

## 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),  $\beta$ -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  $\beta$ -adrenoceptor antagonists ( $P < 0.01$ ).

**5** Subsequently, three hundred and fifty-eight (77%) of the patients prescribed either a NSAID or a  $\beta$ -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  $\beta$ -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  $\beta$ -adrenoceptor antagonists which are often prescribed for asymptomatic hypertension whilst the third was for inhaled ( $\beta_2$ -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  $\beta$ -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.

Figure 1 Leaflet, coloured blue in the original, giving information about  $\beta$ -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.

Figure 2 Leaflet, coloured brown/orange in the original, giving information about inhaled bronchodilators. (a) front, (b) reverse.

**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).

**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 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).

The survey ran for 10 weeks in each town. Patients prescribed an NSAID, a  $\beta$ -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, interviewed 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  $\beta$ -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  $\beta$ -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 main-frame 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  $2 \times 2$  tables). Where significant  $\chi^2$  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  $\chi^2$ -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  $\chi^2$  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  $\beta$ -adrenoceptor antagonist and 165 an inhaled bronchodilator. Of these, 232 NSAID patients, 122 patients prescribed a  $\beta$ -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  $\beta$ -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)

Leaflet	NSAIDs		Medicine $\beta$ -adrenoceptor antagonists		Bronchodilators	
	Yes	No	Yes	No	Yes	No
Total number	232	100	122	100	65	100
<i>Sex</i>						
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)
<i>Age (years)</i>						
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)
**						
<i>Social class</i>						
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  $\beta$ -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 ( $\chi^2_1 = 9.17$ ,  $P < 0.01$ ).  $\beta$ -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])

Leaflet	NSAIDs		Medicine $\beta$ -adrenoceptor antagonists		Bronchodilators	
	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)	†	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  $\beta$ -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  $\beta$ -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  $\beta$ -adrenoceptor antagonists was the kitchen. Inhalers were more commonly kept in a handbag or pocket. Eighty-nine per cent of patients prescribed NSAIDs or  $\beta$ -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	
	Yes	No	Yes	No	Yes	No
Leaflet 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)	21 (17.2) **	4 (4.0)	18 (27.7) *	11 (11.0)
Ringling in ears	23 (9.9) **	0 (0)	10 (8.2) *	1 (1.0)	4 (6.2)	2 (2.0)
Dizziness	43 (18.5) ***	1 (1.0)	9 (7.4) *	0 (0)	9 (13.8)	11 (11.0)
Rash	14 (6.0)	1 (1.0)	2 (1.6)	0 (0)	2 (3.1)	0 (0)
Wheezing	12 (5.2) *	0 (0)	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  $\beta$ -adrenoceptor antagonists.

*Patient compliance* Tablet counts were conducted during 70% of the interviews with patients prescribed NSAIDs and 67% of interviews about  $\beta$ -adrenoceptor antagonists. No such assessment of patient compliance was possible for inhaled bronchodilators. Compliance rates were calculated from the tablet counts as:

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)  $\times$  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  $\beta$ -adrenoceptor antagonists.

More patients showed compliance rates between 80–120% if they had received a leaflet, but the differences between 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  $\beta$ -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  $\beta$ -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 ( $\chi^2_1$  test for trend = 45.11,  $P < 0.001$ ). The same was true for patients prescribed  $\beta$ -adrenoceptor antagonists ( $\chi^2_1$  test for trend = 34.27,  $P < 0.001$ ). This trend in favour of the leaflets was apparent also for bronchodilators ( $\chi^2_1$  test for trend = 13.86,



**Table 4** Patients' satisfaction with information received (Percentages are shown in brackets)

Leaflet	NSAIDs		Medicine $\beta$ -adrenoceptor antagonists		Bronchodilators	
	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  $\beta$ -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%)  $\beta$ -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  $\beta$ -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  $\beta$ -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  $\beta$ -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)

	<i>Medicine</i>			
	<i>NSAIDs</i>		<i>β-adrenoceptor antagonists</i>	
Leaflet	Yes	No	Yes	No
Total number	145	63	74	76
<i>Sex</i>				
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)
<i>Age (years)</i>				
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)
<i>Social class</i>				
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 ( $\chi^2_1$  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 ( $\chi^2_1$  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)

Leaflet	Medicine			
	NSAIDs		$\beta$ -adrenoceptor antagonists	
Total number	Yes	No	Yes	No
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  $\beta$ -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  $\beta$ -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  $\chi^2_1$  test for trend = 31.89,  $P < 0.001$ ;  $\beta$ -adrenoceptor antagonists  $\chi^2_1$  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  $\beta$ -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])

Source of leaflet	Medicine			
	NSAIDs		$\beta$ -adrenoceptor antagonists	
	Pharmacist	GP	Pharmacist	GP
Total number	150	82	60	62
<i>Knowledge</i>				
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)
<i>Satisfaction with information</i>				
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  $\beta$ -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  $\beta$ -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  $\beta$ -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  $\beta$ -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  $\beta$ -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  $\beta$ -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  $\beta$ -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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