Recruitment and retention of primary care patients into a research study investigating medication adherence

Shih Yen Chang MA, BA (Hons);[1] **Simon Horsburgh** PhD, MA (Hons), BA (Hons);[2] **Pauline Norris** PhD, MA (Hons), BA;[1] **Rhiannon Braund** PhD, BPharm, BSc (Bioc), MPS, FNZCP, RegPharmNZ[1]

[1] School of Pharmacy, University of Otago, Dunedin, New Zealand

[2] Department of Preventive and Social Medicine, University of Otago, Dunedin

ABSTRACT

INTRODUCTION: General practitioners (GPs) and patients are key sources of information for investigating primary health care. However, recruiting these into health care studies has been reported to be difficult.

AIM: This study aimed to determine the recruitment and retention rates of GP practices and patients into a research project in the primary health care setting.

METHODS: All general practices in Dunedin, New Zealand, with three or more practitioners were invited to participate in a study investigating medication adherence. In practices that agreed to participate, 100 patients were recruited from waiting rooms and followed up by telephone over six months. The main outcome measures included recruitment rates of GPs and patients, the level of retention and loss to follow-up of patients over a six-month period, the drop out and reasons for this drop out.

RESULTS: Only two of the 15 practices agreed to participate. To recruit 100 patients, 203 people were approached. Reasons for not wanting to participate were recorded where possible. Of those that agreed to participate, 86% of doctor consultations resulted in a prescription and, of these prescriptions, 87% were reported to be collected as prescribed. At the end of six months, 68 patients still remained in the study.

DISCUSSION: Patients were interested in being involved in this type of study and were recruited at a rate of 82% and 56% depending on the practice. After the initial drop out, most patients remained in the study until the conclusion. Recruitment of general practices remains challenging.

KEYWORDS: Patient compliance; patient recruitment; primary health care

Introduction

It is well established that lack of adherence to medication regimes can lead to treatment failure, adverse health outcomes and increased health care costs.[1–3]

While there are several subgroups of adherence, these are often thought of as two types: primary adherence, and secondary or medication adherence.[4] Primary adherence refers to the time after the consultation when the patient may or may not redeem an initial prescription at a pharmacy, whereas secondary or medication adherence refers to the correct use of the medications at home after the prescription has been redeemed.[4]

Studies have attempted to measure primary and secondary adherence by the rate of prescription collection[4] but much more information may be obtained if researchers can recruit patients at the time the prescription is written and follow them prospectively over time.

Previous studies investigating patients' expectations of prescriptions found that almost 70% of patients hoped to receive a prescription, and that 11% of patients felt that they had wasted the doctor's time if they did not receive a prescription.[5] The communication between patients and professionals has consequences for adherence, as many patients are reluctant to share concerns

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CORRESPONDENCE TO:
Rhiannon Braund
School of Pharmacy, University of Otago, PO Box 56, Dunedin 9054, New Zealand
Rhiannon.braund@otago.ac.nz

about medications with health care providers.[6] However, including patients in the discussions surrounding medication decisions can increase understanding and adherence to medication.[6]

Recruitment of patients, and indeed general practices, is reported to be difficult for health research in primary care.[7,8] Yet these participants are key for health research. There is evidence that paying health care professionals per patient may increase the recruitment rate of patients into some studies.[9] However, a further study showed that patient recruitment via a newspaper advertisement was as effective as recruitment via a general practitioner (GP),[10] and so the need for direct GP involvement is questioned for some types of studies. In particular, academic studies may wish to separate research activities from the clinical consultation and to use an independent person to recruit patients.[8] The task of recruitment should not be underestimated.[11] For a larger study to investigate primary and secondary adherence it is important to ensure that the recruitment methodology is feasible. It is also important to identify any potential obstacles to recruit practices and patients.

The aims of this study were to determine the feasibility of recruiting general practices and their patients into a study about primary and secondary adherence; to assess retention rates for patient participants over a six-month period, and to investigate reasons for lack of participation or loss to follow-up. It is intended that these findings will identify potential issues to be identified and be of use to researchers in other disciplines considering strategies for patient recruitment.

WHAT GAP THIS FILLS:

What we already know: Lack of adherence to medication regimes can lead to treatment failure. Primary and secondary adherence can be measured by prescription collection, but more information can be obtained by recruiting patients at the time of prescription generation.

What this study adds: Patients were interested in participating in this type of study; however, recruitment of general practices remains challenging. Eighty-six of the 100 consultations resulted in a prescription generation and, of these, 87% were collected as prescribed.

Methods

Following ethical approval from the Lower South Regional Ethics Committee (LRS/09/03/005), recruitment was initiated.

Recruitment of GP practices

This study was located in Dunedin city, which has a population of approximately 125 000. A cluster sampling design was used, with general practices as clusters and recruitment of patients within them. Dunedin has 28 practices listed in the local telephone book. To reduce prescriber bias, only practices consisting of three or more independent prescribers were included in the study. Of these, 16 met the criteria of three or more prescribers. One of these practices was excluded (Student Health) due to the homogenous patient population (exclusively university students).

Letters were sent to the practice managers at the 15 general practices, outlining the proposed study and requesting permission to recruit patients in their waiting rooms. Practice managers were contacted rather than individual GPs for two main reasons. Practice managers often mediate contact with GPs anyway and so act as gatekeepers to them. It therefore made sense to contact the practice managers directly. Furthermore, since waiting rooms are often shared by patients from all of the practice GPs and therefore under the control of practice administrative staff, the awareness and cooperation of these staff were seen as vital for recruitment.

The letters were followed up by telephone calls, and messages were left if contact could not be made. Reasons for not choosing to participate, as given by the practice manager, were recorded where possible. If the practice did not reply, despite several messages having been left, they were recorded as non-responders. Practices were not paid for their participation in the study.

Recruitment of participants

One of the researchers (SYC) acted as recruiter and approached patients in the waiting room of the practices. These visits were conducted at various times through the days on differing days

of the weeks. Parents with distressed children or patients waiting to see health professionals other than the GP, such as the physiotherapist or practice nurse, were not approached.

The first question asked was: "Excuse me, are you waiting to see the doctor?" to exclude patients seeing other health professionals. Those responding "yes" were invited to participate in the research study. Patients who expressed interest were given an information sheet. Those not interested were thanked, and where possible their reasons for declining were recorded.

Patients interested in participating who had read the study information signed a consent form and completed a questionnaire collecting demographic data and contact information for follow-up calls. They then were given a piece of paper to take in to their consultation requesting that the doctor produce a second copy of any prescriptions. This second prescription copy was given to the recruiter following the consultation. The time taken and number of patients approached to successfully recruit 100 patients were recorded.

The participants were followed up by telephone calls at one week, one month, three months and six months after recruitment from the practices. During these follow-up phone calls they were asked about medications they had been prescribed, which medications were new, whether they had collected the medications from a pharmacy and whether they were actually taking the medications. All reported changes and medicines involved were recorded.

After each follow-up call participants were sent a $5 grocery voucher as a token of appreciation.

Table 1. Patient demographics

Age	Male	Female
Not specified		1
<20	1	1
21–30	2	5
31–40	4	3
41–50	5	11
51–60	12	16
61–70	8	10
71–80	9	6
>80	2	1

* no information received for three participants

Results

Recruitment of practices

Of the 15 practices that were invited to participate, two agreed, five declined, two asked to be contacted at a later date and six practices did not respond. Of the five practices that declined to be involved, the reasons given were that they did not want their patients approached in the waiting room and felt that it may lead to patients querying their medications; they felt it was an intru-

Table 2. Reasons given for not wanting to participate separated by practice and gender

	Practice #1 (n=11)		Practice #2 (n=39)	
	Females (n=7)	Males (n=4)	Females (n=22)	Males (n=17)
Were accompanying children/family member seeing the doctor	2			5
Would not be around for follow-up	2	1	1	
Did not like the idea of follow-up calls		1		
Did not want the time commitment		1	2	1
Did not feel up to it	1		8	3
Gave no reason	2	1	8	6
Had a language barrier			1	
Filling in too many questionnaires/Involved in research studies			1	2
Claimed to have already participated in the study			1	

sion to ask patients what they actually did with their medications; they were concerned that the waiting room was not sufficiently private; they were concerned that patients would feel obliged to participate; and they were too busy with accreditation of the practice. The two practices that were contacted at a later date declined to participate because they were still too busy and had some doctors absent.

As only two practices agreed to participate and the intent was to recruit 100 participants, it was decided to continue recruitment in each of the practices until 50 patients at each was obtained.

Recruitment of patients

Fifty patients (30 female and 20 male) were recruited from practice 1. In order to recruit 50 people, 87 people were approached. Of these 87, 13 were not seeing the doctor, and 13 were not receiving a prescription. Eleven people (seven female and four male) declined to participate. This gave a recruitment rate of 82% (50/61).

In practice 2, 116 people were approached. Twenty people were not seeing the doctor and seven were not receiving a prescription. This gave a recruitment rate of 56% (50/89). Those who chose not to participate consisted of 22 females and 17 males. It took 15 working days of five hours a day to recruit the 50 participants.

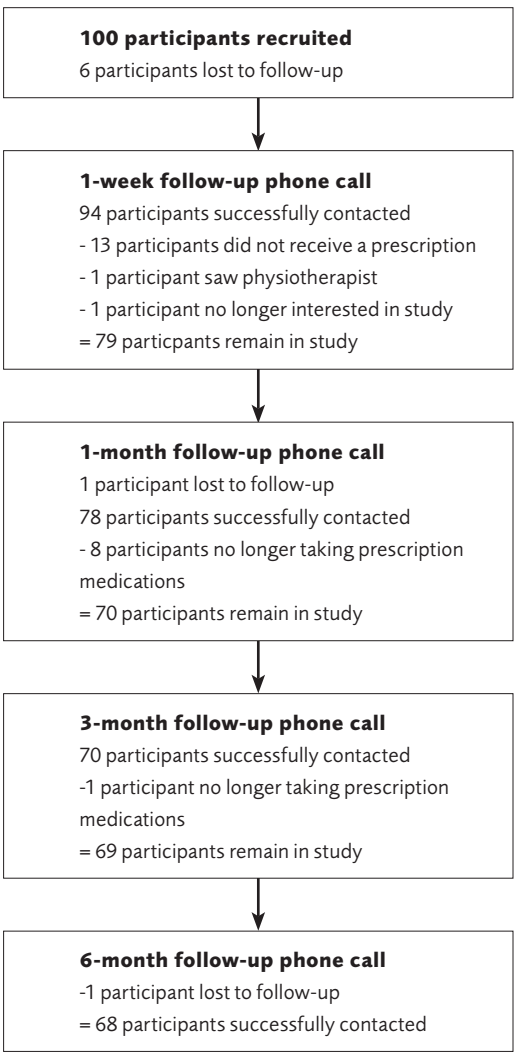
The age range of the patients recruited is shown in Table 2. The majority of the patients identified as New Zealand European, the others were Asian (2), Canadian (1), Celtic (1), Indian (1), Maori (2), Pacific Islander (2).

The reasons given for not participating are listed in Table 2. Of those that chose not to participate, a large proportion did not want to give a reason (17%). When reasons were given, many did not feel up to it (12%), did not want the time commitment (4%), or the follow-up calls (4%).

Drop out

Figure 1 records drop-out rate. Of the 100 participants recruited, 94 (94%) were successfully contacted at the one week follow-up. The six lost to follow-up had signed the consent form, but had provided either no or an invalid phone number, or could not be contacted after eight calls (made at different times and on different days).

Figure 1. Flow diagram indicating where participants were lost during the study period.



Following the first phone call, 13 people were considered to have completed the study as they had not received a prescription after seeing the doctor, one participant actually saw the physiotherapist and one person withdrew from the study.

At the one-month phone call, eight had finished the study because they were no longer taking any prescription medications. They had been

prescribed short courses of treatment which were now finished. One patient was lost to follow-up, after 13 unsuccessful phone calls on different days and at different times. At the three-month call, all 70 remaining participants were contacted with only one no longer taking prescription medications. At the six-month call, one participant of the 69 was lost to follow-up, because s/he had provided only a work number, and subsequently had taken indefinite leave from work. The remaining 68 participants were successfully contacted.

Discussion

Of the 15 GP practices approached, we could not contact six of the practices (practice managers) after repeated attempts. While a few of them were busy with accreditation and staff shortages, it was of concern that two of the practices felt that it was an intrusion to ask patients what they actually did with the medications. Given that improving adherence leads to better treatment outcomes,[1-3] it is surprising that practice managers said they were not interested in finding out more about whether their patients take their medicines. Low participation rates by general practices presents a considerable challenge for research in this area.

While a few of them were busy with accreditation and staff shortages, it was of concern that two of the practices felt that it was an intrusion to ask patients what they actually did with the medications.

In total, 203 patients were approached to reach a recruitment total of 100. There were differences in the number needed to approach to recruit 50. In practice 1, only 87 were approached and in practice 2, 116 were needed. Practice 2 had more prescribers and was 'busier', but this 'busy' waiting room did not result in a higher recruitment rate. This may be due to people feeling more self-conscious in front of other patients.

The reasons for not wanting to participate were recorded where possible, but many patients did not want to give a reason. Of those who did, the majority did not feel up to it (which may be due to being unwell), or did not want to make the time commitment or have follow-up calls.

With any study of this type there is the potential for immediate loss of participants and, in this study, 94 were contactable at the first time point. Those lost immediately were because of no phone number or a non-valid phone number. However, few were subsequently lost to follow-up over the full six months. This may be because the recruiter established a rapport with them. Providing vouchers at each time point rather that at the end of the study may also have encouraged continued participation.

Thirteen of the 92 remaining at the first week had not received a prescription from the doctor, leaving 79 (86%) consultations resulting in a prescription which may reflect the dynamic between prescriber and patient expectations of a prescription.[5] From these participants, 69 (87%) collected all of their medication as prescribed. This is the same as an earlier New Zealand study conducted in 1996 which found that 87% of prescriptions generated were actually issued from a pharmacy.[12] Eight collected only some of their medications, one collected none and one could not remember. This was self-reported and not verified by contacting their pharmacy, and so may be higher than in reality. It also does not address secondary adherence, and the drop-off that occurs with long-term chronic use,[2] a recent New Zealand study found that over 50% of medications returned to pharmacies for disposal contained more than 75% of the original dispensing.[13]

This study has some limitations, including the reliance on self-reporting. The intention was to determine recruitment into and retention in this type of study, but future studies intend to investigate the changes in the medications that patients are taking which would include contact with the patients' pharmacies to verify any dose and/or medication changes.

Given that only two practices allowed us to recruit participants, this may have introduced some

bias based on the demographics of the patients at the practice which was not further identified in this study. Further liaison with potential recruitment sites may encourage a better response.

The major barrier identified in this study was recruitment of practices. This may be improved with direct contact with the prescribers. Personal relationships with GPs may also be important. Another New Zealand study found that GP researchers who knew GPs in individual practices led to successful recruitment.[11]

The success rate of recruitment in one practice was 82% which suggests that patients are willing to assist with research projects. Additionally, the majority recruited remained in the study until the six-month end period. This might have been aided by the vouchers as tokens of appreciation sent after each call and not just at the end of the study.

This study illustrates the value that a well-documented, well-designed pilot study has in informing the design of a larger study.

Conclusion

This study found that many patients recruited from a general practice were interested in participating in a study investigating adherence, and were able to be recruited at a rate of 82% and 56% depending on the practice. Busier waiting rooms did not result in a higher recruitment rate. The recruitment of general practice surgeries was more difficult. While there was some drop out at the two initial timepoints, at the conclusion of the six-month study, 68 participants still remained. Eighty-six of the consultations generated a prescription and, of these prescriptions, 87% were collected as prescribed.

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COMPETING INTERESTS
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