Peak flow based asthma self-management: a randomised controlled study in general practice

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Abstract

Background **– Peak flow based asthma self-management plans have been strongly advocated in consensus statements, but convincing evidence for the effectiveness of this approach has been largely lacking.**

Methods **– A randomised controlled trial was conducted in 25 general practices comparing an asthma self-management programme based on home peak flow monitoring and surgery review by a general practitioner or practice nurse with a programme of planned visits for surgery review only over a six month period.**

Results **– Seventy two subjects (33 in the self-management group and 39 in the planned visit group) completed the study protocol, but diary card data for at least three months were available on a total of 84 (39 in the self-management group and 45 in the planned visit group). Teaching self-management took longer than the planned visit review. In the self-management group home peak flow monitoring was felt to be useful by doctors and patients in 28 (85%) and 27 (82%) cases, respectively. There were no between group differences during the study period in terms of lung function, symptoms, quality of life, and prescribing costs. Only within the self-management group were improvements noted in disturbance of daily activities and quality of life. Possible explanations for these negative results include small numbers of subjects, the mild nature of their asthma, and inappropriate self-management strategies for such patients.**

Conclusions **– Rigid adherence to long term daily peak flow measurement in the management of mild asthma in general practice does not appear to produce large changes in outcomes. Self-management and the use of prescribed peak flow meters need to be tailored to individual circumstances.**

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Encouraging patients with asthma to take a greater part in the management of their own disease has become part of asthma care in the past few years, and is emphasised in recent consensus statements both in the UK and elsewhere.[1–3] This concept of self-management has been commonplace in the USA for some time[4–7] but has largely been restricted to non-therapeutic measures and actions taken in emergency situations – an area shown to be poorly perceived by patients.[8] Self-management of this sort did not include altering anti-inflammatory drug dosages in response to home peak flow monitoring.

Beasley *et al* in 1989 published the first positive results of such peak flow based self-management in the UK using a small uncontrolled sample of adults with moderate to severe asthma attending a hospital outpatient clinic.[9] This work led to a number of cautious endorsements of peak flow based self-management, all accompanied by strong calls for more evidence of effectiveness.[10–12] Charlton *et al* subsequently compared peak flow and symptom based self-management schemes in general practice and did not find any significant differences between the two approaches.[13] Another primary care study was unable to show beneficial outcomes from self-management in a nurse-run asthma clinic.[14] More recent evidence has questioned the accuracy of the currently available peak flow meters[15 16] and of the records patients produce with them.[17] The effectiveness of self-management was also put in doubt by the GRASSIC study of shared care between hospital specialists and general practitioners which concluded that "prescribing peak flow meters and giving self management guidelines to all asthma patients is unlikely to improve mortality or morbidity".[18] This UK view is in contrast to the benefits from self-management in the community shown recently in New Zealand by Beasley *et al*,[19] although subjects in that study showed little preference between self-management plans based on peak flow or symptoms only.

Most asthma care at all ages is provided in general practice.[20 21] There is therefore a need to provide more evidence concerning the use of peak flow based self-management in a primary care setting so that appropriate decisions may be made about its cost effectiveness. The present study, which was commenced just before peak flow meters were placed on prescription, aimed to demonstrate in primary care that peak flow based self-management was better than proactive care alone, that this approach was acceptable among adults with asthma in the community, that home peak flow monitoring was cost effective on a wider scale, and that Beasley's original results[9] could be confirmed in a controlled trial within general practice. Since general practice based asthma care was so variable at the time the study protocol was designed, it was felt that a contol group where

"normal care" continued as before was not helpful. We therefore planned the two groups so that the only difference between them was the use of home peak flow based self-management.

Methods

Approximately 90 practices in the Wessex region were invited in 1990 to participate in the study. These were connected with the academic department in Southampton or had at least one partner in the General Practitioners in Asthma Group or a nurse trained at the Asthma Training Centre in Stratford. Asthma morbidity has been shown to be a considerable problem even in well resourced and innovative practices.[22] Thirty four practices agreed to enter the study after a detailed briefing meeting by KJ.

Practices were asked to identify asthmatic patients aged 15–40 years using a metered dose steroid inhaler, the dose of which did not exceed 1000 μg per day, or its dry powder equivalent. Subjects needed to have been on inhaled steroids for at least one month before entry to the study. Those on regular oral steroids and those already possessing and regularly using a peak flow meter at home were ineligible. The study aimed to show the same magnitude of change when compared with controls in lung function, night wakening, and days off work or school as that found by Beasley *et al*,[9] but using baseline data from a previous community based study.[22] Thus, a 16 point change in forced expiratory volume in one second (FEV_1) percentage predicted based on a starting level of 67% and a standard deviation (SD) of 19% required a sample size of 23 subjects per group at a significance level of 5% and a power of 80%. Similarly, a sixfold reduction in any night wakening with a starting point of 51% required 21 per group. An eightfold reduction in any days off work or school with a starting point of 31% required 37 per group. To allow for dropouts we attempted to recruit 120 subjects for the study to encompass each of these three main outcome variables, equating to a very manageable and realistic number per practice.

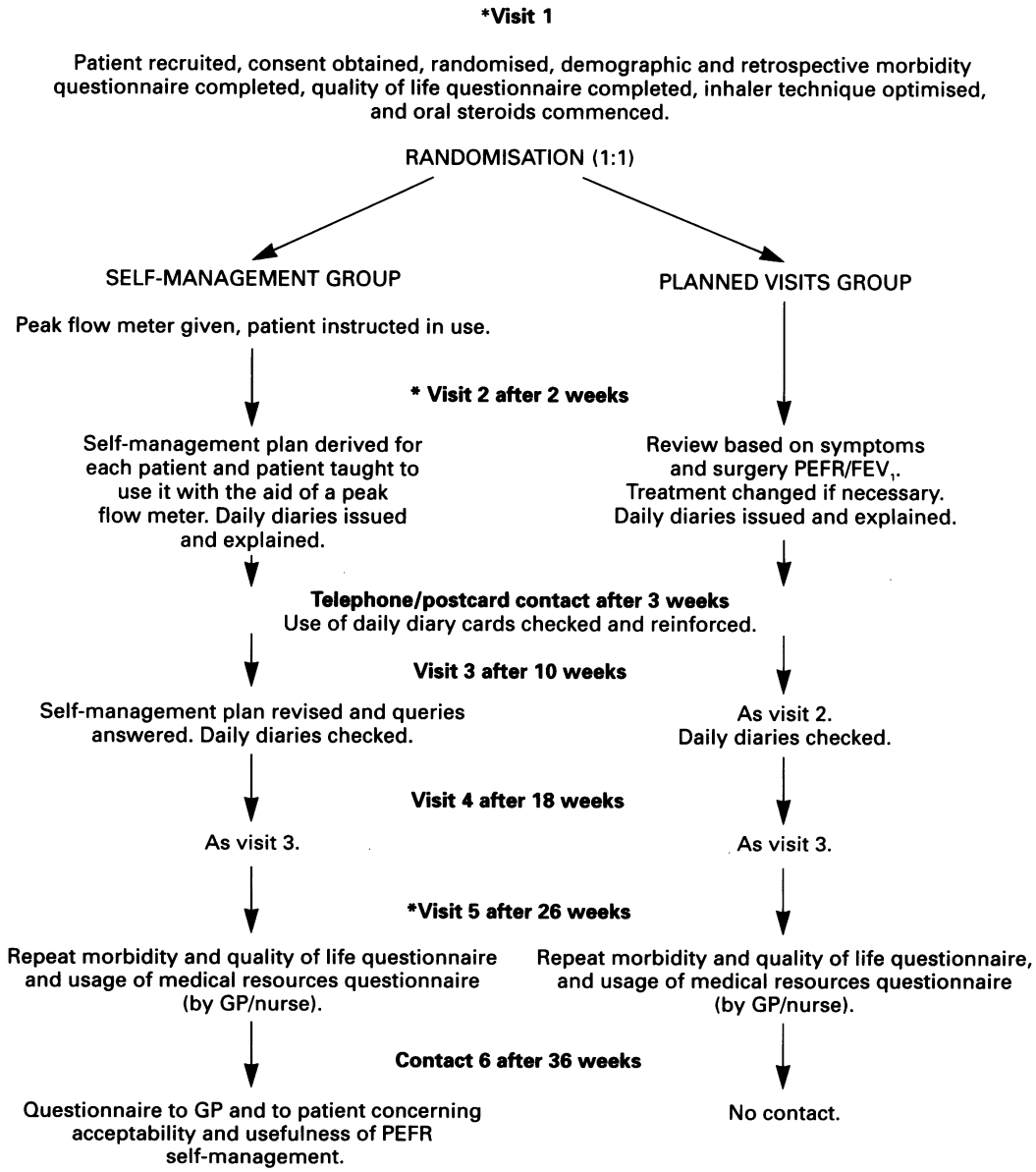

*Figure 1 Summary of study design. *Spirometric parameters were measured at visits 1, 2, and 5.*

Peak flow >75% PNV

(a) continue "maintenance regimen"
(b) inhaled bronchodilator as required
(c) inhaled steroid twice daily

Peak flow <75% PNV

(a) double dose of inhaled steroid for number of days required to regain 75% PNV
(b) continue on this increased dose for the same number of days
(c) return to previous dose of maintenance regimen

Peak flow <50% PNV

(a) start oral prednisolone 40 mg daily and contact general practitioner
(b) continue on this dose for the number of days required to regain 75% PNV
(c) reduce oral prednisolone to 20 mg for the same number of days
(d) stop oral prednisolone

Peak flow <25% PNV

(a) take 40 mg of oral prednisolone immediately and 5–10 puffs/doses of your bronchodilator immediately
(b) contact your general practitioner urgently or, if unavailable,
(c) contact the ambulance service or, if unavailable,
(d) go directly to hospital

Figure 2 Asthma management plan. PNV = potential normal value.

The design of the six month study period is summarised in fig 1. Each subject had a total of five study visits to their surgery at 0, 2, 10, 18 and 26 weeks. Hyland's 68 item self-completed quality of life questionnaire[23] was used and lung function was measured as the best of three forced vital capacity (FVC) manoeuvres on a Micromed turbine spirometer.[24] All patients were given a two week course of oral prednisolone (40 mg daily) to optimise lung function. Randomisation to either a self-management group or a planned visits group was stratified by centre in blocks of six. Those in the self-management group were given a mini-Wright peak flow meter, instructed in its use, and asked to keep a standard twice daily peak flow chart over the ensuing two weeks.

In the self-management group the 14 day peak flow record was examined and a best or "potential normal value" (PNV) established. This value was the highest morning or evening value on the chart unless it was more than 50 l/min above the next highest, in which case the next highest was taken.

Each patient in the self-management group was taught how to alter their regime in a manner similar to that of Beasley *et al*[9] on the basis of the best of three peak flow manoeuvres each morning as summarised in fig 2. The written instructions also advised the patients to seek an extra consultation with their general practitioner if their peak flow had not risen above 75% after 14 days of oral steroids or 28 days of double dose inhaled steroids.

All patients were asked to keep daily diary cards recording data on morbidity and bronchodilator use for 26 weeks. Cough, wheeze, and shortness of breath were scored on a four point scale (0–3) per day; actual numbers of bronchodilator doses were requested; and night waking, activity restriction, and time off work or school were scored 1 or 0 for each day.

After visit 5, the use of medical resources and prescribing data were extracted from their NHS practice records. The duration of each study consultation was measured using a stopwatch.

All data were rendered anonymous and analysed on an IBM compatible personal computer using the SPSS-PC + version 3 package.[25] Intergroup comparisons were performed using *t* tests, Mann–Whitney U tests, χ^2 tests, and log rank tests on survival curves based on time to first symptom. Intragroup comparisons were performed using paired *t* tests, Wilcoxon signed rank tests, and McNemar's tests.

Ethical permission for this study was granted by the Southampton and South West Hampshire ethical committee and the protocol was agreed by the British Thoracic Society Research Committee.

Results

During the period August 1990 to February 1992 only 25 practices of the original 34 successfully recruited patients, with 127 entered overall. Seventy two subjects completed the

Table 1 Comparisons between self-management and planned visits groups

	Self-management		*Planned visits*		*t*	*p value*
	n	*Mean (SD)*	*n*	*Mean (SD)*		
Age (years)	33	30·4 (11·5)	39	28·6 (7·0)	0·80	0·43
M:F	14:19		13:26			
Non-smokers	18 (55%)		14 (36%)			
Passive smokers	5 (15%)		10 (26%)			
Smokers	10 (30%)		15 (38%)			
Social class						
I–IIIa	15 (45%)		17 (45%)			
IIIb–V	12 (36%)		16 (42%)			
Others*	6 (18%)		5 (13%)			
FEV_1 % pred (at visit 1)	33	85·1 (20·8)	39	80·2 (19·9)	1·03	0·31
FVC % pred (at visit 1)	33	89·2 (17·4)	39	86·6 (16·7)	0·65	0·52
PEF % pred (at visit 1)	31	88·2 (15·4)	39	86·8 (13·7)	0·41	0·68
Age at diagnosis (years)	32	12·0 (4·2–21·0)	39	12·0 (2·0–22·0)	−0·24	0·81†

FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity; PEF = peak expiratory flow.
* Includes students and unemployed persons.
† Mann–Whitney U test. Quoted median (interquartile range) and z test statistic.
% pred = percentage of predicted value.

Table 2 Comparison between "completers" and "non-completers"

	Non-completers		Completers		t	p value
	n	Mean (SD)	n	Mean (SD)		
Age (years)	49	25·1 (8·8)	72	29·4 (9·3)	2·52	0·01
M:F	28:22		27:45			
Non-smokers	15 (31%)		32 (44%)			
Passive smokers	17 (35%)		15 (21%)			
Smokers	17 (35%)		25 (35%)			
Social class						
I–IIIa	16 (33%)		32 (44%)			
IIIb–V	17 (35%)		28 (39%)			
Others*	16 (33%)		11 (15%)			
FEV_1 % pred (at visit 1)	48	77·1 (17·9)	72	82·5 (10·6)	1·48	0·14
FVC % pred (at visit 1)	47	77·6 (18·0)	72	87·8 (16·9)	3·14	<0·01
PEF % pred (at visit 1)	49	82·3 (14·8)	70	87·4 (14·4)	1·90	0·06
Age at diagnosis (years)	48	10 (4–16)	69	29 (23–35)	−0·37	0·71†

FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity; PEF = peak expiratory flow.
* Includes students and unemployed persons.
† Mann–Whitney U test. Quoted median (interquartile range) and z test statistic.
% pred = percentage of predicted value.

whole study protocol (33 in the self-management group and 39 in the planned visits group) but diary card data for at least three months were available on a further 12 (six in each group), so these are included in the analysis of this part of the data.

There were no significant demographic or initial lung function differences between the two study groups in the "completers" (table 1). The median and modal initial total daily steroid doses were 400 μg in both groups. The "non-completers" tended to be younger, more often male ($\chi^2 = 4{\cdot}08$, $p<0{\cdot}05$) and to have lower initial FVC values than the "completers", but were otherwise similar and came from the two groups equally (table 2).

LUNG FUNCTION

Lung function tended to improve between visits 1 and 2 as a result of the oral steroid course and to decline between visits 2 and 5 at the end of the study (table 3). No significant intergroup differences were found but the rises in peak flow rate, FEV_1, and FVC between visits 1 and 2 in the planned visits group only were statistically significant ($p<0{\cdot}05$). The decline in FVC in the self-management group and the decline in FEV_1 in the planned visits group between visits 2 and 5 were also significant ($p<0{\cdot}05$). No statistically significant within group differences were noted in either group when visits 1 and 5 were compared.

Table 3 Mean (SD) lung function data in percentages of predicted values

	Visit 1	Visit 2	Visit 5
Self-management:			
FEV_1	85·1 (20·8)	87·1 (16·9)	83·2 (18·0)
FVC	88·7 (17·8)	90·8 (17·0)	85·0 (20·3)
PEF	88·0 (15·7)	90·6 (14·5)	89·8 (17·5)
Planned visits:			
FEV_1	80·2 (20·2)	85·4 (17·5)	81·2 (18·3)
FVC	86·2 (16·7)	89·5 (17·5)	86·4 (21·0)
PEF	87·1 (13·7)	89·7 (15·6)	87·7 (16·7)

FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity; PEF = peak expiratory flow.

MORBIDITY

There were no significant changes in either group in days lost from work or school or in night wakening when comparing the four weeks before visits 1 and 5. The number of patients experiencing any interference with daily life did significantly drop in the self-management group (from 21 to nine, McNemar's χ^2 9·0, degrees of freedom (df) = 1, $p<0{\cdot}01$, difference in proportions = −0·39, 95% confidence interval −0·60 to −0·17) but not in the planned visits group (McNemar's χ^2 0·5, df = 1, $p<0{\cdot}5$, difference in proportions = −0·05, 95% confidence interval −0·20 to 0·09). When the diary card morbidity data were analysed, both in terms of time to first symptom and monthly averaged symptom scores, no between group differences were evident (tables 4 and 5) but levels of morbidity were generally low.

QUALITY OF LIFE

There were no significant intergroup differences in Hyland's score (either in total score or in its two subset scores of physical and emotional domains) at the beginning or end of the study, but there was a significant within group improvement in all scores at the end of the study in the self-management group only (mean (SD) total Hyland score excluding "not applicable" returns and cases with more than one missing value: before 0·60 (0·23), after 0·52 (0·26), paired $t = 4{\cdot}0$, df = 32, $p<0{\cdot}01$).

SELF-MANAGEMENT DECISION MAKING

An episode of asthma was defined as any occurrence of lowered peak flow preceded by at least seven days of normal values – that is, above 75% PNV. Of the 39 subjects in the self-management group, 17 had no episodes at all, 13 had 1–3 episodes, and seven 4–7. Three were excluded because the data were not interpretable. Of the 20 subjects who had episodes nine were fully compliant with doubling inhaled steroids during their episodes and a

Table 4 Time to first symptom

Symptom	Self-management		Planned visits		Log rank χ^2	df	p value
	Cases with symptom	Censored	Cases with symptom	Censored			
Wake at night	29	10	35	10	0·20	1	0·65
Cough	36	3	38	7	0·30	1	0·58
Wheeze	36	3	41	4	0·16	1	0·69
Shortness of breath	36	3	43	2	0·001	1	0·97
Asthma restricting normal daily activities	21	18	21	24	0·24	1	0·63
Time off work or school	18	21	21	24	0·004	1	0·95
Seen doctor or hospital doctor	17	22	24	21	0·80	1	0·37

Censored = cases without the symptom during the study period.

Table 5 Monthly symptom scores

Symptom	Maximum possible score	Self-management (n = 39)		Planned visits (n = 45)		z score	p value
		Median	Range	Median	Range		
Wake at night	28	0·35	0–16·9	0·75	0–12·9	1·33	0·18
Cough	84	2·85	0–25·8	4·95	0–27·3	0·53	0·60
Wheeze	84	4·39	0–24·2	5·46	0–28·0	1·16	0·25
Shortness of breath	84	6·50	0–28·0	7·88	0–26·7	0·20	0·84
Asthma restricting normal daily activities	28	0·17	0–6·8	0·0	0–6·3	0·54	0·59
Time off work or school	28	0·0	0–15·3	0·0	0–28	0·11	0·91
Doses of bronchodilator	—	57·0	1·8–329·2	36·0	1·5–327·1	1·19	0·23

For each patient a total for each symptom across the study period was divided by the number of days for which diary data was available multiplied by 28 to give a monthly rate.

further three complied during at least half of their episodes (67% "compliers" in total). Eight never complied. Only 10 instances of peak flows of 50% PNV or below were recorded in total.

DOCTOR'S AND PATIENTS' VIEWS ON PEAK FLOW BASED SELF-MANAGEMENT

Three months after the study period 27 (82%) of the self-management group felt that the peak flow meter had been helpful to them and four (18%) did not. Twenty nine (88%) still knew where their peak flow meter was and 13 (39%) had altered their treatment on the basis of peak flow readings since the study ended. Five subjects had not used their peak flow meter since the study ended but 18 (56%) had used it in the two weeks prior to their postal questionnaire, and a further three within four weeks. Five had not used it for a longer period and data on two were missing. Twenty eight (85%) of the subjects' doctors felt that the peak flow meter had been helpful in their asthma management.

USE OF RESOURCES

Study visits were conducted by the nurse only in 15 cases in the self-management group, by the doctor only in 11, and by both in two (data missing in five cases); the equivalent figures for the planned visits group were 23, 13, and 2, respectively (one case missing). Visit 2, at which self-management was taught in that group, was significantly longer than in the planned visits group (median 14·2 minutes (interquartile range 10·0–19·3 minutes) versus 10·0 (7·9–13·9), z = 2·7, p = 0·01). Data on prescribing costs were incomplete but, again, no intergroup differences were evident. The numbers of subjects using oral steroids during the study period were similar in groups where these data were available (nine of 19 in the self-management group, 10 of 26 in the planned visit group, χ^2 0·36, p = 0·55). The numbers of home visits, outpatient attendances, admissions, and rescue nebulisations were too small for useful intergroup comparisons. Data on asthma consultations in excess of study requirements were inconsistent, but no significant differences seemed likely on the basis of the limited analysis possible.

Discussion

Despite the considerable enthusiasm shown for home peak flow monitoring by both patients and their doctors in this study, our data do not show any major advantage for this procedure over and above a more traditional approach with proactive care. Beasley's original results were not reproduced in this sample of patients from general practice, and the cost effectiveness of giving peak flow based self-management plans to all patients with asthma is clearly questionable.

We were, however, only able to recruit the minimum required number of subjects to the study and their starting levels of lung function and morbidity were better than expected. Post hoc calculations suggest that the magnitude of change (or difference between groups) detectable at 5% significance and 80% power, given our sample size, was 13 points for FEV_1 percentage predicted, 25% for night wakening, and 30% for days off work or school. Though we have clearly shown that differences of this size between the groups did not appear, smaller differences than these may be considered to be both clinically relevant and cost effective.

The study was launched in the summer following the new contract for general practice[26] and our initial contacts with practices found them overwhelmed with new work and less than usually inclined to take part in research.

This is very likely to have adversely affected recruitment. There were certainly too few more serious deteriorations to evaluate the effectiveness of patient initiation of oral steroid courses. Measurement of lung function at visits 3 and 4 might have given a better picture of the earlier benefit of self-management, but this was omitted as a pragmatic method of saving time. Both groups of patients were probably "too good" after their oral steroids and a longer period of follow up – for example, up to 36 weeks – might have been better in this regard.

The practices who participated were better resourced than average and potentially innovative. It could be argued that such practices would already have well organised asthma care and that limited scope was thus present for significant improvement. The relatively high initial lung function readings and generally low symptom scores in both groups support this notion, but previous morbidity data belie it.[22] In addition, it is just this type of practice that is likely to have put peak flow based self-management plans into widespread use among their patients since the study was commenced. It was interesting to note that patients who defaulted from the study were more likely to have worse lung function and thus be in more need of extra care. If sizeable benefits cannot be demonstrated from such populations, considerable wastage of resources may be occurring. This inference has also been levelled at nurse-run asthma care in general.[27]

General practitioners and practice nurses were left to organise recruitment to the study and follow up, with support from the research team where necessary and ony small financial recompense for extra hours worked. This pragmatic approach was deliberate since we were seeking to demonstrate the effectiveness of peak flow based asthma self-management in day to day general practice, and not its efficacy in ideal and artificial study conditions. This may, however, have led to variations in the way self-management was taught and reviewed and in the way care was delivered to the planned visits group (though there was no evidence that self-management was being taught to them in any form during the study). These possible effects were assumed to have balanced out between the two groups, but this may not have been true. Some data collection, particularly of prescribing costs, was also incomplete and thus potentially unreliable. The most detailed part of the data was the daily diary cards and these were very well kept by most participants, which allows us considerable confidence in the messages they reveal.

The original study by Beasley *et al*[9] showed that peak flow based self-management can lead to beneficial outcomes. Our data do not detract from this demonstration of efficacy among selected patients with more severe asthma in the way that the GRASSIC study may be seen to do,[18] but they suggest that this form of management is not likely to bring large benefits to sufferers whose disease is more mild. Similarly, the work of Charlton *et al* revealed that, within a primary care setting, self-management could lead to improved outcomes, but that symptoms only plans were just as good.[13] Beasley *et al* have recently shown, not only beneficial outcomes of self-management in New Zealand Maoris, but also that 48% of subjects found a symptoms only plan just as useful as the peak flow based plan.[19]

What we have shown is that long term home peak flow recording among milder asthmatic subjects cared for in general practice is unlikely to be the main answer to the continuing problem of morbidity from the disease. More of our study subjects complied with once daily peak flow measurement than the 25% shown by McKinley in another community study, but his protocol required three times daily monitoring.[28]

Our data and those of other recent studies[18 19] allow a number of observations to be made. The sort of widespread rigid adherence to peak flow based self-management initially emphasised after Beasley's work is no longer necessary for all asthma sufferers. We now know that large impacts on morbidity and mortality are unlikely with this form of self-management, and have some idea of what proportion of patients will adhere to regular home monitoring outside the confines of a trial. The original Beasley plan had peak flow levels of 70% and 50% to trigger change. These values were guestimates and now appear too low. The recently revised UK guidelines recommend 60% as the point at which oral steroids should be commenced, reflecting the opinions of experts altered more by practice rather than research.

Partridge has recently identified "several unknowns regarding self-management", namely "the need to define better who needs a peak flow meter, who needs a self-management plan, and what steps and interventions the plans should contain".[29] His advice to give detailed self-management plans and peak flow meters "to adults with severe asthma, to those with variable disease, and to those who have been admitted to hospital because of asthma" seems eminently sensible for now, although those felt to have poor perception of the severity of their asthma might also be included. A much simplified self-management plan may be more appropriate for most milder asthma sufferers, but perhaps also the concept of self-management may need refinement.

There are two reasons for monitoring peak flow in patients with chronic asthma. The first is to anticipate severe deteriorations and prevent crises and the second is to monitor control while in relative remission to establish the appropriate treatment to gain maximum symptom relief. These probably require separate approaches. A single low reading should trigger a response relevant to the time scale of rapid deterioration – for example, re-measurement after bronchodilator use or after a short interval, and oral corticosteroids if recovery is not satisfactory. A single low reading is not a sufficient signal to increase baseline therapy, the need for which should be judged over a longer period.

If we are to make the best use of inevitably limited resources in primary care for the better management of asthma, efforts to define outcome measures and to target care as a result

of their use must continue. Some research has already examined this issue[22 30] and more is in progress or planned. This needs to include further exploration of why both patients and doctors give strong support to home peak flow monitoring, as shown by this study. The results will help to assess the proper place for peak flow based self-management in asthma.

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