasons? = 2
OR For other reasons? = 3
N/A = 8
D/K = 9

25

1.6 What does the main wage earner in this household do for a living?

RECORD ANSWER IN FULL, INCLUDING RANK AND POSITION

.....
.....
.....
.....

IF RETIRED OR UNEMPLOYED

1.7 What was the most recent employment?

.....
.....
.....
.....

CODE LATER

CLASS I = 1
II = 2
IIINM = 3
IIIM = 4
IV = 5
V = 6
Unclassifyable = 7

26

SECTION 2: ABOUT THE MEDICINE

Now I'd like to move on to talk about your medicine.

2.1 Can I see the medicines or tablets which you were prescribed by your doctor?

Yes = 1
No = 2
N/A = 8

27

INTERVIEWER HOLDS ON TO MEDICINE

IF MEDICINE CONTAINER NOT SEEN

2.2 Why can't I see your medicine?

disposed of = 1
lost = 2
kept elsewhere = 3
telephone interview = 4
other reason = 5
(specify) .....
no reason given = 6
N/A = 8
D/K = 9

28

IDENTIFY MEDICINE IN QUESTION

2.3 Is this medicine for a child (under 16 years old)?

Yes = 1
No = 2
N/A = 8
D/K = 9

29

IF YES

2.4 What is your child's date of birth? Put age in Box
..... N/A = 888

30 31 32

2.5 What is your medicine called? **CHECK WITH PRESCRIPTION**
..... specific name given = 1
..... group name given = 2
N/A = 8
DK/incorrect name = 9

33

2.6 What did the doctor give you this medicine for?
RECORD REASON IN FULL
.....
.....
.....
.....
Yes = 1
N/A = 8
No/DK = 9

34

2.7 Can you remember ever taking this medicine before?

Yes = 1
No = 2
N/A = 8
D/K = 9

35

IF YES

2.8 When was the last time you took it?

within the last year? = 1
1-5 years ago? = 2
More than 5 years ago? = 3
N/A = 8
D/K = 9

36

2.9 Have you been taking it continuously up to the present day?

IF NO

2.10 How long did you take it for last time?

less than 1 month? = 1
1-6 months? = 2
more than 6 months? = 3
taking it continuously = 4
N/A = 8
D/K = 9

37

2.11 Have any of your family or friends ever had this medicine?

.....

Yes = 1
No = 2
N/A = 8
D/K = 9

38

2.12 Have you started taking your medicine yet?

Yes = 1
Not started new batch = 2
Not at all = 3
N/A = 8
D/K = 9

39

PILL COUNT/MEDICINE ESTIMATION

IF MEDICINE CONTAINER SEEN

Now I'd like to check your medicine.
As part of our research, we are conducting a routine check of how your medicine was dispensed.

2.13 **PILL COUNT/MEDICINE ESTIMATION**

MEDICINE REMAINING

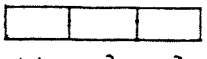
INTERVIEWER RETURNS MEDICINE TO PATIENT

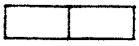
CODE LATER

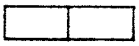
ASSESSMENT OF COMPLIANCE

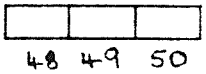
pill count = 1
medicine estimation = 2
patient estimation = 3
N/A = 8

CALCULATION OF COMPLIANCE

Amount dispensed = 

Amount expected to take = no. days since dispensed x no. tabs. per day = 

Amount taken = amount dispensed − amount left = 

Extra tabs/tabs missed = amount taken − amount expected = 

$$\text{Compliance \%} = \frac{\text{amount taken}}{\text{amount expected to take}} \times 100 = \square\square\square$$

N/A = 888

SECTION 3: MEDICINE TAKING

IF THE MEDICINE STARTED GO TO 3.5 (PAGE 9)

IF MEDICINE NOT STARTED

3.1 What was your main reason for deciding not to start the medicine?

felt better = 1
forgot/inconvenient = 2
leaflet = 3
don't like taking medicines = 4
disagree with diagnosis = 5
disagree with choice of medicine = 6
other (specify) ..... = 7
N/A = 8
D/K = 9 ☐ 54

3.2 Have you, or any of your family and friends ever experienced any problems in the past with this medicine?
If yes (specify) .....
.....
.....
Yes = 1
No = 2
N/A = 8
D/K = 9 ☐ 55

3.3 Are you aware of any side effects which may happen when people take this medicine?

seeing things hazy or blurred
M = 1
NM = 2
N/A = 8 ☐ 56

wheezing or shortness of breath
M = 1
NM = 2
N/A = 8 ☐ 57

dizziness or unsteadiness
M = 1
NM = 2
N/A = 8 ☐ 58

feeling sick or being sick
M = 1
NM = 2
N/A = 8 ☐ 59

skin trouble (e.g. itching or rash
M = 1
NM = 2
N/A = 8 ☐ 60

heartburn or stomach ache
M = 1
NM = 2
N/A = 8 ☐ 61

pains in the joints
M = 1
NM = 2
N/A = 8 ☐ 62

cold or numb fingers or toes — M = 1, NM = 2, N/A = 8 — [ ] 63

increased depression — M = 1, NM = 2, N/A = 8 — [ ] 64

ringing or buzzing in the ears — M = 1, NM = 2, N/A = 8 — [ ] 65

feeling more drowsy than usual — M = 1, NM = 2, N/A = 8 — [ ] 66

feeling more worried or nervous than usual — M = 1, NM = 2, N/A = 8 — [ ] 67

headache — M = 1, NM = 2, N/A = 8 — [ ] 68

bowel complaints (diarrhoea or constipation) — M = 1, NM = 2, N/A = 8 — [ ] 69

tarry stools or vomiting blood — M = 1, NM = 2, N/A = 8 — [ ] 70

others (specify) ..... — M = 1
..... — NM = 2
..... — N/A = 8 — [ ] 71

3.4 When taking this medicine, do you think it is necessary for patients to:

avoid drinking alcohol? — Yes = 1, No = 2, N/A = 8, D/K = 9 — [ ] 72

avoid driving? — Yes = 1, No = 2, N/A = 8, D/K = 9 — [ ] 73

avoid operating machines? — Yes = 1, No = 2, N/A = 8, D/K = 9 — [ ] 74

avoid eating certain foods? — Yes = 1, No = 2, N/A = 8, D/K = 9
(Specify) .....
..... — [ ] 75

avoid taking other medicines? Yes = 1
(Specify) ..... No = 2
..... N/A = 8
..... D/K = 9 ☐ 76

avoid anything else? Yes = 1
(Specify) ..... No = 2
..... N/A = 8
..... D/K = 9 ☐ 77

GO TO SECTION 6

ID No. [| | | 2]
1 2 3 4

IF MEDICINE STARTED

Now I'd like to ask you some questions about taking your medicine.

3.5 Are you still taking your medicine now?

Yes = 1
No = 2
N/A = 8

[ ] 5

IF STOPPED MEDICINE

3.6 Why did you stop the medicine?

finished all the medicine = 1
took the prescribed amount = 2
felt better = 3
had side effects = 4
ran out of medicine = 5
felt the medicine was not working = 6
had another reason = 7

(Specify).....
.....
.....

N/A = 8
D/K = 9

[ ] 6

3.7 How many days did you take it for?

..... **PUT NUMBER IN BOX**

N/A = 88
D/K = 99

[|] 7 8

Now I'd like you to think back to yesterday (or the last day you took the medicine).

3.8 How many doses of you medicine did you take yesterday?

.....

3.9 And at each dose, how much medicine did you take?

.....

3.10 And at what times of the day did you take your medicine yesterday?

RING RESPONSE AND ROUND UP TO THE NEAREST HOUR

1 2 3 4 5 6 7 8 9 10 11 12 am
1 2 3 4 5 6 7 8 9 10 11 12 pm

3.11 did you take your medicine yesterday:

before your meals? = 1
after your meals? = 2
with your meals? = 3
OR not in connection with your meals? = 4
N/A = 8
D/K = 9

[ ] 9

3.12 Did you take your medicine:

with water? = 1
with another drink? = 2
on its own? = 3
N/A = 8
D/K = 9

[ ] 10

DOSAGE CODING **CHECK WITH PRESCRIPTION**

taken as directed = 1
dose reduced = 2
dose increased = 3
spacing of doses error = 4
regimen totally altered = 5
other = 6

(specify) .....

N/A = 8
D/K = 9 ☐ 11

3.13 Would you say you are following/did follow the dosage instructions for this medicine

completely? = 1
mostly? = 2
OR not at all? = 3
N/A = 8
No instructions/ D/K = 9 ☐ 12

3.14 Since you last saw the doctor, have you forgotten to take your medicine:

often? = 1
sometimes? = 2
OR never? = 3
N/A = 8
D/K = 9 ☐ 13

3.15 If you discovered you had forgotten to take your medicine, would you:

take it when you remembered it? = 1
take a double dose next time? = 2
miss it out altogether? = 3
OR do anything else? = 4

(Specify) .....
.....

N/A = 8
D/K = 9 ☐ 14

3.16 Have you found it necessary to cut down your dose at all?

Yes = 1
No = 2
N/A = 8
D/K = 9 ☐ 15

IF LESS MEDICINE TAKEN

3.17 Why did you find it necessary to cut down the dose?

felt better M = 1
NM = 2
N/A = 8 ☐ 16

side effects (specify) ..... M = 1
..... NM = 2
..... N/A = 8 ☐ 17

medicine too strong M = 1
NM = 2
N/A = 8 ☐ 18

attitude to medicines — M = 1, NM = 2, N/A = 8 — 19

other reason (specify) ..... — M = 1, NM = 2, N/A = 8 — 20

3.18 Have you needed to increase the dose at all?

Yes = 1
No = 2
N/A = 8
D/K = 9 — 21

IF MORE MEDICINE TAKEN

3.19 Why did you find it necessary to increase the dose?

felt better with medicine — M = 1, NM = 2, N/A = 8 — 22

medicine not working — M = 1, NM = 2, N/A = 8 — 23

attitude to medicines — M = 1, NM = 2, N/A = 8 — 24

other reason (specify) ..... — M = 1, NM = 2, N/A = 8 — 25

3.20 Is there anything about the medicine that makes it unpleasant or difficult to take?

Yes = 1
No = 2
N/A = 8
D/K = 9 — 26

IF YES

3.21 What is it about taking this medicine that makes it unpleasant or difficult?

taste/smell — M = 1, NM = 2, N/A = 8 — 27

difficulty swallowing — M = 1, NM = 2, N/A = 8 — 28

after effects — M = 1, NM = 2, N/A = 8 — 29

difficult to remember — M = 1, NM = 2, N/A = 8 — 30

attitude to medicines

M = 1
NM = 2
N/A = 8

31

other reason

M = 1
NM = 2
N/A = 8

32

IF STILL TAKING MEDICINE

3.22 How long do you think you will be taking this medicine for?

Less than 2 weeks = 1
Up to 3 months = 2
More than 3 months = 3
Life = 4
N/A = 8
D/K = 9

33

3.23 If someone else had the same symptoms as you, would you give them some of your medicine?

Yes = 1
No = 2
N/A = 8
D/K = 9

34

SECTION 4: STORAGE AND DISPOSAL

Now I'd like to ask you a few questions about where you keep you medicine.

4.1 Where do you keep this medicine?

kitchen = 1
bathroom = 2
bedroom = 3
living room = 4
handbag/pocket/briefcase = 5
car = 6
other = 7
(specify) .....
N/A = 8
D/K = 9 ☐ 35

4.2 And where exactly in the room is it kept?

Out of reach = 1
Not out of reach = 2
N/A = 8
D/K = 9 ☐ 36

4.3 What should people think about when deciding where to keep their medicines?

out of reach of children
M = 1
NM = 2
N/A = 8 ☐ 37

near some water
M = 1
NM = 2
N/A = 8 ☐ 38

easy to remember to take it
M = 1
NM = 2
N/A = 8 ☐ 39

dry, cool place
M = 1
NM = 2
N/A = 8 ☐ 40

medicine always with them
M = 1
NM = 2
N/A = 8 ☐ 41

others (specify) .....
.....
.....
M = 1
NM = 2
N/A = 8 ☐ 42

4.4 What is your main reason for keeping your medicine here?

out of reach of children = 1
near some water = 2
easy to remember to take it = 3
dry, cool place = 4
medicine always with you = 5
other reason = 6
(specify) .....
N/A = 8
D/K = 9 ☐ 43

4.5 Are there any young children (under 10 years old) living in this house or regularly visiting, e.g. grandchildren, friends children?

Yes = 1
No = 2
N/A = 8
D/K = 9

44

I'd now like to ask you about left-over medicine.

4.6 What should people do with any medicine they have left over?

return it to the chemist = 1
flush it down the toilet = 2
throw it in the dustbin = 3
throw it on the fire = 4
keep it = 5
give it to someone else = 6
(specify) .....
do something else with it = 7
(specify) .....
N/A = 8
D/K = 9

45

4.7 What <u>will you</u> do with this medicine if you have any left over?

return it to the chemist = 1
flush it down the toilet = 2
throw it in the dustbin = 3
throw it on the fire = 4
keep it = 5
give it to someone else = 6
(specify) .....
do something else with it = 7
(specify) .....
N/A = 8
D/K = 9

46

ID NO. 3 (1 2 3 4) 15

SECTION 5: SIDE EFFECTS

Now I'd like to ask you some questions about your health over the past week.

5.1 I will read out a list of common health problems. I'd like you to tell me if you've had any of these at all since you saw the doctor last week (or since you started the medicine).

		Did you have this problem before you took the medicine?	Do you think the medicine caused this problem?	Did you stop the medicine because of the problem?	Did you tell your doctor about this problem?
Seeing things hazy or blurred	Yes = 1, No = 2, N/A = 8	5	6	7	8	9
Wheezing or shortness of breath	Yes = 1, No = 2, N/A = 8	10	11	12	13	14
Dizziness or unsteadiness	Yes = 1, No = 2, N/A = 8	15	16	17	18	19
Feeling sick or being sick	Yes = 1, No = 2, N/A = 8	20	21	22	23	24
Skin trouble (e.g. itching or rash)	Yes = 1, No = 2, N/A = 8	25	26	27	28	29
Heartburn or stomach ache	Yes = 1, No = 2, N/A = 8	30	31	32	33	34
Pains in the joints	Yes = 1, No = 2, N/A = 8	35	36	37	38	39
Cold or numb fingers or toes	Yes = 1, No = 2, N/A = 8	40	41	42	43	44
Increased depression	Yes = 1, No = 2, N/A = 8	45	46	47	48	49
Ringing or buzzing in the ears	Yes = 1, No = 2, N/A = 8	50	51	52	53	54
Feeling more drowsy than usual	Yes = 1, No = 2, N/A = 8	55	56	57	58	59
Feeling more worried or nervous than usual	Yes = 1, No = 2, N/A = 8	60	61	62	63	64

		Did you have this problem before you took the medicine?	Do you think the medicine caused this problem?	Did you stop the medicine because of the problem?	Did you tell your doctor
Headache	Yes = 1 No = 2 N/A = 8	65	66	67	68
Bowel complaints (diarrhoea or constipation)	Yes = 1 No = 2 N/A = 8	70	71	72	73
Tarry stools or vomiting blood	Yes = 1 No = 2 N/A = 8	75	76	77	78
Others (specify)	Yes = 1 No = 2 N/A = 8	80			
.....					
.....					

ID No. 1 2 3 4

5.2 Are you aware of any side effects or after effects which may sometimes happen when people take this medicine?

Seeing things hazy or blurred	M = 1 NM = 2 N/A = 8	5
Wheezing or shortness of breath	M = 1 NM = 2 N/A = 8	6
Dizziness or unsteadiness	M = 1 NM = 2 N/A = 8	7
Feeling sick or being sick	M = 1 NM = 2 N/A = 8	8
Skin trouble (e.g. itching or rash)	M = 1 NM = 2 N/A = 8	9
Heartburn or stomach ache	M = 1 NM = 2 N/A = 8	10
Pains in the joints	M = 1 NM = 2 N/A = 8	11
Cold or numb fingers or toes	M = 1 NM = 2 N/A = 8	12
Increased depression	M = 1 NM = 2 N/A = 8	13
Ringing or buzzing in the ears	M = 1 NM = 2 N/A = 8	14
Feeling more drowsy than usual	M = 1 NM = 2 N/A = 8	15
Feeling more worried or nervous than usual	M = 1 NM = 2 N/A = 8	16
Headache	M = 1 NM = 2 N/A = 8	17
Bowel complaints (diarrhoea or constipation)	M = 1 NM = 2 N/A = 8	18

Tarry stools or vomiting blood

M = 1
NM = 2
N/A = 8

19

Others (specify) ..... M = 1
..... NM = 2
..... N/A = 8

20

5.3 When taking this medicine, do you think it is necessary for patients to:

avoid drinking alcohol?

Yes = 1
No = 2
N/A = 8
D/K = 9

21

avoid driving?

Yes = 1
No = 2
N/A = 8
D/K = 9

22

avoid operating machines?

Yes = 1
No = 2
N/A = 8
D/K = 9

23

avoid smoking?

Yes = 1
No = 2
N/A = 8
D/K = 9

24

avoid certain foods? (specify) ..... Yes = 1
..... No = 2
..... N/A = 8
..... D/K = 9

25

avoid taking other medicines?

Yes = 1
No = 2
N/A = 8
D/K = 9

26

avoid anything else? (specify) ..... Yes = 1
..... No = 2
..... N/A = 8
..... D/K = 9

27

SECTION 6: PATIENT SATISFACTION

I'd like to discuss your views about your medicine.

6.1 Overall, would you say you are:

completely satisfied = 1
satisfied = 2
indifferent = 3
dissatisfied = 4
OR completely dissatisfied = 5
N/A = 8
D/K = 9

with the medicine you have been given? 28

IF DISSATISFIED

6.2 Why were you dissatisfied with this medicine?
RECORD COMMENTS ..... unnecessary = 1
..... not working = 2
..... side effects = 3
..... difficult/
..... inconvenient
..... to take = 4
..... other = 5
..... N/A = 8
..... D/K = 9 29

6.3 Did you expect to get a prescription when you last saw the doctor?

Yes = 1
No = 2
N/A = 8
D/K = 9 30

6.4 Now I'd like to ask you about your visit to the doctor. Overall, would you say you are:

completely satisfied? = 1
satisfied? = 2
indifferent? = 3
dissatisfied? = 4
OR completely dissatisfied? = 5
N/A = 8
D/K = 9 31

with the consultation you had with your doctor?

IF DISSATISFIED

6.5 Why were you dissatisfied with your visit to the doctor?
..... Administrative = 1
..... Doctor's behaviour = 2
..... Doctor's technical
..... competence = 3
..... Other = 4
..... N/A = 8
..... D/K = 9 32

6.6 Did your doctor tell you anything about your medicine?

Yes = 1
No = 2
N/A = 8
D/K = 9

33

IF YES

Specify .....
.....

6.7 Overall, would you say you are:

completely satisfied = 1
satisfied = 2
indifferent = 3
dissatisfied = 4
completely dissatisfied = 5
N/A = 8
D/K = 9

34

OR

with the information you have received about your medicine from your doctor.

6.8 Did your doctor give you

all of = 1
some of = 2
none of = 3
N/A = 8
D/K = 9

35

the information you wanted about your illness?

I am now going to read a number of comments that have been made by patients about their doctors and treatment. I would like you to tell me which response on this card most closely fits your experience of treatment last week. Remember all your answers are confidential and your doctor will not read them.

GIVE RESPONSE CARD TO PATIENT

Strongly agree = 1
Agree = 2
Uncertain = 3
Disagree = 4
Strongly disagree = 5
N/A = 8

		RING ANSWER						
6.9	The medicine I've been given seems to be just right for my problem.	1	2	3	4	5	8	36
6.10	The doctor seemed to really understand my problem.	1	2	3	4	5	8	37
6.11	Taking this medicine is often very inconvenient.	1	2	3	4	5	8	38
6.12	Far too much time was spent waiting to see the doctor at the surgery.	1	2	3	4	5	8	39
6.13	The consultation with the doctor seemed rushed.	1	2	3	4	5	8	40
6.14	I expected the doctor to prescribe this type of medicine for me.	1	2	3	4	5	8	41
6.15	I'm anxious about possible side effects with this medicine.	1	2	3	4	5	8	42
6.16	The surgery receptionists were courteous and helpful.	1	2	3	4	5	8	43
6.17	All my questions about my medicine were answered.	1	2	3	4	5	8	44
6.18	The doctor seemed too busy to listen to my problem.	1	2	3	4	5	8	45
6.19	It was difficult to get to see my usual doctor.	1	2	3	4	5	8	46
6.20	The doctor I saw last time seemed thorough and competent.	1	2	3	4	5	8	47
6.21	It was easy to make an appointment to see the doctor at the time I wanted.	1	2	3	4	5	8	48
6.22	I would like some more information about my medicine.	1	2	3	4	5	8	49

6.23 Did you receive an information leaflet with this medicine?

Yes = 1
No = 2
N/A = 8
D/K = 9

50

IF YES

6.24 Did the leaflet come from:

the doctor? = 1
the chemist? = 2
OR someone else? = 3
(specify) .....
N/A = 8
D/K = 9

51

6.25 Have you kept the leaflet?

Yes = 1
No = 2
N/A = 8
D/K = 9

52

6.26 Did you:

read the leaflet all the way through? = 1
read parts of the leaflet? = 2
OR not read the leaflet at all? = 3
N/A = 8
D/K = 9

53

IF LEAFLET READ

6.27 Did you read the leaflet:

before you took any medicine? = 1
after you took your medicine? = 2
OR both before and after you took your medicine? = 3
N/A = 8
D/K = 9

54

6.28 Did you find the leaflet:

very helpful? = 1
quite helpful? = 2
OR not at all helpful? = 3
N/A = 8
D/K = 9

55

6.29 Did you find the leaflet:

very useful = 1
quite useful = 2
OR unnecessary = 3
N/A = 8
D/K = 9

56

6.30 Did the leaflet make you feel anxious about taking your medicine?

(If yes, specify) ..... Yes = 1
..... No = 2
..... N/A = 8
..... D/K = 9

57

ALL RESPONDENTS

6.31 Where would you say you got most of your information about this medicine from?

an information leaflet = 1
the label on the medicine = 2
your doctor = 3
your pharmacist = 4
family/friends = 5
the media (e.g. books, papers, T.V. and radio) = 6
Other sources (specify) ..... = 7
.....
.....
I have had no information = 9

58

6.32 Overall, do you think it is a good or a bad idea to be given an information leaflet with your medicine?
RECORD COMMENTS

..... good = 1
..... bad = 2
..... N/A = 8
..... D/K = 9
.....
.....

59

6.33 Would you prefer an information leaflet to come from:

your chemist? = 1
your doctor? = 2
OR either chemist or doctor? = 3
N/A = 8
D/K = 9

60

THANK YOU FOR TAKING PART IN THIS SURVEY

FOR COMPLETION AFTER INTERVIEW

INTERVIEWER'S COMMENTS

Appendix 2

Followup questionnaire and covering letter

THE UNIVERSITY OF SOUTHAMPTON

Professor of Clinical Pharmacology

C. F. George, B.Sc., M.D., F.R.C.P.

Clinical Pharmacology Group

Medical & Biological Sciences Building,
Bassett Crescent East,
Southampton SO9 3TU

Tel: 559122 Ext. 4263/4264

Dear

You may know that the University of Southampton is conducting a survey of people's views about prescribed medicines. You may remember helping us with part of this survey last year.

We need your help once more to complete this research. We would be grateful if you could fill in the enclosed questionnaire. Please answer as many questions as you can - even if you are not taking medicines at the moment. Your answers will be confidential and your doctor will not read them.

When you have filled in the questionnaire, please send it back in the envelope provided. No stamp is needed. Please return the questionnaire even if you have decided not to take part.

Thank you for your help in this important research.

Yours sincerely,

C. F. George

Sharon Gibbs

S Gibbs

For Office Use

1 2 3

SURVEY ON MEDICINES

* Please answer as many questions as you can, even if you are not taking medicines at the moment.

* Put a tick in the box beside the answer you wish to make.

* Please answer this questionnaire without looking anything up or asking anyone for help.

1. In the past year has your doctor prescribed any medicines or tablets for you?

Yes ☐ No ☐ Uncertain ☐ Tick one box ☐ 5

If you have had any medicines or tablets:

What were they prescribed for?	What are they called?	
.....	.....	
.....	.....	
.....	.....	
.....	.....	☐ 6
.....	.....	☐ 7
.....	.....	
.....	.....	

IF YOU HAVE HAD ..... TABLETS IN THE PAST YEAR FOR ..... PLEASE ANSWER THE FOLLOWING QUESTIONS

2. Are you still taking these tablets?

Yes ☐ No ☐ Uncertain ☐ Tick one box ☐ 8

If you are no longer taking them, when did you stop?

..... ☐ 9

Did you stop these tablets because you:

Tick any boxes that apply

-felt better	☐	☐ 10
-felt the tablets were not working	☐	☐ 11
-finished or ran out of tablets	☐	☐ 12
-had side effects (please describe)	☐	☐ 13
-other reason (please describe)	☐	☐ 14
-can't remember the reason for stopping	☐	☐ 15

REMEMBER, ALL THESE QUESTIONS ARE ABOUT YOUR ..... TABLETS

3. How many of these tablets <u>should</u> you take each day?
   .....

   <u>Should</u> you take these tablets:

   Tick any boxes that apply

   -at breakfast time? ☐
   -at lunchtime? ☐
   -at dinnertime? ☐
   -at bedtime? ☐ 16
   -at other times (please write times here) ☐
   ..... ☐
   -uncertain ☐

4. <u>Should</u> you take these tablets:

   Tick one box

   -before meals? ☐
   -after meals? ☐
   -with meals? ☐
   -not in connection with meals? ☐ 17
   -uncertain? ☐

5. How <u>should</u> you swallow these tablets?

   Tick one box

   -on their own? ☐
   -with water? ☐
   -with another drink? (write it here) ☐ 18
   ..... ☐
   -uncertain? ☐

6. If you forgot to take a dose of these tablets <u>should</u> you:

   Tick one box

   -take it as soon as you remember? ☐
   -take a double dose next time? ☐
   -miss it out altogether? ☐
   -do something else? (please describe) ☐
   ..... ☐
   -not applicable ☐
   -uncertain ☐

For Office Use

REMEMBER, ALL THESE QUESTIONS ARE ABOUT YOUR ..... TABLETS

7. If someone else had the same symptoms as you should you give them some of your tablets?

Yes ☐ No ☐ Depends ☐ Tick one box ☐ 20

8. Where should people keep these tablets?

Tick any boxes that apply

-out of reach of children	☐	☐ 21
-near some water	☐	☐ 22
-in the fridge	☐	☐ 23
-in a pocket or handbag	☐	☐ 24
-in the freezer	☐	☐ 25
-on the mantlepiece	☐	☐ 26
-in a bathroom cupboard	☐	☐ 27
-on the windowsill	☐	☐ 28
-in a place where it is easy to remember to take them	☐	☐ 29
-in a dry cool place	☐	☐ 30
-anywhere else (please describe)	☐	☐ 31
-uncertain	☐	☐ 32

9. What should people do with these tablets if they have any left over?

Tick any boxes that apply

-return them to the chemist	☐	☐ 33
-flush them down the toilet	☐	☐ 34
-return them to the doctor	☐	☐ 35
-throw them in the dustbin	☐	☐ 36
-keep them	☐	☐ 37
-throw them on the fire	☐	☐ 38
-give them to someone else	☐	☐ 39
-anything else (please describe)	☐	☐ 40
-uncertain	☐	☐ 41

For Office

REMEMBER, ALL THESE QUESTIONS ARE ABOUT YOUR ..... TABLETS

10. Are you aware of any side effects or after effects which may sometimes happen when people take these tablets?

Yes ☐ No ☐ Uncertain ☐ Tick one box ☐

Please list any you are aware of here

.....
.....
.....
.....

11. Have you yourself had any side effects or after effects when taking these tablets?

Yes ☐ No ☐ Uncertain ☐ Tick one box ☐

If you think you have, please describe them here

.....
.....
.....

12. Overall, how satisfied have you been with these tablets?

Tick one box

-completely satisfied ☐
-satisfied ☐
-indifferent ☐
-dissatisfied ☐
-completely dissatisfied ☐
-not applicable ☐

If you have been dissatisfied with them, please explain why here

.....
.....
.....

13. Have you ever received an information leaflet about your tablets?

Yes ☐ No ☐ Uncertain ☐ Tick one box ☐

If you have, did you keep the leaflet?

Yes ☐ No ☐ Not applicable ☐ Tick one box ☐

Did you use this leaflet to help you fill in this questionnaire?

Yes ☐ No ☐ Not applicable ☐ Tick one box ☐

For office use

REMEMBER, ALL THESE QUESTIONS ARE ABOUT YOUR ..... TABLETS

14. Overall, how satisfied are you with the information you have been given about your tablets?

Tick one box

-completely satisfied ☐
-satisfied ☐
-indifferent ☐
-dissatisfied ☐
-completely dissatisfied ☐

☐ 51

If you have been dissatisfied, please explain why here

.....

.....

☐ 52

If you have any other comments, please write them here

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

☐ 53

Thank you very much for taking part in this survey - your help is greatly appreciated.

PLEASE RETURN THIS QUESTIONNAIRE IN THE ENVELOPE PROVIDED - NO STAMP IS NEEDED

Appendix 3

Publications

Pharmaceut. Med. (1987), **2**, 23–33

The Design of Prescription Information Leaflets and Feasibility of their Use in General Practice

S. Gibbs[1], W.E. Waters[2] & C.F. George[1]

Departments of [1]Clinical Pharmacology and [2]Community Medicine, University of Southampton, UK

1 Generic prescription information leaflets (PILS) were designed for non-steroidal anti-inflammatory drugs (NSAIDs) and oral penicillins. These leaflets provided summarised written and pictorial information on the front and detailed material on the reverse and they were compared with single-sided, detailed information sheets similar to the reverse of the two-sided ones.
2 One hundred patients attending an urban general practice were shown the leaflets and interviewed to assess their initial reactions and knowledge. All but six patients were able to read the leaflets.
3 Eighty-five per cent of the sample thought the two-sided leaflets had the better design. After 3 min to read the leaflet, 22 patients (47.8%) who had the two-sided version could name the main side-effects of the medicines, compared with 14 (29.2%) of those who had the one-sided version.
4 In a second study, 174 patients attending two rural surgeries and who were prescribed either a penicillin or a NSAID were identified. One hundred and forty-two of them (82%) were interviewed later in their homes. Of these, 39 (27%) either did not receive a leaflet or had not bothered to read it.
5 Thirty-seven (62.7%) of the patients who read the two-sided leaflet knew the main side effects of their medicine, compared with 23 (52.3%) who read the one-sided version. Similar trends were found for knowledge about what to do with left over medicines, action if a dose was missed, whether the medicine should be swallowed with a drink and how to store the medicine safely.
6 Patient satisfaction with the information received was significantly higher ($P = 0.02$) among those who read a two-sided leaflet.
7 We conclude that the two-sided information leaflets have advantages over their one-sided equivalents, but further controlled studies are required to evaluate their effects in the community.
8 General practitioners experienced problems in remembering to issue the leaflets and seven of the nine thought they should be distributed by pharmacists when medicines are dispensed.

Introduction

In order to use medicines correctly and to derive benefit from them patients need certain basic information.[1] General practitioners and pharmacists have a responsibility for providing this information. However, recent studies[2,3] have shown that, in many instances, this is either not done, or the patients feel that not enough has been explained to them.

One possible way of overcoming existing deficiencies in the imparting of information is to provide written material in the form of prescription information leaflets (PILs). In a pilot study,[4] it was shown that such leaflets could improve knowledge about medicines being taken (particularly about their side effects) and lead to improvements in compliance with antibiotic therapy. Furthermore, in a postal survey of Southampton residents (1:200 sample), 83.1% of those who responded welcomed the idea of receiving a PIL.[2] However, despite the apparent benefits and acceptability of PILs, several problems remain. First, there are individual differences in the level of information expected by patients. For example, in Southampton, 54% of people surveyed wanted detailed information whereas another 43% expressed a preference for short, summarised points. Second, doubts exist as to whether their routine use in surgeries in general practice would be feasible.

We have tested two methods of presenting prescription information in a leaflet. In addition, we have studied the ways in which general practitioners use them.

Methods

The leaflets

Leaflets were designed for two groups of medicines, oral penicillins and non-steroidal anti-inflammatory drugs (NSAIDs). These medicines were chosen because both are commonly prescribed and one, penicillins, is usually given for acute infections while the other, NSAIDs, is used more frequently for chronic conditions, such as rheumatoid arthritis and osteoarthritis.

The contents of the leaflets were those suggested by Hermann *et al.*[1] with the exception of 'how to tell if the medicine is working'. This omission was agreed by a Steering Group (see Acknowledgements) and takes into account the findings of Ridout, Waters & George.[2] However, the leaflets included other items identified by the latter authors as being of importance to patients.

The leaflets (PILs) were constructed according to general principles for design of technical information.[5,6] In particular, the type face was bold and clear because many elderly patients have problems with failing eyesight which makes it difficult for them to read small typewritten instructions on medicine bottles.[7] A graphic artist advised on other important typographic variables, such as the use of space and upper/lower case letters.

In order to improve patients' comprehension, the style of each PIL was edited by an educational psychologist using readability formulae.[8] Short sentences were used and specific information was given rather than general statements; other features included the use of the second person and questions, so that the leaflets were interactive.[9] The contents were organised into self-contained sections of related information to increase understanding and recall.[10] Headings were used so that people could scan the information and pick out points of interest[11] as well as to increase patients' expectations about the ease of readability and comprehension.[12]

Two designs were developed: a one-sided PIL and a two-sided version. The contents and presentation of the 'reverse' side of the latter were essentially similar to

those of the one-sided PIL. But, to accommodate the views of patients who preferred brief summarised information, the main points were presented on the 'front' of the two-sided PILs and pictures were used, as well as colour, to attract attention and to motivate the patient to read the accompanying prose.[13]

Recognising that some patients might want further information and that our leaflets did not cover everything, for example, rare unwanted effects, a reference to a popular paperback book on medicines was included at the bottom of the detailed side of both versions of each PIL.

Study 1: initial reaction to the leaflets

Patients waiting to see a doctor at a general practice in central Southampton were approached by one of us (S.G.) and asked whether they would take part in the study. Each patient was given one leaflet to read for 3 min. They were then questioned to assess gain in their short term knowledge and to seek their opinions on the content and presentation of the PIL. The four different leaflets were distributed in a systematic order throughout (1,2,3,4,1,...).

The patients were not necessarily taking a medicine described in the leaflet. Towards the end of the interview each patient was shown the alternative version of the PIL for NSAIDs or penicillins. Patients were encouraged to comment freely during the interview and their comments and answers were recorded.

Study 2: use of PILs in a general practice setting

A second study was conducted in order to compare the effects of the two designs of PIL when these were issued with a prescription for either a penicillin or a NSAID. This study was carried out in two rural Hampshire towns, A and B, which were of similar size, each with only one surgery. The leaflets were distributed by the general practitioners at consultation. During the consultation, patients were asked for their consent to be interviewed by 'a research worker interested in their treatment'. Details of these patients were recorded and collected weekly from the surgeries involved. In town A the two-sided PIL for penicillins and the one-sided PIL for NSAIDs were used. In town B, the leaflets used were the one-sided version for penicillins and the two-sided NSAID PIL. This gave a balanced experimental design.

Patients were contacted within a few days and, if willing, they were interviewed in their homes by the research worker who used a structured questionnaire. This sought knowledge on the medicine, any side effects experienced and the patient's satisfaction with treatment and information received. Compliance was assessed by direct questioning and by tablet counts. Finally, patients' views on the leaflet they had received were recorded along with comments on the alternative version which had been shown to them.

The survey ran for 12 weeks in each town. During the survey period, a detailed record was kept of the distribution of PILs by individual general practitioners. At the end of the survey the general practitioners were interviewed and their views sought about the use of leaflets and patient information in general.

The leaflet designs are shown in the Appendix.

Data analysis

Questionnaires were coded and transferred to the University of Southampton computer on which the data were analysed using the SPSS^{x} program. Measures of association were tested by a χ^2 analysis, whereas scores for content and presentation of our leaflets were examined by the Mann–Whitney U test.

Results

Study 1: initial reaction to the leaflets

One hundred patients were approached and all agreed to take part in the study. Of these, 42 were male and 58 female; the majority came from the surrounding working class area of Southampton. Six per cent of this sample (2 males and 4 females) were unable to read the leaflets because they came without their glasses. They have been excluded from further analysis.

Patients' knowledge. After reading the leaflets, patients knew more about penicillins than about NSAIDs, irrespective of the type of leaflet read. Mean knowledge scores out of 5 were 3.24 ± 1.39 (SD) and 2.96 ± 1.27 (SD) respectively (n.s.). For those questioned, 39% achieved high knowledge scores (>3 questions correct), 46% medium scores (2 or 3 correct) and 15% had poor knowledge scores (<2 correct). Patients were best informed about the safe storage and disposal of medicines, over 85% responding correctly to questions on these matters. However, their knowledge of side effects and reasons to avoid these medicines was poor. Although overall there were no significant differences between knowledge scores and the type of leaflet received, 22 (47.8%) of patients who read the two-sided leaflets could name the main side effects of the medicines compared with 14 (29.2%) of those who read a one-sided leaflet ($P = 0.07$).

Opinions of the leaflets. The content of all four leaflets was rated highly by the patients (Table 1).

All four leaflets were thought to be clear, composed in a sensible order and easy to read and understand. Patients appeared to prefer the way in which the information was presented in the two-sided leaflet (Table 1). The most frequent reason why patients preferred the two-sided leaflets was the use of colour pictures which attracted their attention – 'You want to know what the pictures are all about'. Nine patients said they preferred the two-sided leaflet because it had a summary. Twenty-eight people claimed that they would not bother to read the one-sided leaflet because there was too much writing and it looked 'boring and clinical'. When asked to compare the two designs of leaflet, 85% thought the two-sided version had the better design.

Table 1 Mean scores (± SD) out of 10 for content and presentation of the leaflets in Study 1

	One-sided leaflets ($n = 48$)	*Two-sided leaflets* ($n = 46$)
Content	8.50 ± 1.66	8.39 ± 1.58 n.s.
Presentation	7.75 ± 1.87	8.56 ± 1.75 n.s.

Study 2: use of PILs in a general practice setting

The patients in this study consisted of 92 from Town A and 82 from Town B (174 in total). Of these, 113 (65%) had been prescribed a penicillin and 61 (35%) a NSAID. The number of patients entering the study in town B in each of the 12 weeks diminished over time. For the first seven weeks of the study, the number of patients receiving NSAID PILs in town B fluctuated between one and six, after which time no further NSAID leaflets were used. In the same town between 10 and 15 penicillin PILs were given out each week for the first four weeks, but their use was then discontinued until the last week of the study, when 10 were issued. The behaviour pattern of all 9 doctors taking part is shown in Table 2 which illustrates the marked differences between general practitioners in their use of the leaflets.

Of the 174 patients eligible for interview, 142 (82%) agreed to be seen; 5 declined and 27 were unobtainable – mainly in the summer months. Eighty-nine of these patients were prescribed penicillins and 53 NSAIDs. A total of 62 patients were in the one-sided leaflet group and 80 were in the two-sided leaflet group.

Demographic variables. Sixty-eight per cent of the patients were female (Table 3). Of all those interviewed, 72.5% had only one prescribed medicine, 16.2% were receiving one other medicine and 11.3% were taking three or more prescribed medicines. Most (62.7%) had previous experience of either penicillins or NSAIDs and 34 prescriptions were for a child under 16 years of age.

Table 2 GP's use of the leaflets in Study 2

Dr	*Town A*	*Dr*	*Town B*
01	57	06	46
02	17	07	20
03	10	08	13
04	8	09	3
05	0		

The doctors have been coded 01–09. The figures alongside each doctor refer to the number of patients entered by him/her into the study.

Although all 142 patients who were interviewed should have received a leaflet with their medicine, 25 of them (18%) claimed not to have had one. Twelve were in the 'one-sided group' and 13 in the 'two-sided group'. A further 14 said that they had not actually read their leaflet, 6 from the 'one-sided group' and 8 from the 'two-sided group'. Thus, 39 (27%) either did not receive a leaflet or had not bothered to read it. Fifty-nine of 68 patients (86.8%) who admitted to receiving a two-sided leaflet read it, compared to 44 of 51 (86.2%) who remembered receiving a one-sided version. Only patients who claimed to have read a leaflet have been included in the further analysis.

Patients' knowledge. Some differences were apparent in the level of knowledge attained, although few reached statistical significance (Table 4). With the exception of the name of their medicine, its purpose and problems associated with secondary usage, patients who read a two-sided leaflet knew more about their medicine than those who read a one-sided version. More patients who read the two-sided leaflets knew the main side effects of their medicine. For example, 26 patients (78.8%) who read a two-sided penicillin leaflet knew that penicillins can cause rashes compared to 21 patients (60%) receiving the one-sided PIL. Eleven (42.3%) who read a two-sided NSAID leaflet knew that these drugs could cause indigestion compared with 2 (22.2%) in the one-sided PIL group. There were also trends in the same direction for knowledge about what to do with left-over medicines, what to do if a dose was

Table 3 Demographic characteristics of the respondents in Study 2

		No.	%
Sex	Male	45	32
	Female	97	68
Age	<30	36	25
	30–60	78	55
	>60	28	20
Social class	Non-manual	88	62
	Manual	51	36
	Unclassifiable	3	2
Number of prescribed medicines	1	103	73
	2	23	16
	3 or more	16	11
Previous experience of medicine		89	63
*Medicine prescribed for a child (under 16 years)		34	24

* When the medicine was prescribed for a child under 16 years, the parent or guardian was interviewed.

Table 4 Number of patients giving correct answers to questions of knowledge in Study 2 (% in parentheses)

	One-sided leaflets ($n = 44$)	*Two-sided leaflets* ($n = 59$)	*P*
When to take it	44 (100)	59 (100)	—
Swallowed with a drink	26 (59)	45 (76)	0.06
Main side effects	23 (52)	37 (63)	0.29
Name of medicine	43 (88)	49 (83)	0.04
Purpose of treatment	32 (73)	33 (64)	0.49
What to do if a dose is missed	31 (71)	50 (85)	0.08
Safe storage	9 (21)	21 (36)	0.40
Safe disposal	38 (86)	54 (92)	0.09
Problems connected with secondary usage	37 (84)	48 (81)	0.31

missed, whether medicine should be swallowed with a drink and safe storage of medicines.

Compliance. No difference was seen in the patterns of compliance for the two main leaflet groups.

Patient satisfaction. There was a high level of satisfaction with treatment and with the information received (Table 5). For both leaflet groups, more than two-thirds of patients said that they were satisfied with their treatment and the information they had received about it, but the level of satisfaction with information was significantly higher ($P = 0.02$) in those who read the two-sided version. When asked to compare the two leaflets directly, 99% of the patients who had read leaflets preferred the two-sided version.

Table 5 Satisfaction with treatment and information received about the medicine in Study 2 (% in parentheses)

	Satisfaction with treatment		*Satisfaction with information*	
	One-sided leaflets ($n = 44$)	*Two-sided leaflets* ($n = 59$)	*One-sided leaflets* ($n = 44$)	*Two-sided leaflets* ($n = 59$)
Completely satisfied	16 (36)	27 (46)	12 (27)	33 (56)
Satisfied	13 (30)	18 (31)	21 (48)	13 (22)
Uncertain	6 (14)	5 (9)	8 (18)	9 (15)
Dissatisfied	7 (16)	7 (12)	3 (7)	3 (5)
Completely dissatisfied	2 (5)	2 (3)	0	1 (2)
	$P = 0.12$		$P = 0.02$	

General practitioner opinions. The nine general practitioners who took part in this study were all in favour of patient information leaflets. They liked the leaflets and all preferred the two-sided versions.

Seven of the general practitioners thought leaflets should ideally be distributed by the pharmacist, or in the pack with the medicine, rather than by the general practitioners at the consultation. The main reason given was that this method would ensure that the patient received the information; most general practitioners experienced difficulty in remembering to give leaflets in this study.

Discussion

In a previous study of Southampton residents,[2] 83.1% of respondents indicated that they would like to have written information about prescribed medicines. Further evidence for patients' interest in the use of information leaflets is provided by the two studies reported here. Although women and those over 55 years were over-represented in our samples compared with the general population, this bias was to be expected since women and the elderly have been found to consult their general practitioners more often and to take more medicines than young men.[2,14] The most important finding of this study was the fact that patients found both types of leaflet design to be easy to read and understand. This is in contrast to patients' views about some other PILs currently available, for example, those which are supplied with the oral contraceptive tablets. Many of these are difficult to read and understand[15] and appear to be designed to protect against litigation rather than to inform patients about their medicines. The present study provides additional support for use of the rules of good design for instructional text.[5] However, our previous survey of Southampton residents suggested that some would prefer short, summarised points, rather than detailed information. In order to accomodate their requirements, we designed the two-sided leaflets and compared their effectiveness with the equivalent 'details only' (one-sided) version.

When patients were asked to rate the two styles of leaflet they gave higher scores for the two-sided format and the majority preferred these when asked to compare the two versions. As suggested previously,[13,16,17] the use of colour and of pictures appeared to draw attention to the text. Patients frequently stated that they would read the two-sided leaflet because 'it caught their eye and looked interesting'. They perceived the one-sided leaflets as being more complicated, boring and perhaps technical. 'Do I have to read all that?' was one reaction.

In our second study, patients who read a two-sided PIL were significantly more satisfied with the information they had been given than those who read a one-sided version. There was also a trend in the same direction for satisfaction with medical treatment. Since satisfaction with treatment has been found to be associated with better patient compliance[18,19] this might be advantageous. However, further studies are necessary to prove whether this is the case, since no differences in patient compliance were found in this study.

Patients who read the two-sided PILs also tended to know more about their medicine, particularly the unwanted effects, how to store it and how to dispose of it

safely. None of these trends reached statistical significance and the analysis was complicated by the greater knowledge patients had of penicillins than of NSAIDs. However, the better knowledge of side effects among recipients of two-sided PILs may reflect the impact of summaries which enable the reader to identify sections of interest from a text.[5,6] In this context, many patients in our initial study (Study 1) were observed to scan the PIL summary and then turn straight to the side effects section on the reverse. Thus, although we failed to demonstrate statistically significant advantages for many features of our two-sided PILs, the trends were mostly in their favour and we intend to use this format of leaflet in future studies.

An important issue which remains is who should distribute PILs. One suggestion is that general practitioners should do so at the consultation. However, our second study suggests that this is unlikely to be generally successful. Although all the general practitioners who took part thought that patients should receive written information, most had problems in remembering to distribute the PILs. One practitioner in each town found it much easier to distribute leaflets than the others. In the light of their experience, seven out of nine felt that it would be better for PILs to be issued by pharmacists when the medicine was dispensed. Five of them favoured their inclusion with the packaging of the medicine.

Because the general practitioners frequently forgot to give out leaflets, the number of patients included in our second study was smaller than we had anticipated, expecially among patients prescribed NSAIDs. It is possible that some form of selection bias could have been introduced by these omissions. Another potential problem was that patients might have associated the visit by a research assistant with the PIL they had received. As a result they might have read it thoroughly before the interview. In practice, surprisingly few patients appeared to link these two events with one another, and some did not remember having received a leaflet at all. It is not clear whether the general practitioner failed to issue a leaflet or if the patient just did not bother to read it.

In conclusion, these studies provide additional evidence in favour of the use of prescription information leaflets. The inclusion of a summary appears to confer advantages, but even so, some patients will not bother to read them. Our findings cast doubt on whether most general practitioners will remember to distribute PILs. We consider it may be more practicable for pharmacists to undertake this task when prescriptions are collected. The PIL might either be included in an original pack or given out by the pharmacist.

We would like to thank all the patients and general practitioners who took part in these studies. The practices were: Southampton (St James: Drs A. H. Laxton, G. P. Coleman, W. P. Munro, D. B. Percy, P. Pritchard); Alresford (Drs G. C. Brill, P. F. B. Riley, M. J. Clark, D. J. Green, S. C. Thorpe); Bishops Waltham (Drs S. J. Hillier, P. A. Hemming, D. G. Crutchley, D. J. Ibbitson).

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Appendix – The Leaflets

What you should know about Penicillins.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is .....
This is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Things to remember about Penicillin.

1 **Do not take Penicillin** if you are allergic to it.

2 **Look at the label** on your Penicillin. It will tell you when to take it.

3 **Keep taking your Penicillin** until it is finished. **Don't stop** just because you feel better.

4 **Penicillin sometimes causes problems** You can find these listed on the back of this leaflet. ✽

5 Keep your Penicillin **out of reach of children.**

You will find more about Penicillin on the back of this leaflet.

A Front of two-sided penicillin PIL.

Penicillins.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

Your medicine is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Before taking your medicine

- Has anyone ever told you you are allergic to Penicillin? If so, tell your doctor or pharmacist. You can be given another medicine instead of Penicillin.

Taking your medicine

- You must take your medicine regularly. The label will tell you when to take your medicine. It will also tell you how much to take. *Ask your doctor or pharmacist if you are not sure.*
- This medicine works best swallowed with water when your stomach is empty. This is 1 hour before a meal or 2 hours after a meal. But sometimes your doctor will tell you to take it at other times.
- If the medicine is for a baby the best time to give it is between feeds.
- Shake all liquid medicines before you take a dose.
- Keep taking your medicine until it is finished. Don't stop just because you feel better. The medicine may not have killed all the germs. If you stop too soon the infection may start up again.
- If you forget to take a dose take another as soon as you remember. Then go on as before.

✽ After taking your medicine

A few people can be upset by this medicine. They have frequent loose bowel motions or feel like being sick.
If you suffer from either of these very badly or you vomit the medicine tell your doctor.
Tell your doctor if you START suffering from any of the following:

- Rashes, itching, or any other skin trouble.
- Wheezing.
- Pain in your joints for the first time.

Tell your doctor about any other unusual problems as soon as you can.

Storing your medicine

- Keep liquid Penicillin in the refrigerator but **not** in the freezer compartment. Liquid Penicillin lasts only a few days even in the refrigerator. The label will tell you how long. Don't take the medicine after this date.
- Keep your medicine in a safe place where children cannot reach it. Your medicine could harm them.
- If your doctor decides to stop the treatment, flush any left-over medicine down the toilet or return it to the pharmacist. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

B One-sided penicillin PIL.

What you should know about Anti-Inflammatory Analgesics.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is .....
This is one in a group of medicines called Anti-Inflammatory Analgesics. These can relieve pain such as headache, toothache, arthritis and period pain. They can also reduce fever.

Things to remember about Anti-Inflammatory Analgesics.

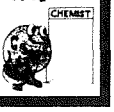
1 **Make sure it is safe for you** to take Anti-Inflammatory Analgesics *(see the back of this leaflet).* ♦

2 **Look at the label** on your tablets. It will tell you when to take them.

3 **Anti-Inflammatory Analgesics sometimes cause problems** You can find these listed on the back of this leaflet. ✱

4 Keep your tablets **out of reach of children.**

5 **Remember to return any unused tablets** to the pharmacist or flush them down the toilet.



You will find more about Anti-Inflammatory Analgesics on the back of this leaflet.

C Front of two-sided NSAID PIL.

Anti-Inflammatory Analgesics.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

Your medicine is an Anti-Inflammatory Analgesic. Anti-Inflammatory Analgesics can relieve pain such as headache, toothache, arthritis, and period pain. They can also reduce fever.

♦ Before taking your medicine

- Are you already taking aspirin or another drug used to treat arthritis?
- Have you had an allergic reaction or wheezing after taking aspirin?
- Have you experienced stomach discomfort, felt like being sick or had heartburn after taking aspirin?
- Have you had a stomach ulcer previously?
- Are you on medicines for thrombosis (eg Warfarin) or gout?
- Are you pregnant?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, *ask your doctor or pharmacist.*
- Tablets or capsules should be swallowed with a glass of water or milk. Soluble tablets should be dissolved in water before taking them.
- If you forget to take a dose take another as soon as you remember. Then go on as before.
- In the event of an accidental overdose contact your nearest hospital casualty department or tell your doctor immediately.

✱ After taking your medicine

This medicine sometimes causes side-effects in some people.
If you get any of the following, tell your doctor as soon as possible:

- Ringing in the ears or dizziness.
- Skin troubles such as rash or itching for the first time.
- Wheezing.
- You develop stomach discomfort or heartburn for the first time.
- You vomit blood or pass tarry stools.

Storing your medicine

- Keep your tablets in a safe place where children cannot reach them. Your tablets could harm them.
- If your doctor decides to stop the treatment, flush any left-over tablets down the toilet or return them to the pharmacist. Only keep them if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

D One-sided NSAID PIL.

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The benefits of prescription information leaflets (1)

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1 Prescription information leaflets (PILs) giving information about non-steroidal anti-inflammatory drugs (NSAIDs), β-adrenoceptor antagonists and inhaled bronchodilators were evaluated in three small Hampshire towns, while a fourth, in which no leaflets were distributed, acted as a control.

2 Seven hundred and nineteen (82%) patients prescribed one of these medicines agreed to be interviewed in their homes, 1 to 2 weeks after the medicine had been prescribed. Four hundred and nineteen of them had received leaflets, while 300 received no written information. Two hundred and sixty patients received their leaflets from a pharmacist while 159 were given them by their general practitioner.

3 Patients who received leaflets were better informed about every item of knowledge tested, except for the name of the medicine. Awareness of the side effects showed the greatest improvement, but there was no evidence that these leaflets produced spurious side effects.

4 Much improved levels of satisfaction were recorded amongst patients who received leaflets, especially those for NSAIDs ($P < 0.001$) and for β-adrenoceptor antagonists ($P < 0.01$).

5 Subsequently, three hundred and fifty-eight (77%) of the patients prescribed either a NSAID or a β-adrenoceptor antagonist 1 year earlier responded to a postal questionnaire. The benefits in terms of knowledge and satisfaction were still apparent, although less marked than previously. Of the patients still taking β-adrenoceptor antagonists 70% had retained their leaflets over the intervening 12 months.

6 Ninety-seven per cent of patients read their leaflet regardless of whether it was distributed by a general practitioner or pharmacist. However, those who obtained it from a pharmacist tended to be more knowledgeable and satisfied.

7 We conclude that patients welcome the idea of receiving PILs. They improve patients' knowledge of how to take their medicines correctly and their awareness of potential side effects. Importantly, patients who receive leaflets are more satisfied than those who do not. These overall benefits justify the use of leaflets on a routine basis.

Introduction

Despite the widespread prescription of medicines, patients' knowledge about what they take is often inadequate. Awareness of potential side effects is particularly poor (Ridout *et al.*, 1986) and over half of the respondents to a national pharmacy survey did not know precisely how, when, or with what to take their medicines (Busson & Dunn, 1986). Many people feel that not enough

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is explained by doctors and pharmacists (Fletcher, 1973; Waitzkin & Stoekle, 1976; Cartwright & Anderson, 1981; McMahon *et al.*, 1987), and even when information is given verbally it is often forgotten (Ley *et al.*, 1976) or misunderstood (Boyle, 1970). One way to deal with this problem might be to provide information leaflets with prescribed medicines. Although patients would welcome additional information (Morris *et al.*, 1977; Ridout *et al.*, 1986) there have been few systematic studies performed in this country to examine the effects of leaflets.

Outside the UK, benefits such as improvements in patients' knowledge about medicines, their compliance with treatment and their opinions about information received have been reported (Clark & Bayley, 1972; Sackett *et al.*, 1975; Udkow *et al.*, 1979; Gotsch & Ligouri, 1982; Wiederholt & Kotzan, 1983). However, the leaflets tested in these studies varied considerably in content, readability and intent. Furthermore, it is often difficult to disentangle the effects of written information from those of the larger health education programmes of which they were sometimes part. Much of the research into the effects of leaflets has focused on a limited range of medicines, mainly those prescribed for acute conditions. Since the effects of leaflets are likely to vary according to the characteristics of the drugs prescribed and the patients taking them, the range of medicines investigated needs to be broadened to include those prescribed on a long term basis. It is unclear at present whether any initial benefits associated with leaflets will be stable over time. Furthermore, the optimum method of leaflet distribution has not been determined.

In order to clarify these issues, we have developed generic information leaflets for three types of medicines all of which are commonly prescribed in general practice. The first gave information about non-steroidal anti-inflammatory drugs (NSAIDs) which are used both in the treatment of mild or intermittent pain and for continuous or regular pain associated with inflammation. The second discussed β-adrenoceptor antagonists which are often prescribed for asymptomatic hypertension whilst the third was for inhaled (β_2-adrenoceptor agonist) bronchodilators which can be used both to alleviate and 'prevent' asthma (British National Formulary, 1988). This paper describes the effects of these three leaflets on patients' knowledge, behaviour and satisfaction with their medicines in the setting of general practice, both initially and after a period of 12 months. In addition, we have compared the merits and disadvantages of leaflet distribution by the general practitioner or pharmacist.

Methods

Approval was obtained from the local ethics committee to conduct a series of surveys to evaluate the effects of leaflets in small Hampshire towns. The leaflets were based on those piloted by George *et al.* (1983) and developed by Gibbs *et al.* (1987). Briefly, they are 'generic' and contain information suggested by Hermann *et al.* (1978), with the exception of how to tell if the medicine is working, together with additional information requested by patients (Ridout *et al.*, 1986). They were constructed according to general principles for design of technical information (Hartley, 1978) and each was 'style edited' by an educational psychologist to improve readability (Cripwell, 1981). A two sided design with details on the back and a short summary on the front was employed in order to provide different levels of information requested by patients (Ridout *et al.*, 1986). The leaflet giving information about NSAIDs has already been published (Gibbs *et al.*, 1987). Those for β-adrenoceptor antagonists and inhaled bronchodilators are shown in Figures 1 and 2.

Short term effects of the leaflets

Study design As a result of discussions with the Hampshire Family Practitioner Committee and the Wessex Faculty of the Royal College of General Practitioners, eight small towns were identified where general practitioners were willing to take part in our studies. These towns (a) had no more than three general practice surgeries or three pharmacies, (b) were within a 30 mile radius of Southampton and (c) had populations of under 15,000 (Office of Population Censuses and Surveys, 1985). Two of these towns participated in a previous study (Gibbs *et al.*, 1987). A further three towns were selected at random for the present study. These towns were randomly allocated to one of three procedures:-

1) Leaflets were given to patients by general practitioners during a consultation.
2) Leaflets were issued by pharmacists when the medicine was dispensed.
3) No leaflets were issued.

In town C (population 12,964) leaflets were distributed by pharmacists; general practitioners issued leaflets in town D (population 2,965) and town E (population 14,719) was the 'control' town, where no leaflets were distributed. Because of the small size of town D it was necessary to extend the study and a further town, town F (population 5,091), was randomly selected in which leaflets were issued by general practitioners.

a

What you should know about Beta Blockers.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is .....
This is one of a group of medicines called Beta Blockers.
Beta Blockers can help you in a number of ways:
- They can reduce high blood pressure.
- They can lessen or prevent chest pain (angina).
- They can control heart beats which are irregular or too fast.
- Some medicines of this type are used to calm people who are anxious or worried.

Things to remember about Beta Blockers

1 **Make sure it is safe for you** to take Beta Blockers *(see the back of this leaflet).*♦

2 **Look at the label** on your Beta Blockers. It will tell you when to take them.

3 **Keep taking your Beta Blockers** until they are finished or your doctor says otherwise. **Don't stop** just because you feel better.

4 **Beta Blockers can cause problems.** You can find these listed on the back of this leaflet.✱

5 Keep your Beta Blockers **out of reach of children.**

6 **Remember to return any unused Beta Blockers** to your pharmacist or flush them down the toilet unless your doctor has told you to keep them.

You will find more about Beta Blockers on the back of this leaflet.

b

Your medicine is one in a group of medicines called Beta Blockers. Beta Blockers can help you by reducing high blood pressure, by lessening or preventing chest pain (angina) or by controlling heart beats which are irregular or too fast. Some medicines of this type are used to calm people who are anxious or worried.

♦ Before taking your medicine

- Do you suffer from asthma or attacks of wheezing?
- Are you diabetic and taking insulin or tablets?
- Are you pregnant?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, *ask your doctor or pharmacist.*
- Take the tablets or capsules with a glass of water.
- Keep taking your medicine until your doctor tells you to stop. Don't stop just because you feel better. If you stop too soon your condition may get worse.
- If you forget to take a dose take another as soon as you remember. Then go on as before.
- If you take an overdose by accident contact your nearest hospital casualty department or tell your doctor immediately.

✱ After taking your medicine

Although most people benefit from taking this medicine, a few people can be upset by it. If you get any of the following *tell your doctor.*
- Dizziness or lightheadedness or wheezing.
- A very slow pulse (under 50 beats per minute)
- Skin trouble such as rash or itching for the first time.

Very occasionally, this type of medicine can cause sleeplessness or vivid dreams. Don't be worried because they are not serious. But tell your doctor when you go next time.
If you are taking this medicine for chest pains **don't** stop it suddenly, otherwise the pain will get much worse. Your doctor will tell you how to reduce the dose slowly. This will take about two weeks.

Storing your medicine

- Keep your medicine in a safe place where children cannot reach it. Your medicine could harm them.
- If your doctor decides to stop the treatment, return any left over medicine to the pharmacist or flush it down the toilet. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody." (Penguin Books)

Figure 1 Leaflet, coloured blue in the original, giving information about β-adrenoceptor antagonists. (a) front, (b) reverse.

a

What you should know about Bronchodilators

Please read this carefully before you start using your inhaler. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is .....
This is one in a group of medicines called Bronchodilators.
Bronchodilators relieve asthma by relaxing muscle spasm in the lungs. If you use this medicine regularly it may also help to prevent attacks of asthma.

Things to remember about Bronchodilators

1 **Make sure you know how to use your inhaler.** There are instructions in the box it came in.

2 **Bronchodilators sometimes cause problems.** You can find these listed on the back of this leaflet.✱

3 Keep your medicine **out of reach of children.**

4 **Dispose of old inhalers safely.** Do NOT throw inhalers on to the fire.

You will find more about Bronchodilators on the back of this leaflet.

b

Your medicine is a Bronchodilator. Bronchodilators relieve asthma by relaxing muscle spasm in the lungs. If you use this medicine regularly it may also help to prevent attacks of asthma.

Taking your medicine by inhaler

- Use your inhaler at the right times. Your doctor will tell you how often to use it. Ask if you are not sure.
- Make sure you know how to use your inhaler.

The medicine will only work if it reaches your lungs. The leaflet which comes with your inhaler will tell you how to use it properly. If you are not sure ask your doctor or pharmacist to show you.
- If you forget to take a puff, take another as soon as you remember. Then go on as before.
- Don't take more puffs than your doctor tells you to. If your usual dose doesn't work, tell your doctor.

✱ After taking your medicine

Most people benefit from using this medicine but it can cause side-effects. If you get any of the following, tell your doctor.
- Rapid or irregular heart beats.
- Feeling extremely nervous.

Some people get a bad taste in their mouths after using their inhaler. This is not dangerous. You can get rid of the bad taste by rinsing your mouth out with water. Some people find that their hands become a little shaky. This is not dangerous and usually wears off after a few days.

Storing your inhaler

- Keep your inhaler in a safe place out of reach of children. It could harm them.
- Don't use your inhaler after its expiry date.
- Make sure you throw your old inhalers away. Do NOT throw them on to the fire, because they may explode.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptons are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody." (Penguin Books)

Figure 2 Leaflet, coloured brown/orange in the original, giving information about inhaled bronchodilators. (a) front, (b) reverse.

The survey ran for 10 weeks in each town. Patients prescribed an NSAID, a β-adrenoceptor antagonist or an inhaled bronchodilator during this period were eligible for the study, but only those who received prescriptions at a consultation were included in an attempt to standardise patient experience. General practitioners and pharmacists were requested not to go through the leaflet with the patient or give any more verbal information than was their usual practice. In addition, the local media were informed about the survey well in advance in order to avoid publicity in the middle of the study which might have affected the outcome.

Data collection Data were collected by means of a personal interview using a structured questionnaire developed in a previous study (Gibbs *et al.*, 1987). All patients were asked to consent to an interview by way of a standard letter from their general practitioner. This informed the patient that, 'The Department of Clinical Pharmacology in the University of Southampton is carrying out research on medicines which are commonly prescribed. As part of its research, they would like to talk to you about the medicine which you are taking'. Patients were contacted by one of the two interviewers 1–2 weeks after the consultation and, if willing, inteviewed in their homes. Each interview lasted approximately 30 min. The questionnaire assessed knowledge about the medicine, medicine taking behaviour and satisfaction with information received. Tablet counts were conducted to assess patient compliance and patients were asked their opinions about the provision of information in general and, finally, about the leaflets.

Long term effects of the leaflets

An assessment of the longer term effects of the leaflets on patients' knowledge and satisfaction was conducted 1 year after the original interview survey in the same four towns. A postal questionnaire was designed, piloted and sent to patients originally prescribed either a NSAID or a β-adrenoceptor antagonist. It was decided not to follow up the patients using bronchodilators because the numbers receiving leaflets in this group were inadequate and the age distribution of the patients in the experimental and control towns was significantly different. General practitioners were contacted and a check was made to ascertain that the patients were still alive and registered with the practice. If no reply was received from the patient within 1 month, a reminder was posted together with another copy of the questionnaire.

Distribution of the leaflets

The design of the study enabled the relative merits of pharmacist and general practitioner leaflet distribution to be compared. Patients who received leaflets about NSAIDs or β-adrenoceptor antagonists from pharmacists in town C. and from general practitioners in towns D and F were compared.

Data analysis Data were coded and transferred to the University of Southampton IBM 3090 mainframe computer. Analysis was conducted using the SPSSx statistical package. Throughout the analysis patients 'intended' to receive leaflets were assumed to have done so. Associations were tested using the Chi-squared statistic (with Yates correction for 2×2 tables). Where significant χ^2 values were produced for contingency tables with more than 2 rows or 2 columns, the cells were partitioned in order to determine whether non-independence of the two variables occurred throughout or in a specific part of the table (Everitt, 1977). The satisfaction data were ranked from 'completely satisfied' to 'completely dissatisfied' and a χ^2-squared test for trend performed. This assumes that 'satisfaction' has the characteristics of a continuous variable to enable numerical values to be allotted to each category so as to detect trends in the tables. Thus a more sensitive test can be obtained than by the use of the usual χ^2 statistic (Everitt, 1977).

Results

Short term effects of the leaflets

Sample characteristics The overall response rate to interview was 82%. A total of 719 patients were interviewed, 419 in leaflet towns and 300 in the control town. Three hundred and thirty-two patients had been prescribed a NSAID, 222 a β-adrenoceptor antagonist and 165 an inhaled bronchodilator. Of these, 232 NSAID patients, 122 patients prescribed a β-adrenoceptor antagonist and 65 patients using bronchodilators were given leaflets. No significant differences in response rate were observed between the study towns for patients prescribed NSAIDs or bronchodilators. However, the response from patients prescribed β-adrenoceptor antagonists was significantly lower in the control town (73%) than that in the leaflet towns (83%) ($\chi^2_1 = 6.24$, $P < 0.05$).

Demographic characteristics of patients interviewed in this study are shown in Table 1. Sixty-three per cent of the respondents were women

Table 1 Demographic characteristics of the patients interviewed (Percentages are shown in brackets)

	NSAIDs		*Medicine β-adrenoceptor antagonists*		*Bronchodilators*	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Sex						
Male	81 (34.9)	27 (27.0)	45 (36.9)	43 (43.0)	22 (33.8)	42 (42.0)
Female	151 (65.1)	73 (73.0)	77 (63.1)	57 (57.0)	43 (66.2)	58 (58.0)
Age (years)						
16–34	†36 (15.7)	9 (9.0)	3 (2.5)	5 (5.0)	14 (21.5)	35 (35.0)
35–64	117 (50.9)	54 (54.0)	65 (53.3)	51 (51.0)	25 (38.5)	51 (51.0)
65 and over	77 (33.5)	37 (37.0)	54 (44.3)	44 (44.0)	26 (40.0)	14 (14.0)
						**
Social class						
I and II	76 (32.8)	35 (35.0)	39 (32.0)	38 (38.0)	26 (40.0)	40 (40.0)
III	111 (47.8)	31 (31.0)	62 (50.8)	40 (40.0)	29 (44.6)	43 (43.0)
IV and V	34 (14.7)	26 (26.0)	19 (15.6)	16 (16.0)	5 (7.7)	13 (13.0)
		**				
Unclassifiable	11 (4.7)	8 (8.0)	2 (1.6)	6 (6.0)	5 (7.7)	4 (4.0)

** $P < 0.01$.
† 2 missing values were excluded from the analysis.

and 35% were 65 years and over. More patients were interviewed from the non-manual social classes (classes I, II and IIINM made up 53%) than from the manual social classes (42% from classes IIIM, IV and V) as classified according to the Registrar General's Classification of Occupations (Office of Population Censuses and Surveys, 1980), but 5% of respondents were unclassifiable using this method. With the exception of those taking bronchodilators, no significant differences in age or sex distribution were found between those who received a leaflet and others who did not. Bronchodilator users interviewed in the control town were significantly younger than those in the leaflet towns ($\chi^2_2 = 18.62$, $P < 0.01$). There were no significant differences in social class between patients who received leaflets giving information about β-adrenoceptor antagonists and those who did not. The same was true for patients prescribed bronchodilators. However, more NSAID patients who received leaflets were found to come from social class III (non-manual and manual combined), whereas there was an excess of social classes IV and V in the control group ($\chi^2_2 = 9.78$, $P < 0.01$).

Patients' knowledge Patients who received a leaflet were found to be better informed about their medicines than those who did not (Table 2). More patients who received a leaflet were aware of how to take their medicine correctly. Significantly more NSAID takers who received a leaflet knew they should take their tablets with food ($\chi^2_1 = 8.57$, $P < 0.05$). In addition, knowledge of when to use the inhaler was significantly greater amongst bronchodilator users who received a leaflet ($\chi^2_1 = 6.37$, $P < 0.05$).

Awareness of the side effects of all three medicines was significantly higher among patients who were given leaflets (Table 3). More NSAID patients in the leaflet group knew that their medicine could cause stomach problems ($\chi^2_1 = 13.52$, $P < 0.001$), dizziness ($\chi^2_1 = 17.19$, $P < 0.001$) and ringing in the ears ($\chi^2_1 = 9.17$, $P < 0.01$). β-adrenoceptor antagonist takers who received leaflets were more aware that their therapy sometimes causes dizziness ($\chi^2_1 = 8.32$, $P < 0.001$), wheezing ($\chi^2_1 = 4.61$, $P < 0.05$), rash ($\chi^2_1 = 5.91$, $P < 0.05$) and sleeplessness or vivid dreams ($\chi^2_1 = 4.33$, $P < 0.05$). Shakiness was identified as a potential side effect of bronchodilators by significantly more patients who received a leaflet ($\chi^2_1 = 6.47$, $P < 0.05$).

Trends in favour of the leaflets were found for all other items tested except for knowledge of the name of the NSAIDs: Only about half of the NSAID patients who received a leaflet could name their medicine correctly.

'Side effects' experienced A variety of health problems were experienced by the respondents

Table 2 Patients' knowledge about their medicine (Numbers are those giving correct answers [percentages in brackets])

	NSAIDs		*Medicine β-adrenoceptor antagonists*		*Bronchodilators*	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	122	122	100	65	100
Name of medicine	126 (54.3)	65 (65.0)	89 (73.0)	60 (60.0)	60 (92.3)	95 (95.0)
Purposes of therapy	228 (98.3)	97 (97.0)	115 (94.3)	88 (88.0)	65 (100.0)	99 (99.0)
When to take it	183 (83.6)	73 (74.5)	117 (95.9)	89 (90.8)	52 (81.3) *	60 (61.2)
Take with fluid	202 (92.2)	89 (90.8)	119 (97.5)	86 (87.8)	—	—
Take with food	177 (80.8) **	67 (68.4)	—	—	—	—
What to do if dose is missed †	126 (58.1)	44 (47.3)	76 (62.3)	52 (54.2)	21 (60.0)	8 (50.0)
Storage out of reach	200 (91.3)	82 (83.7)	110 (90.2)	86 (87.8)	51 (79.7)	66 (67.3)
Safe method of disposal	196 (89.5)	80 (81.6)	93 (76.2)	79 (80.6)	52 (81.3)	86 (87.8)
Aware not to share medicines	204 (93.2)	89 (90.8)	120 (98.4)	96 (98.0)	56 (87.5) *	66 (67.3)

* $P < 0.05$, ** $P < 0.01$

Questions were answered by 93–100% of respondents (with the exception of † what to do if a dose is missed, which was answered by less than 50% of patients using bronchodilators). Missing values were excluded from the percentages.

after starting their medicine. For the most part, these problems were not connected with the medicine. There was no evidence of an increased reporting of the side effects listed in any of the leaflets. In fact, for β-adrenoceptor antagonists significantly more patients who did not receive a leaflet reported wheezing ($\chi^2_1 = 5.57$, $P < 0.05$) and the trend was in the same direction for side effects mentioned in the other leaflets.

Generally, health problems not listed on the leaflets were more frequently reported by patients in the control group. An exception to this were headaches among the NSAID takers who had received a leaflet ($\chi^2_1 = 5.41$, $P < 0.05$). Subsequent analysis of these data revealed that 10 of the patients who reported this symptom had been prescribed indomethacin, which is known to produce headaches (British National Formulary, 1988). Nine of these patients were in the leaflet group. The increased reporting of joint pains and stomach problems by bronchodilator users who received a leaflet may reflect their older age.

NSAID patients were more likely to connect their own experiences of side effects with the medicine if they had received a leaflet. Thus, of the patients who reported stomach discomfort, 26 (47.3%) who received a leaflet associated the problem with their tablets compared with 8 (27.6%) in the control group ($\chi^2_1 = 2.29$, $P < 0.13$). Few β-adrenoceptor antagonist or bronchodilator takers connected their treatment with any side effects experienced.

However, there was some evidence to suggest that patients who experienced non-specific health problems whilst using their medicine were more likely to blame the medicine if they had received a leaflet. Among the 37 NSAID takers who recorded having felt sick or being sick whilst taking their tablets, 14 (37.8%) thought this problem was probably caused by the medicine. Twelve of these patients were among those given leaflets ($\chi^2_1 = 2.68$, $P < 0.10$).

Storage and disposal The most common place for storage of NSAIDs and β-adrenoceptor antagonists was the kitchen. Inhalers were more commonly kept in a handbag or pocket. Eighty-nine per cent of patients prescribed NSAIDs or β-adrenoceptor antagonists were aware of the need to store their medicines out of reach of

Table 3 Patients' awareness of the side effects of their medicine (Percentages are shown in brackets)

		NSAIDs			*Medicine β-adrenoceptor antagonists*			*Bronchodilators*	
Leaflet		Yes	No		Yes	No		Yes	No
Total number		232	100		122	100		65	100
Aware of any side effects		99 (42.7) ***	15 (15.0)		37 (30.3) **	12 (12.0)		24 (36.9) *	18 (18.0)
Awareness of individual side effects	Stomach discomfort	83 (35.8) ***	15 (15.0)	Dizziness	21 (17.2) **	4 (4.0)	Shakiness	18 (27.7) *	11 (11.0)
	Ringing in ears	23 (9.9) **	0 (0)	Wheezing	10 (8.2) *	1 (1.0)	Nervousness	4 (6.2)	2 (2.0)
	Dizziness	43 (18.5) ***	1 (1.0)	Rash	9 (7.4) *	0 (0)	Rapid heart beat	9 (13.8)	11 (11.0)
	Rash	14 (6.0)	1 (1.0)	Slow pulse	2 (1.6)	0 (0)	Bad taste in mouth	2 (3.1)	0 (0)
	Wheezing	12 (5.2) *	0 (0)	Sleeplessness or vivid dreams	14 (11.5) *	1 (1.0)			
	Tarry stools	26 (11.2)	4 (4.1)						

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.
Questions were answered by 100% of the respondents.

children. However, on inspection the interviewers found that only about half of the patients took this precaution. All three medicines were more likely to be stored out of reach if children lived in or regularly visited the house: this factor was a more important influence on the place of storage than the receipt of a leaflet.

Knowledge of the correct method of disposal was found to be generally high. However, more NSAID takers who received leaflets said they would either return unused medicines to the pharmacist or flush them down the toilet ($\chi^2_1 = 3.95$, $P < 0.05$). Fewer patients (12.8%) who received an NSAID leaflet said that they would keep any left over medicine, compared with 24.5% in the control group ($\chi^2_1 = 5.94$, $P < 0.05$). The trend was in the same direction for β-adrenoceptor antagonists.

Patient compliance Tablet counts were conducted during 70% of the interviews with patients prescribed NSAIDs and 67% of interviews about β-adrenoceptor antagonists. No such assessment of patient compliance was possible for inhaled bronchodilators. Compliance rates were calculated from the tablet counts as:

$$\text{Compliance (\%)} = \frac{\text{Amount removed from container}}{\text{Amount expected to be taken}} \times 100$$

[The amount expected to be taken was determined from the number of days after start date (which was either the date given on the label, or one subsequent to that, agreed with each patient) × the dosage on the label.]

The rates were found to vary markedly with a range of 0–390% but with a median of 83% for NSAIDs and 98% for β-adrenoceptor antagonists.

More patients showed compliance rates between 80–120% if they had received a leaflet, but the differences betweeen the two groups were not significant for either medicine. (For NSAIDs 47.9% *cf* 42.9% ($\chi^2_2 = 0.05$, $P = 0.76$) and for β-adrenoceptor antagonists 60.8% *cf* 45.7% ($\chi^2_2 = 4.81$, $P = 0.09$) respectively.)

Despite the wide variation in compliance rate obtained from the tablet counts, 81% of all respondents claimed to be following the dosage instructions for their medicine (irrespective of whether they received a leaflet).

Around a third of patients prescribed NSAIDs had stopped their tablets by the time of interview, and a larger proportion of those who stopped had received a leaflet; (77 (35.2%) *cf* 28 (28.6%), $\chi^2_1 = 1.05$, $P = 0.31$). Of the patients who received an NSAID leaflet and discontinued the treatment, 21 patients said they had taken the prescribed amount, 17 stopped because they felt better and 10 felt the medicine was not working whereas six patients were unsure why they had discontinued treatment. Twenty-three patients claimed to have stopped their medicine because they were worried about the side effects listed on the leaflet. Almost all (94.1%) of the patients prescribed β-adrenoceptor antagonists were still taking their medicine at the time of interview and 145 (89.5%) of bronchodilator patients were still using their inhalers. There was no evidence that receipt of a leaflet influenced whether treatment was discontinued for these two medicines.

Overall, 20 patients interviewed did not start their medicine at all. Fifteen of them had been prescribed NSAIDs, of whom 13 had received a leaflet ($\chi^2_1 = 1.35$, $P = 0.25$). The leaflet was given as a major reason for deciding against taking the medicine by seven patients. Five of these decided their problems (arthritis, earache, hip pain, neck and shoulder pain, and 'rheumatism' and backache) were not serious enough to risk the side effects listed. 'I'd prefer to see if it cleared up on its own rather than take the risk' was one comment and another patient 'decided it wasn't worth taking the risk. I can put up with by backache (and I have stomach trouble anyway).' The remaining two patients said they were frightened by the leaflet. One who suffered with arthritis thought the leaflet meant the drug was new, whereas the other, who had a frozen shoulder, was 'scared because other medicines often give me side effects'. None of the people who gave the leaflet as the reason for not starting their medicine had ever taken these tablets before and only one person knew of someone who had experienced problems whilst taking the tablets in question. The ages of the seven ranged from 37 to 78 years, six of them were female and they all came from the non-manual social classes. Two of these patients did not collect their prescriptions from the pharmacy, one took the tablets back to the doctor but the remainder had kept their tablets.

Patients' satisfaction Highly significant improvements were found in the level of satisfaction with information received amongst recipients of leaflets (Table 4). NSAID patients who received leaflets were more satisfied with the information they received than those who did not (χ^2_1 test for trend = 45.11, $P < 0.001$). The same was true for patients prescribed β-adrenoceptor antagonists (χ^2_1 test for trend = 34.27, $P < 0.001$). This trend in favour of the leaflets was apparent also for bronchodilators (χ^2_1 test for trend = 13.86,

Table 4 Patients' satisfaction with information received (Percentages are shown in brackets)

	NSAIDs		*Medicine β-adrenoceptor antagonists*		*Bronchodilators*	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
Completely satisfied	171 (73.7)	35 (35.0)	91 (74.6)	36 (36.0)	32 (49.2)	29 (29.0)
Satisfied	51 (22.0)	43 (43.0)	28 (23.0)	47 (47.0)	28 (43.1)	45 (45.0)
Indifferent	5 (2.0)	8 (8.0)	3 (2.5)	3 (3.0)	1 (1.5)	11 (11.0)
Dissatisfied	2 (0.9)	8 (8.0)	0 (0)	7 (7.0)	1 (1.5)	12 (12.0)
Completely dissatisfied	0 (0)	0 (0) ***	0 (0)	5 (5.0) ***	0 (0)	0 (0) **
Don't know	3 (1.3)	6 (6.0)	0 (0)	2 (2.0)	3 (4.6)	3 (3.0)

** $P < 0.01$, *** $P < 0.001$.
Questions were answered by 100% of the respondents.

$P < 0.01$), but the overall level of satisfaction was lower than that reported for the other two types of medicine.

The leaflets were associated with improvements in patients' satisfaction with the medicine itself and with the consultation but these trends did not reach statistical significance.

Reaction to the leaflets Not all patients who should have received a leaflet in this study remembered being given one. Altogether, 202 (87%) NSAID takers remembered receiving a leaflet as did 108 (89%) of the β-adrenoceptor antagonist takers. However, only 39 bronchodilator patients (60%) claimed to have received a leaflet. One hundred and fifty-four (76.2%) NSAID and 89 (82.4%) β-adrenoceptor antagonist patients said they had kept their leaflet, whereas only 26 (66.7%) bronchodilator takers claimed to have kept it. Three hundred and forty of the 349 patients who remembered receiving a leaflet said they had read it. Of those who read a leaflet, 10.8% of bronchodilator patients and 13.2% of the β-adrenoceptor antagonist takers found it 'worrying'. The number of patients worried by the NSAID leaflet was higher, with 55 patients (27.9%) who read it claiming it caused anxiety about their treatment. Forty-one of these patients said they were worried about the side effects listed on the leaflet. Patients who found this leaflet worrying were not significantly different in age, sex or social class from those who were not worried by the leaflet. However, there was a tendency for the leaflet to cause concern more often amongst patients who had no previous experience of the medicine ($\chi^2_1 = 1.13$. $P = 0.29$).

Longer term effects of the leaflets

Sample characteristics Four hundred and sixty-four (84%) of the NSAID and β-adrenoceptor antagonist takers originally interviewed were included in the follow up study. The remaining 90 patients were excluded from the second study by their general practitioner. Seventy-nine of these patients had either moved or died and five were excluded because they were considered too ill. No reasons were given for the exclusion of the other six. Three hundred and sixty-eight questionnaires were returned of which 10 forms were blank. Three hundred and fifty-eight questionnaires were analysed, giving a 77% response rate. The demographic characteristics of the respondents are shown in Table 5. The age, sex and social class distribution of those who responded to the follow up questionnaire did not differ significantly from the patients who were not involved in the second study. Patients who received a leaflet with a NSAID or a β-adrenoceptor antagonist about 1 year previously were not found to differ significantly in age or sex distribution from those who did not get one. An excess of social class III was still present amongst NSAID patients who received leaflets, with more social class IV and V respondents in the control group ($\chi^2_2 = 10.01$, $P < 0.05$).

Table 5 Demographic characteristics of respondents to the follow up study (Percentages are shown in brackets)

	Medicine			
	NSAIDs		*β-adrenoceptor antagonists*	
Leaflet	Yes	No	Yes	No
Total number	145	63	74	76
Sex				
Male	50 (34.5)	17 (27.0)	28 (37.8)	35 (46.1)
Female	95 (65.5)	46 (73.0)	46 (62.2)	41 (53.9)
Age (years)				
16–34	23 (15.9)	5 (7.9)	3 (4.1)	4 (5.3)
35–64	76 (52.4)	35 (55.6)	41 (55.4)	37 (48.7)
65 and over	46 (31.7)	23 (36.5)	30 (40.5)	35 (46.1)
Social class				
I and II	45 (31.0)	22 (34.9)	18 (24.3)	31 (40.8)
III	76 (52.4)	20 (31.7)	45 (60.8)	30 (39.5)
IV and V	19 (13.1) *	17 (27.0)	10 (13.5) *	11 (14.5)
Unclassifiable	5 (3.4)	4 (6.3)	1 (1.4)	4 (5.3)

* $P < 0.05$.
Questions were answered by 100% of the respondents.

Thirty-three NSAID takers and 11 of those on β-adrenoceptor antagonists said that they did not remember being prescribed the medicine in question 12 months previously. Because of this, no useful data could be obtained from these patients who have therefore been excluded from further analysis. One hundred and seventy-five NSAID patients and 139 β-adrenoceptor antagonist patients remembered being prescribed the 'original' medicine. Of these 122 (69.7%) should have received the NSAID leaflet and 70 (50.4%) that giving information about β-adrenoceptor antagonists.

Still taking the medicine Only 64 patients (37.2%) were still taking the NSAID they were prescribed 'originally' whereas 111 (81%) of those prescribed a β-adrenoceptor antagonist were still taking it. Significantly more patients who received a leaflet had stopped their NSAIDs (90 patients (75%) compared with 18 (34.6%) of those who did not receive one ($\chi^2_1 = 23.63$, $P < 0.001$)).

Patients' knowledge Patients who originally received leaflets were found to be more knowledgeable about their medicine than those who did not, regardless of whether they were still taking the medicine (Table 6). NSAID patients who received a leaflet were still more aware of what to do if a dose is missed than those who did not get one 12 months previously, and this difference reached statistical significance ($\chi^2_1 = 3.83$, $P < 0.05$). The trend was in the same direction for those originally given leaflets about β-adrenoceptor antagonists: 74.2% were aware what to do if a dose is missed compared with 68.4% of the controls ($\chi^2_1 = 0.24$, $P = 0.62$). Sixty-four patients (71.1% of the replies) in the leaflet group knew their NSAID tablets should be taken with food compared with 29 (65.9%) in the control group ($\chi^2_1 = 0.17$, $P = 0.68$). Of the β-adrenoceptor antagonist patients who originally received leaflets 92.4% knew they should take their tablets with fluid compared with 78.5% in the control group ($\chi^2_1 = 4.08$, $P < 0.05$). Awareness of methods of safe storage and disposal of medicines remained high in both groups.

More patients who received leaflets were aware of the side effects of their 'original' medicine. However, the level of awareness of the side effects of NSAIDs fell over the 12 month period, especially amongst those who were originally given leaflets, irrespective of whether they were still taking the medicine. Nevertheless, almost twice as many NSAID patients who originally received leaflets could name at least one side effect, but the difference did not quite reach statistical significance ($\chi^2_1 = 3.46$, $P = 0.07$). Awareness of the side effects of β-adrenoceptor antagonists was also higher amongst patients

Table 6 Patients' knowledge of a medicine prescribed 12 months earlier (Numbers are those giving correct answers [percentages in brackets])

	Medicine			
	NSAIDs		*β-adrenoceptor antagonists*	
Leaflet	Yes	No	Yes	No
Total number	122	53	70	69
Take with fluid	† 89 (91.8)	45 (95.7)	61 (92.4)	51 (78.5) *
Take with food	†† 64 (71.1)	29 (65.9)	—	—
What to do if dose is missed	††† 49 (53.3)	14 (33.3) *	46 (74.2)	39 (68.4)
Aware of any side effects	45 (43.7)	12 (26.1)	24 (36.4)	10 (16.4) *
Number of side effects known about	1) 24 2) 7 3) 2 4) 0 5) 1	1) 9 2) 1	1) 7 2) 3 3) 2	1) 4
Storage out of reach	102 (83.6)	44 (83.0)	59 (84.3)	54 (78.3)
Safe method of disposal	119 (97.5)	44 (83.0)	67 (95.7)	58 (84.1)
Aware not to share medicines	107 (99.1)	47 (100.0)	67 (100.0)	64 (98.5)

* $P < 0.05$.
Questions were answered by 80–100% of the respondents (with the exception of † take with fluid [79.5% response], †† take with food [73.8% response], and ††† what to do if a dose is missed [75.4% response] amongst NSAID patients who received leaflets). Missing values were excluded from the percentages but the table includes patients who stopped their tablets during the 12 month period.

who had received a leaflet 12 months previously ($\chi^2_1 = 5.47$, $P < 0.05$). However, in this case no significant decrease in awareness of side effects was observed over the 12 month period.

'Side effects' experienced Twenty-seven (20.6%) patients prescribed β-adrenoceptor antagonists who responded to the follow up study claimed they had experienced one or more of the side effects listed on the leaflet during the past year. Thirteen of these patients had received leaflets whereas 14 were in the control group. Similarly, during the past 12 months 30 (20.4%) of the NSAID patients who responded to the follow up claimed to have experienced one or more side effects. However, in this case 26 of these patients had received leaflets whereas only 4 were in the control group ($\chi^2_1 = 4.65$, $P < 0.05$). Fifteen (50%) of the NSAID takers who experienced side effects had stopped their tablets for this reason: 14 of them had received a leaflet.

Patients' satisfaction The number of patients claiming to be completely satisfied with the information they received about their medicine was found to be lower than that recorded in the initial survey for both types of medicine (Table 7). Despite this, 93.9% of the patients given a leaflet about β-adrenoceptor antagonists claimed to be either completely satisfied or satisfied with the information received compared with 73.7% of the controls (χ^2_1 test for trend = 4.88, $P < 0.05$). Amongst patients who were originally given a NSAID leaflet, 87.2% were either satisfied or completely satisfied with the information received compared with 77.8% of those who did not get a leaflet (χ^2_1 test for trend = 2.40, $P < 0.2$).

Table 7 Patients' satisfaction with information received about a medicine prescribed 12 months earlier (Percentages are shown in brackets)

	Medicine			
	NSAIDs		*β-adrenoceptor antagonists*	
Leaflet	Yes	No	Yes	No
Total number	122	53	70	69
Completely satisfied	43 (42.6)	18 (40.0)	28 (43.1)	24 (39.3)
Satisfied	45 (44.6)	17 (37.8)	33 (50.8)	21 (34.4)
Indifferent	9 (8.9)	5 (11.1)	1 (1.5)	5 (8.2)
Dissatisfied	4 (4.0)	3 (6.7)	3 (4.6)	9 (14.8)
Completely dissatisfied	0 (0)	2 (4.4)	0 (0)	2 (3.3)
			**	

** $P < 0.01$.
Questions were answered by 80–100% of the respondents.
Missing values were excluded from the percentages.

Reaction to the leaflets 62.5% of the respondents who should have received a leaflet remembered receiving one 12 months previously. Thirty-two patients originally prescribed a β-adrenoceptor antagonist (69.6%) had kept their leaflet compared with only 29 (39.2%) patients prescribed an NSAID. The proportion was higher amongst NSAID patients who were still taking their medicine: 17 of these patients (56.5%) had kept the leaflet.

Distribution of the leaflets

All 419 patients interviewed in the leaflet towns were initially included in this part of the survey. Two hundred and sixty were in the town where leaflets were distributed by pharmacists and 159 obtained their leaflets from general practitioners. One hundred and fifty NSAID takers received leaflets from their pharmacist and 82 from their general practitioner. Sixty patients prescribed β-adrenoceptor antagonists were given leaflets by a pharmacist and 62 received them from their general practitioner. Only 15 bronchodilator leaflets were distributed by general practitioners. For this reason it was not considered appropriate to analyse the bronchodilator data further.

General practitioners tended to distribute leaflets to older patients and those drawn from the higher social classes. These differences between general practitioner and pharmacist distribution were significant for NSAIDs ($\chi^2_2 = 11.94$, $P < 0.01$ and $\chi^2_2 = 17.86$, $P < 0.001$ respectively).

More patients who received a leaflet from a pharmacist were able to give correct answers to knowledge questions than those who were given a leaflet by a general practitioner (Table 8). In addition, those who received a leaflet from the pharmacist were more satisfied than those who were given one by their general practitioner. For both medicines, these findings were statistically significant (NSAIDs χ^2_1 test for trend = 31.89, $P < 0.001$; β-adrenoceptor antagonists χ^2_1 test for trend = 4.29, $P < 0.05$). However, more patients who received a leaflet from the pharmacist said it made them 'feel anxious about taking their medicine.' This was particularly marked amongst patients prescribed β-adrenoceptor antagonists, 12 (25%) of whom found the leaflet worrying when it came from a pharmacist compared with only 2 (3.4%) who expressed anxiety when it came from their general practitioners ($\chi^2_1 = 8.84$, $P < 0.01$). Nevertheless, all but one of these patients thought the leaflet was a good idea.

Discussion

In a previous postal survey of knowledge and attitudes to medicines in the Southampton community we obtained a 60% response rate (Ridout *et al.*, 1986). The response rates achieved in the two studies reported here were higher. This may be due, in part, to the involvement of patients, all of whom had recently received a prescribed medicine and might therefore be expected to be more interested in the survey than the general population. It has also been

Table 8 Knowledge and satisfaction amongst patients who received leaflets from either a pharmacist or a general practitioner (Numbers are those giving correct answers [percentages in brackets])

	Medicine			
	NSAIDs		*β-adrenoceptor antagonists*	
Source of leaflet	Pharmacist	GP	Pharmacist	GP
Total number	150	82	60	62
Knowledge				
When to take it	122 (85.9)	61 (79.2) **	56 (93.3)	61 (98.4)
Take with fluid	128 (90.1)	74 (96.1)	57 (95.0)	62 (100.0)
Take with food	118 (83.1)	59 (76.6) *	—	—
What to do if a dose is missed	87 (62.1)	39 (50.6)	35 (58.3)	41 (66.1)
Aware of side effects	70 (46.7)	29 (35.7)	25 (41.7)	12 (19.4) *
Storage out of reach	128 (90.1)	72 (93.5)	55 (93.2)	55 (88.7)
Safe disposal	128 (90.1)	68 (88.3)	44 (73.3)	49 (79.0)
Secondary usage	137 (96.5)	67 (87.0) *	59 (98.3)	61 (98.4)
Satisfaction with information				
Completely satisfied	129 (86.0)	42 (51.2)	49 (81.7)	42 (67.7)
Satisfied	17 (11.3)	34 (41.5)	11 (18.3)	17 (27.4)
Indifferent	2 (1.3)	3 (3.7)	0 (0)	3 (4.8)
Dissatisfied	0 (0)	2 (2.4) ***	0 (0)	0 (0)

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.
Questions were answered by 94–100% of the respondents. Missing values were excluded from the percentages.

noted that recruitment by general practitioners can improve the response from patients (Smith *et al.*, 1985). The main advantage of the high response rates is that they reduce the possibility of the results being biased by the non-respondents. The excess of women and those over 65 years in the sample was expected, since both groups consult their general practitioners more often and are prescribed more medicines than others in the general population (Ridout *et al.*, 1986; Dunnell & Cartwright, 1972; Cartwright & Smith, 1988). The likelihood that a sample drawn from residents of small, rural Hampshire towns would be biased in favour of the non-manual social classes was also recognised, but the class distribution of the samples was found to be representative of that for south-east England (Office of Population Censuses and Surveys, 1981). Comparison between patients who received a leaflet about β-adrenoceptor antagonists and others who did not was possible because no significant differences in the demographic characteristics were found between the two groups. However, there were demographic differences between patients who received leaflets about NSAIDs or bronchodilators and the control group who were not given any written information. Patients prescribed bronchodilators were significantly younger in the control town than those who received leaflets. An above average rate of childhood asthma is suspected in the control town (Charlton *et al.*, 1983; Burney *et al.*, 1987). There was an excess of patients drawn from social class III and a deficiency of those from social classes IV and V amongst patients who received leaflets about NSAIDs. Since

written information may have been more effective amongst well educated patients, it is possible that the effects of the NSAID PIL have been overestimated in this study. However, we do not believe this is the case, because trends in favour of the leaflets were still apparent when comparisons were made within each social class group. Secondly, the results obtained for patients prescribed β-adrenoceptor antagonists make it unlikely that social class was a confounding variable. The social class mix of these patients was not significantly different in the experimental and control groups, but trends in favour of the leaflets were clearly apparent amongst patients who received them. Thirdly, there was no evidence that social class influenced whether or not patients read their leaflet.

It is unlikely that these differences in class distribution are a true reflection of the social class mix of the study towns, since these were found to be similar (Office of Population Census and Surveys, 1984). We believe that these differences reflect a trend amongst general practitioners to issue leaflets to 'suitable' patients from the higher social classes. In particular, 42% of NSAID takers who received leaflets from their general practitioner were from social classes I and II, whereas only 28% who received leaflets from pharmacists were in this group ($\chi^2_2 = 7.18$, $P < 0.05$).

More patients who received leaflets were aware of how to use their medicines correctly, a finding supported by studies conducted in the USA (Morris & Halperin, 1979; Gotsch & Ligouri, 1982; Wiederholt & Kotzan, 1983) and pilot studies conducted in the UK (George *et al.*, 1983; Gibbs *et al.*, 1987). The most marked difference was the increased awareness of the side effects amongst patients who received leaflets. However, despite this improvement, the proportion of patients who could name any side effects of their medicine was only 30%. Thus, although patients may read about side effects of their medicine when given a leaflet, this information may not be retained in the memory, particularly if a course of treatment remains problem free. Nevertheless, the fact that leaflets were kept by many of the patients for up to 12 months, suggests that they have a ready source of reference if a side effect should occur.

For some items, knowledge was found to be high whether or not a leaflet was received. Almost all patients interviewed were aware of the purpose for which the medicine was prescribed, a finding which is in agreement with those studies which have shown that patients remember diagnostic information given in verbal consultations (Ley, 1979). The widespread awareness that medicines should be kept out of reach of children may be connected with the increased use of such warnings on medicine bottles (the warning 'Keep out of reach of children' is a legal requirement on all dispensed medicines (British National Formulary, 1988)). Despite this, tablets were not stored out of reach in about half of the homes visited. In most cases, these patients did not perceive their tablets as a safety risk because no small children lived in, or regularly visited, the household. NSAIDs and β-adrenoceptor antagonists were most frequently kept in the kitchen where they were visible and therefore not forgotten. Inhalers were usually carried about the person in case of need. The high levels of awareness of what to do with unused medicines was in contrast with that recorded for NSAIDs in a previous study (George *et al.*, 1983). It is possible that this apparently recent improvement in public awareness may be due in part to recent 'DUMP' campaigns run in community pharmacies to encourage the return of unused medicines for disposal. Although there was little difference in awareness of correct methods of disposal of medicines between those who received leaflets and others who did not, the finding that some patients who received leaflets were discouraged from hoarding old medicines is encouraging.

The only item of knowledge found not to be higher amongst those who received leaflets was the name of the medicine. This was in contrast to previous findings for leaflets about penicillins and NSAIDs (George *et al.*, 1983). It is possible that the 'generic' nature of the leaflets distributed, which gave information about the group of medicines rather than the specific product prescribed, may have confused patients. Although a space was left for the product name to be inserted by the doctor or pharmacist, it is likely that this was not filled in on every occasion. Evidence that product specific leaflets might be more effective comes from the widespread ability of the patients interviewed about bronchodilators, all of whom received a manufacturer's leaflet with their medicine, to name their inhaler.

Since no previous studies have investigated the long term effects of leaflets it is particularly interesting that many of the initial 'improvements' in knowledge amongst patients who received leaflets were still apparent 1 year later for NSAIDs and β-adrenoceptor antagonists. However, the effect appeared to diminish over time, suggesting there may be advantages associated with the provision of leaflets each time a repeat prescription is issued. Reduction in awareness of the side effects was found to be particularly

marked. An explanation for this might be that patients still taking their tablets are likely to be those who have not experienced any problems and, therefore, have not needed to refer to the side effects listed, or to commit them to memory.

The much voiced fear that improvements in knowledge will increase the reporting of side effects, by suggestion, was not supported by these studies. In fact, the frequency of reporting of possible side effects listed on the leaflet by those who received one was lower than amongst the controls who were given no additional information. Amongst NSAID takers who reported 'side effects', those who received leaflets were more likely to identify the problem as being due to the medicine and might, therefore, be more likely to take appropriate action.

As has often been found to be the case in general practice surveys (Cartwright & Anderson, 1981) overall levels of patients' satisfaction were high. Nevertheless, significant differences in satisfaction with the information received have been demonstrated amongst those who received the leaflets. This finding is in agreement with the earlier pilot study (George *et al.*, 1983). In addition, the 'improvements' in satisfaction have been sustained for up to 12 months after a leaflet was received. However, little change in medicine taking behaviour accompanied the improved levels of satisfaction. This was surprising since several studies have established that satisfied patients are more likely to comply (Korsch *et al.*, 1968; Kincey *et al.*, 1975; Hulka *et al.*, 1976; Larsen & Rootman, 1976; Ley, 1982). It is possible that the failure to demonstrate this relationship could be because our assessment of patient compliance was inadequate. The difficulty in obtaining an accurate measurement of patient compliance from tablet counts is widely recognised (Gordis *et al.*, 1969), particularly in non-hospitalized patients (Sackett & Haynes, 1976), and even when a valid measure is obtained the definition of 'good compliance' itself is arbitrary. Since tablet counts could only be conducted when medicines were made available to the interviewers (in two-thirds of the interviews with people prescribed NSAIDs or β-adrenoceptor antagonists) the true pattern of compliance might be further obscured. Another possible explanation concerns the nature of patient satisfaction itself. In contrast to the substantial improvements in satisfaction with information amongst those who received leaflets, improvements in satisfaction with the consultation, and with the treatment itself, were modest. Greater improvements in patients' satisfaction with the communication exchange between doctor and patient may be needed before any changes in medicine taking behaviour follow. Support for this suggestion comes from several studies which have found that it is only in combination with verbal counselling that the best effects of written information can be realised (Richards, 1975).

It is clear that, for NSAIDs and β-adrenoceptor antagonists, patients who received leaflets were only slightly more likely to comply with medicine taking instructions. This is in agreement with studies of leaflets provided with long-term treatment for hypertension (Sackett *et al.*, 1975) or warfarin therapy (Clark & Bayley, 1972), but in contrast to the improved compliance reported in association with leaflets for short-term antibiotic therapy (George *et al.*, 1983; Dodds, 1986). Although patients with long-term illnesses welcome written information, it would appear to become just one of many influences on compliance when medicine taking is a central part of everyday life (Becker & Maiman, 1974; Stimson & Webb, 1975; Conrad, 1985).

Although more of those who received leaflets were satisfied with the information received, the level of satisfaction was found to be lowest amongst patients prescribed bronchodilators. Three explanations for this seem possible. Firstly, our leaflet may be inadequate. Many of the patients interviewed wanted to know more about the condition of asthma itself, an area not covered in our leaflet. Secondly, these patients already received a manufacturers leaflet with their medicine and this may have diminished the impact of further written information. Finally, the patients interviewed about bronchodilators were younger than for the other two groups of medicines. The young have often been found to expect more from health care than older people (Cartwright & Anderson, 1981; Fitzpatrick, 1984).

Almost all patients who received a leaflet liked it and claimed to have read it. Although women are often found to be more interested in health matters than men, there was no evidence that they were more likely to read the leaflets in this study. However, not everyone who should have been given a leaflet actually remembered receiving one. It is impossible to tell whether these people had simply forgotten about the leaflet or whether they really had not received one. The evidence suggests that both general practitioners and pharmacists experienced difficulty in remembering to issue the leaflets. It is likely that some selection of suitable patients occurred, particularly by general practitioners, who tended to distribute leaflets to older patients from a higher social class than those given leaflets by pharmacists.

The effect of the source of the leaflet on its

impact has not been examined previously and as such the findings of this study may be of importance. Despite there being no evidence that the source of the leaflet influenced whether or not it was read, both knowledge and satisfaction were higher amongst patients who received leaflets from pharmacists. However, more patients said it made them feel anxious about taking their medicine if it came from a pharmacist, especially patients prescribed β-adrenoceptor antagonists. Although these differences might be accounted for by the demographic characteristics of the patients in the two groups, they should be borne in mind when considering the optimum method of leaflet distribution.

These studies clearly demonstrate that patients who received leaflets had a better understanding of their treatment and were more satisfied with the information received than patients who did not receive written information. However, the finding that some patients (especially those prescribed NSAIDs for the first time) were alarmed by the side effects listed on the leaflet is cause for slight concern. Nevertheless, almost all patients thought their introduction would be a good idea. Together these findings highlight the need for further improvements in communication between doctors and patients now that leaflets are to be provided with prescribed medicines in the UK (Association of the British Pharmaceutical Industry, 1987).

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The benefits of prescription information leaflets (2)

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Prescription information leaflets (PILs) for penicillins, diuretics and benzodiazepines were evaluated in a small Hampshire town. A second town, in which no leaflets were distributed, acted as a control. Knowledge about these medicines was greater amongst the 252 patients who received leaflets compared with 247 controls. Significantly more patients who received leaflets knew the potential side-effects of their treatment and, with the exception of those taking penicillins, were more satisfied with the information they received. These findings add further support for the routine use of PILs in general practice.

Keywords information leaflets communication knowledge patient satisfaction general practice

Introduction

Patients want and need more information about medicines than they currently receive (Ridout *et al.*, 1986). However, few systematic studies have investigated the effects of providing information leaflets in the UK. But, patients given PILs with non-steroidal anti-inflammatory drugs (NSAIDs), β-adrenoceptor antagonists and inhaled bronchodilators knew more about their medicine and were significantly more satisfied with the information received than those in a control group (Gibbs *et al.*, 1989). In order to extend the range of drug groups studied, we have developed a further three generic PILs which give information about penicillins, diuretics (of the loop or benzothiadiazine type) and benzodiazepines. We have studied their effects when issued by community pharmacists.

Methods

The leaflets were developed as described by Gibbs *et al.* (1987). That for penicillins has been published elsewhere (Gibbs *et al.*, 1987), whereas those for diuretics and benzodiazepines are shown in Figure 1.

The study design was based on that used previously (Gibbs *et al.*, 1989). Briefly, a series of studies have been conducted in eight small Hampshire towns, six of which participated in previous studies (Gibbs *et al.*, 1987, 1989). The remaining two took part in the present study. Town G (population 10,068) was assigned to be the experimental town, where leaflets were issued by pharmacists. The second, Town H (population 11,100), acted as a control town, where no leaflets were distributed. The survey ran for 10 weeks in each town and included patients who received at consultation a prescription for a penicillin, a diuretic or a benzodiazepine. One to two weeks after consultation, they were sent a letter asking for permission for a 30 min interview to be carried out in their homes. Further details of the study design have been published previously (Gibbs *et al.*, 1989). Data on patients' knowledge about their medicine, medicine taking behaviour, satisfaction with information received and opinions about information provision were recorded on a structured questionnaire. Compliance rates were assessed from tablet counts as:

$$\text{Compliance (\%)} = \frac{\text{Amount removed from container}}{\text{Amount expected to be taken}} \times 100$$

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What you should know about Diuretics

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____

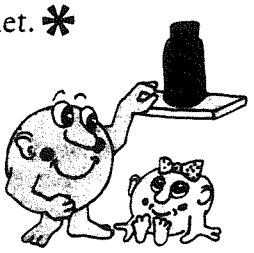
This is one in a group of medicines called Diuretics. Diuretics are "water tablets" which help your body get rid of excess water and salt. They bring down swollen ankles and improve shortness of breath. They also help reduce high blood pressure.

Things to remember about Diuretics

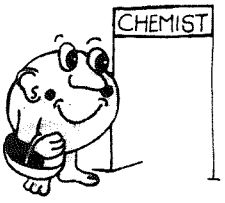
1 Make sure it is safe for you to take Diuretics *(see the back of this leaflet).*♦

2 Look at the label on your medicine. It will tell you when to take it.

3 Diuretics sometimes cause problems. You can find these listed on the back of this leaflet. ✱



4 Keep your medicine **out of reach of children.**



5 Remember to return any unused Diuretics to your pharmacist or flush them down the toilet.

You will find more about Diuretics on the back of this leaflet.

Figure 1a Front of leaflet, coloured purple in the original, giving information about diuretics.

Your medicine is a Diuretic. Diuretics are "water tablets" which help your body get rid of excess water and salt. They bring down swollen ankles and improve shortness of breath. They also help reduce high blood pressure.

♦ Before taking your medicine

- Are you taking any of the following medicines:
  - Other water tablets?
  - Medicine for heart trouble eg. digoxin?
  - Insulin or tablets for diabetes?
  - Lithium?
- Have you ever had a rash after taking water tablets or Sulphonamides?
- Do you get gout?
- Are you pregnant?
- Are you breast feeding?

If the answer is YES to any of these questions tell your dotor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, ask your doctor or pharmacist.
- Take your tablets or capsules with a glass of water or milk.
- Keep taking your medicine until your doctor tells you to stop. Don't stop just because you feel better. If you stop the tablets your condition may get worse.
- If you forget to take a dose, take another as soon as you remember. Then go on as before.

✱ After taking your medicine

Most people benefit from taking this medicine but it can cause side-effects.
If you get any of the following, tell your doctor:

- Dizziness or lightheadedness
- Feeling extremely thirsty.
- Muscle pains or cramps.
- Skin trouble such as rash or itching for the first time.

You may lose potassium from your body while you are taking water tablets. You may be given tablets or sachets or told to eat plenty of foods rich in potassium, such as bananas, oranges and fruit juices.
Your doctor will tell you about this.

Storing your medicine

- Keep your medicine in a safe place out of reach of children. Your medicine could harm them.
- Return any left-over medicine to the pharmacist or flush it down the toilet. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptons are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Figure 1b Reverse of leaflet giving information about diuretics.

What you should know about Benzodiazepines

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____

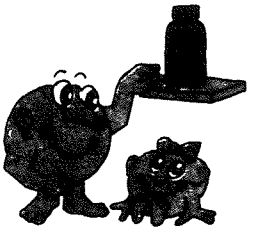
Your medicine is one in a group of medicines called Benzodiazepines. These medicines calm anxious or worried people and help them to sleep. They also relax muscle spasms.

Things to remember about Benzodiazepines

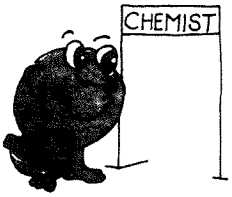
1 Make sure it is safe for you to take Benzodiazepines *(see the back of this leaflet).*♦

2 Look at the label on your tablets. It will tell you when to take them.

3 Benzodiazepines can cause problems. You can find these listed on the back of this leaflet. ✱



4 Keep your tablets **out of reach of children.**



5 Remember to return any unused tablets to the Pharmacist or flush them down the toilet unless your doctor has told you to keep them.

You will find more about Benzodiazepines on the back of this leaflet.

Figure 1c Front of leaflet, coloured pink in the original, giving information about benzodiazepines.

Your medicine is one in a group of medicines called Benzodiazepines. These medicines calm anxious or worried people and help them to sleep. They also relax muscle spasms.

♦ Before taking your medicine

- Do you suffer from chronic bronchitis or lung problems?
- Are you on other medicines for nerves or epileptic fits or to help you sleep?
- Are you pregnant?
- Are you breast feeding?

If the answer is YES to any of these questions tell your doctor or pharmacist.

Taking your medicine

- It is important to take your medicine at the right times. The label will tell you how much to take and how often. If it doesn't or you are not sure, ask your doctor or pharmacist.
- To help you sleep take your tablets ½ hour before you go to bed.
- Take your tablets or capsules with a glass of water.
- If you forget to take a dose take another as soon as you remember. Then go on as before. Don't take a double dose next time.
- If you take an overdose by accident contact your nearest hospital casualty department or tell your doctor immediately.

✱ After taking your medicine

A few people can be upset by this medicine. If you get any of the following, tell your doctor.

- Seeing things hazy or blurred
- Dizziness, unsteadiness or not walking straight
- Feeling more depressed than usual
- Skin trouble such as rash or itching for the first time.

Your tablets may make you feel drowsy during the day. Don't drive a car or work a machine while you are on these tablets.

Don't drink alcohol while you are on these tablets. The two together will make you very drowsy and this could be dangerous.

Stopping your medicine

- Have you been taking these tablets for 3 months or more? If you have make sure you talk to your doctor about it. He may want to stop your tablets.
- If your doctor decides to stop your tablets, he will reduce your dose slowly over several weeks. Your body may need time to adjust so don't stop taking your tablets suddenly.
- When you stop the tablets you may feel sick, anxious and shaky and find it hard getting to sleep. If this happens to you take another tablet as soon as possible. Tell your doctor about it next time.

Storing your medicine

- Keep your tablets in a safe place where children cannot reach them. Your tablets could harm them.
- If your doctor decides to stop the treatment, return any left-over tablets to the pharmacist or flush them down the toilet. Only keep them if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptons are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Figure 1d Reverse of leaflet giving information about benzodiazepines.

Table 1 Knowledge of and satisfaction with the study medicines. (Numbers are those giving correct answers (percentages in brackets))

	Penicillins		*Diuretics*		*Benzodiazepines*	
Leaflet	Yes	No	Yes	No	Yes	No
Total number	83	100	99	90	70	57
Knowledge						
Name of medicine	69(83.1)	92(92.0)	64(64.6)	63(70.0)	40(58.0)	30(52.6)
Purposes of therapy	83(100.0)	99(99.0)	90(90.9)	81(90.0)	68(98.6)	53(93.0)
When to take it	75(91.5)	90(90.0)	90(90.9)	76(85.4)	49(77.8)	34(59.6)
					*	
Take with fluid	48(58.5)	57(57.0)	91(91.9)	83(94.3)	57(90.5)	46(80.7)
Take on empty stomach	69(84.1)	59(59.0)				
	***					
What to do if a dose is missed	71(86.6)	58(58.0)	64(64.6)	49(55.7)	12(24.5)	13(26.0)
	***					
Aware of any side-effects listed	51(61.4)	35(35.0)	28(28.3)	7(7.8)	22(31.4)	8(14.0)
	***		***		*	
Storage out of reach of children	73(89.0)	71(71.0)	95(96.0)	71(80.7)	58(92.1)	43(76.8)
	**		**			
Safe method of disposal	66(80.5)	79(79.0)	81(81.8)	63(71.6)	49(77.7)	44(77.2)
Aware not to share medicines	77(93.9)	96(96.0)	96(97.0)	80(89.9)	60(95.2)	45(78.9)
					*	
Satisfaction						
Completely satisfied with information received	17(20.5)	19(19.0)	47(47.5)	32(36.0)	35(50.7)	17(29.8)
			*			

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.
Questions were answered by 90–100% of respondents except 'what to do if a dose of benzodiazepine was missed'.

Data were analysed using the SPSSX statistical package. Associations were tested using the Chi-squared statistic (with Yates correction for 2 × 2 tables).

Results

A total of 499 patients were interviewed, 252 in the leaflet town and 247 in the control town, giving an 84% response rate. Women outnumbered men by 3:1 and the mean age of patients prescribed a diuretic or a benzodiazepine was 67.8 years, whereas for penicillins it was 42.2 years. No significant differences in response rate, age, sex or social class distribution were found between those who received a leaflet and others who did not.

Patients who received leaflets were better informed than those who did not (Table 1). Awareness of the side-effects of all three medicines was significantly higher among patients who were given leaflets, but there was little evidence of an increased reporting of the 'side-effects' listed on the leaflets for penicillins or diuretics. However, more patients who read a leaflet about diuretics reported having had a rash ($\chi^2_1 = 4.87$, $P < 0.05$). In contrast, 3 of the 5 'side-effects' listed on the benzodiazepine leaflets (including depression $\chi^2_1 = 4.24$, $P < 0.05$) were reported more frequently by patients who received leaflets.

Trends in favour of the leaflets were found for all other items tested, except for knowledge of the name of the medicine. Two-thirds of the takers of diuretics and benzodiazepines allowed the interviewers to perform tablet counts. Amongst these patients, 36 (51.4%) of those who received a leaflet about diuretics showed compliance rates between 80–120%, compared

with 29 (55.8%) in the control group ($\chi^2_1 = 0.09$, $P = 0.77$). For those taking benzodiazepines, 16 (34.4%) who received a leaflet recorded compliance rates between 80–120%, whereas 17 (47.2%) of the control group achieved this level of compliance ($\chi^2_1 = 0.57$, $P = 0.45$). Patients receiving leaflets for diuretics and benzodiazepines were more satisfied than those who did not receive a leaflet ($\chi^2_4 = 9.11$, $P < 0.05$: $\chi^2_4 = 7.40$, $P = 0.06$ respectively). However, there was little difference in the level of satisfaction reported amongst the penicillin takers ($\chi^2_3 = 5.30$, $P = 0.26$). Six patients prescribed penicillins and seven of the diuretic takers said that the leaflets 'made them feel anxious about taking their medicine'. However, 10 (14.3%) patients taking benzodiazepines said that the leaflets made them feel anxious. Nevertheless, 8 of the 10 thought the leaflets were a good idea.

Discussion

The high response rate (84%) achieved in this study was comparable with that in a previous survey (Gibbs *et al.*, 1989). As expected, women, the elderly and the non-manual social classes were disproportionately represented. However, the similar demographic characteristics of those who received leaflets and others who did not enabled comparisons to be made between the two groups.

The finding that patients who received leaflets knew more about their medicines, particularly potential side-effects, is consistent with previous studies on NSAIDs, β-adrenoceptor antagonists and inhaled bronchodilators (Gibbs *et al.*, 1989). Similarly, patients who received leaflets for diuretics and benzodiazepines were more satisfied. Even allowing for the problems of assessing compliance by tablet counts, there was no evidence of a higher level of compliance amongst those who received leaflets.

With the exception of rash (the prevalence of which was unexpectedly high for all three medicines investigated in town G) there was little evidence that greater knowledge encouraged the reporting of 'spurious' side-effects with either penicillins or diuretics. However, in contrast to the other leaflets which we have studied, those for benzodiazepines do appear to have caused spurious side-effects. Overall, three of the five side-effects mentioned on this leaflet were reported more frequently by patients who received a leaflet. About 80% of those affected were female and three-quarters of them had taken benzodiazepines before. However, our benzodiazepine PIL is inadequate in several ways. Firstly, the statement 'if you forget to take a dose, take another as soon as you remember' is confusing and open to misinterpretation by those taking benzodiazepines as hypnotics. Secondly, some benzodiazepines can be used to control epilepsy and this would need to be mentioned in redesigned leaflets for specific drugs of this type, e.g. clonazepam. Thirdly, in view of current concern about the over use of benzodiazepines the leaflets could contain a statement encouraging patients to try alternative methods to reduce anxiety or relieve sleeplessness.

Nevertheless, this study provides further support for the routine use of simple informative leaflets when medicines are prescribed in the setting of general practice.

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