

Primary care

Proactive asthma care in childhood: general practice based randomised controlled trial

Nicholas J Glasgow, Anne-Louise Ponsonby, Rachel Yates, Justin Beilby, Paul Dugdale

Abstract

Objectives To assess the feasibility and effectiveness of a general practice based, proactive system of asthma care in children.

Design Randomised controlled trial with cluster sampling by general practice.

Setting General practices in the northern region of the Australian Capital Territory.

Participants 174 children with moderate to severe asthma who attended 24 general practitioners.

Intervention System of structured asthma care (the 3+ visit plan), with participating families reminded to attend the general practitioner.

Main outcome measures Process measures: rates for asthma consultations with general practitioner, written asthma plans, completion of the 3+ visit plan; clinical measures: rates for emergency department visits for asthma, days absent from school, symptom-free days, symptoms over the past year, activity limitation over the past year, and asthma drug use over the past year; spirometric lung function measures before and after cold air challenge.

Results Intervention group children had significantly more asthma related consultations (odds ratio for three or more asthma related consultations 3.8 (95% confidence interval 1.9 to 7.6; $P=0.0001$), written asthma plans (2.2 (1.2 to 4.1); $P=0.01$), and completed 3+ visit plans (24.2 (5.7 to 103.2); $P=0.0001$) than control children and a mean reduction in measurements of forced expiratory volume in one second after cold air challenge of 2.6% (1.7 to 3.5); $P=0.0001$) less than control children. The number needed to treat (benefit) for one additional written asthma action plan was 5 (3 to 41) children. Intervention group children had lower emergency department attendance rates for asthma (odds ratio 0.4 (0.2 to 1.04); $P=0.06$) and less speech limiting wheeze (0.2 (0.1 to 0.4); $P=0.0001$) than control children and were more likely to use a spacer (2.8 (1.6 to 4.7); $P=0.0001$). No differences occurred in number of days absent from school or symptom-free day scores.

Conclusions Proactive care with active recall for children with moderate to severe asthma is feasible in general practice and seems to be beneficial.

Introduction

General practice includes activity characterised as "largely organised for the diagnosis and treatment of acute conditions."¹ Strategies for managing chronic illness include using explicit guidelines, closer follow up, and systematic attention to the needs of patients in terms of information and behavioural change.¹ Delivering care in chronic illness requires health systems to move from a reactive orientation towards a proactive orientation.

Proactive care (regular review), in conjunction with written asthma action plans and training in self management, improves outcomes for adults with asthma.² No similar evidence base exists for children with asthma. Given the high prevalence of asthma in children,³ evaluating proactive asthma care in this population is important.

Guidelines endorsing proactive asthma care have been promoted in Australia in the form of the National Asthma Council's six step plan.⁴ The six step plan has been adapted for the fee for service environment of Australian general practice with the introduction of the 3+ visit plan (3+ plan).⁵ Box 1 summarises the features of this plan.

Components of the six step plan are scheduled over three or more general practice visits, with two or more of these visits occurring outside the treatment of an acute exacerbation. The 3+ plan does not demand an active recall system. Active recall systems increase attendance for proactive general practice consultations.⁶ We aimed to evaluate the feasibility and effectiveness of the 3+ plan combined with active recall in the proactive management of children with moderate to severe asthma.

Methods

The figure summarises the design of the clustered randomised controlled trial.

Recruitment

Primary schoolchildren in the Australian Capital Territory received a health survey between February and April 2000. Children were eligible for recruitment if the returned questionnaire indicated that they had moderate to severe asthma and a usual general practitioner. Box 2 summarises how we determined moderate to severe asthma, defined by National Asthma Council cri-

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Box 1: The 3+ visit plan**Visit 1**

Often a visit at which the patient presents with an unrelated problem and does not mention asthma until the end of the consultation. Manage the issue that caused asthma to be discussed—for example, worsening asthma symptoms, request for a prescription. Introduce the concept of a “contract” for care (the 3+ visit plan) and the reasons for review. If the patient presents solely for an asthma related problem, or it is clinically appropriate and possible, include the items in visit 2. Give the 3+ visit plan handout to the patient.

Visit 2

New patient—Ascertain status, including history, drug treatment, and management.

Existing patient—Assess current situation, including review of medical records and consolidation or collection of information on history, drug treatment, and management. What do they know and what do they need to know (knowledge)? How do they feel about their asthma (perception)? What do they want from you, the general practitioner? Review inhalation devices and technique. Do physical examination (including spirometry). Grade severity and level of control of asthma. Consider two weeks of recording and charting of peak expiratory flow rate. Is a change in drug needed?

Visit 3 (approximately two weeks later)

Review patient and his or her peak expiratory flow record. Do spirometry (if not already done, or consider redoing). Complete written asthma action plan. Further identify trigger factors: consider radioallergen sorbent test (RAST), skin prick tests (if not already done). Is a change in drug needed? Check on, reinforce, and expand education. Answer any questions.

Visit 4 (approximately four weeks later)

Assess progress. Review asthma action plan. Discuss results of trigger factor tests (if applicable). Check on, reinforce, and expand education. Answer any questions.

teria,⁴ from the survey responses. General practitioners had to have at least three children meeting these criteria to be included in the trial.

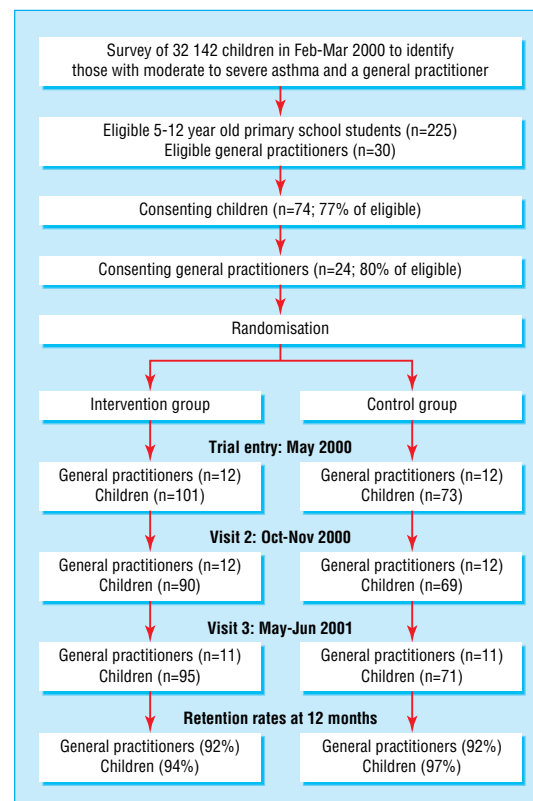
Randomisation

The returned surveys identified usual general practitioners and their practices. We enrolled only one general practitioner in each practice to avoid within practice contamination. We used SPSS version 10 to randomly assign 30 eligible practices to control and intervention groups. Within each practice, we ranked general practitioners according to the number of children with moderate to severe asthma and selected the highest ranking general practitioner from each practice. Twenty four general practitioners (12 in each group) agreed to participate. Of 225 children managed by these 24

Box 2: Criteria to determine the presence of moderate to severe asthma

For a child to have moderate to severe asthma, respondents had to answer “Yes” to the following item:

- Does your child have asthma?
and then “Yes” to at least one of the following additional items:
- Has your child ever been admitted overnight to intensive care for asthma?
- Have your child's normal or sports activities been restricted at least one to three days a week over the past 12 months?
- Has your child experienced wheeze, night cough or night wheeze, or shortness of breath at least one to three days a week over the past 12 months?
- Has your child used a preventer medication at least one to three days a week or a reliever medication four or more days a week over the past 12 months?



Summary of trial timeline and participant retention rates

general practitioners, 175 (78%) consented and attended the research clinic for baseline assessment at trial entry. One child withdrew immediately after this appointment, leaving 101 children in the intervention arm and 73 in the control arm. No temporal differences in the recruitment rates by study arm occurred.

Intervention

The chief investigator gave a one to one academic detailing session to all general practitioners. We asked control general practitioners to continue their usual paediatric asthma care and intervention general practitioners to administer care according to the 3+ plan. We instructed them in the plan and gave them a 3+ plan patient and practitioner resource kit. We prompted intervention general practitioners when a child's next 3+ visit was due. We offered a supplementary trial information evening separately to each general practitioner group. We classified a 3+ plan as fully complete if over the 12 month trial period the child attended their general practitioner for at least two asthma related visits, one of which was proactive, and if each of the two visits showed at least one different 3+ plan content item. We classified 3+ plans as partially complete if during the same period the child attended their general practitioner for at least two asthma related visits, one of which was proactive.

Allocation concealment and consent

We told participants that the study was examining the effects of reminder systems in proactive care and that some children would be reminded to return to their doctor for asthma care. We based this approach on ethical considerations for cluster randomised trials.⁷ General practitioners were aware that two study groups existed but were not informed of their

Table 1 Classification of consultation types

Consultation type	Definition
Reactive	A consultation that occurred because the child had an exacerbation of asthma symptoms
Proactive	A consultation that occurred when the child was well and involved asthma management
Opportunistic	A consultation that occurred for some reason other than asthma, but during which asthma was addressed
Indeterminate	A consultation that could not be assigned to one of the other three categories

allocation. We assessed concealment at trial end by asking general practitioners which arm of the trial they thought they were in. Six control general practitioners said the control group, and the rest did not know. Six intervention general practitioners said the control group, two said the intervention group, and three did not know.

Data collection

Children attended three assessment clinics during the trial. These were at trial entry, five to six months, and trial completion. We administered standard questionnaires, including items from the international study of asthma and allergies in childhood.⁸ The children then had spirometric tests (Fleisch-type electronic spirometer, Vitalograph alpha 2, model AL0642; Vitalograph, Buckingham, UK) before and after a standard cold air challenge test.^{9 10}

We audited general practitioners' case notes for all patients at trial end to assess the number and type of asthma related visits made by participants to their nominated general practitioner during the trial period. For each participant, general practitioners also gave a verbal report of their written medical records of asthma related consultations, which two independent auditors classified into consultation types (table 1). One auditor was blind to the general practitioners' study group allocation, and the other was not. We used the data of the blinded auditor for all analyses. We carried forward six month pilot audit data for analysis for two of the initial general practitioners, one "control" and one "intervention," who were unavailable for audit at trial end because of illness or interstate relocation.

Outcome measures

Study endpoints comprised process, clinical, and spirometric measures as shown in tables 2, 3, and 4. We obtained the process and clinical measures by using questionnaires completed by parents. Spirometric measures comprised the percentage reduction and absolute reduction in forced expiratory volume in one second (FEV₁) after cold air challenge.

Statistical methods

We estimated sample sizes by using the approach of Campbell et al,¹² assuming that each general practitioner would have between three and seven children with asthma. For a power of 80% and a significance level of 0.05 we needed between 13 and 21 general practitioners (91 and 63 children) to detect a change from a baseline rate for a written asthma action plan of 30% to 70% at 12 months.

We compared the children in the intervention and control groups with respect to study outcomes by using two by two contingency tables with a χ^2 test or Fisher's exact test. Table 2 summarises the differences in baseline

measures for trial outcomes. The total numbers differ slightly by variable in tables 3 and 4, because not all parents reported on all variables. We then used generalised estimating equations with fixed and random components with a logit link and a binomial error structure to provide odds ratios and associated confidence intervals for the effect of the intervention on the questionnaire outcomes examined.¹³ Inclusion of a term for the baseline value of each outcome ensured that the models were adjusted for any differences in baseline values that arose by chance through the randomisation process. We examined spirometric measures of lung function by using a generalised estimating equation regression model, adjusting for the intervention and baseline values as fixed effects and general practitioners as random effects. We also estimated the within general practitioner correlations for each outcome. They ranged from 0.16 (completion of 3+ plan) to -0.05 with a mean of -0.002. We used Stata 6 for intention to treat analyses.

Table 2 Baseline characteristics of general practitioners and children. Values are numbers (percentages) unless stated otherwise

Characteristics	Control	Intervention
General practitioner		
Total	12	12
Age group (years):		
30-39	0	1 (8)
40-49	6 (50)	7 (58)
50-59	6 (50)	4 (33)
Men	8 (67)	8 (67)
Children per general practitioner:		
1-4	4 (33)	3 (25)
5-9	5 (42)	7 (58)
10-14	3 (25)	1 (8)
≥15	0	1 (8)
Children		
Total	73	101
Age group (years):		
5-6	14 (19)	30 (30)
7-8	16 (22)	25 (25)
9-10	26 (36)	33 (33)
11-12	17 (23)	13 (13)
Boys	40 (55)	56 (55)
Outcome measures		
General practitioner consultations in past six months:		
None	22 (31)	34 (34)
1	18 (25)	29 (29)
2	16 (22)	15 (15)
≥3	16 (22)	23 (23)
Unknown	1 (1)	0
Have a written asthma action plan	20/72 (28)	23 (23)
Attended emergency department 1-3 times in past 12 months	15/67 (22)	14/95 (15)
Did not miss any school days with wheezing or asthma in past 12 months	23/71 (32)	30 (30)
Mean (SD) symptom-free day score*	3.4 (0.9)	3.5 (0.8)
Mean (SD) percentage change in FEV ₁ after cold air challenge†	-0.7 (4.9)	-2.2 (6.3)
Mean (SD) absolute difference (ml) in FEV ₁ after cold air challenge†	-14 (88)	-36 (109)
Four or more episodes of wheeze in past 12 months	35/71 (49)	46/100 (46)
Wheeze severe enough to limit speech to one or two words in past 12 months	15/72 (21)	17 (17)
Normal activities restricted by respiratory symptoms in past 12 months	6/71 (8)	7/98 (7)
Sports or exercise activities restricted by respiratory symptoms in past 12 months	9/71 (13)	16/100 (16)
Uses preventers more than four days a week on average	40/69 (58)	43/95 (45)
Uses relievers more than four days a week on average	15/69 (22)	14/100 (14)
Uses pressurised metered dose inhalers alone	25/73 (34)	31 (31)
Uses pressurised metered dose inhalers with spacer	45 (62)	66 (65)
Uses nebuliser	29 (40)	36 (36)

FEV₁=forced expiratory volume in 1 second.

*1=average of 4+ symptom days/week; 5=no symptom days/week.

†Control group n=69; intervention group n=92.

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Table 3 Process and clinical outcome measures at 12 months

	No (%)		Odds ratio (95% CI)	P value	Number needed to treat (benefit)* (95% CI)
Outcome measure	Control (n=73)	Intervention (n=101)			
Process measures					
Asthma related visits to general practitioner during trial period† (audit of general practitioner records at trial end):					
0	29 (40)	19 (19)	1 (reference)	NA	NA
1-2	29 (40)	42 (42)	2.1 (1.0 to 4.5)	0.05	NA
≥3	15 (21)	40 (40)	3.8 (1.9 to 7.6)	0.0001	NA
Proactive general practitioner consultations during trial period:					
0	59 (81)	46 (46)	1 (reference)	NA	NA
1-2	8 (11)	24 (24)	3.7 (1.8 to 7.4)	0.0001	NA
≥3	6 (8)	31 (31)	7.3 (2.2 to 23.9)	0.001	NA
Reactive general practitioner consultations during trial period:					
0-1	61 (84)	74 (73)	1 (reference)	NA	NA
2	7 (10)	18 (18)	2.6 (1.3 to 4.9)	0.005	NA
≥3	5 (7)	9 (9)	1.7 (0.7 to 3.8)	0.2	NA
Have written action plan†	24/71 (34)	42/95 (44)	2.2 (1.2 to 4.1)	0.01	5 (3 to 41)
Completed 3+ plan:					
No	65 (89)	53 (52)	1 (reference)	NA	
Partial	6 (8)	20 (20)	3.8 (1.1 to 13.1)	0.04	6 (2 to 146)
Yes	2 (3)	28 (28)	24.2 (5.7 to 103.2)	0.0001	3 (1 to 8)
Clinical measures					
Attended emergency department 1-3 times for respiratory symptoms in past 12 months†	8/71 (11)	4/95 (4)	0.4 (0.2 to 1.04)	0.06	17 (12 to ∞)
Did not miss any school days with wheezing or asthma in past 12 months†	32/71 (45)	49/95 (52)	0.8 (0.5 to 1.2)	0.3	22 (6 to ∞)
Four or more episodes of wheeze in past 12 months†	24/71 (34)	25/95 (26)	0.6 (0.3 to 1.3)	0.2	11 (5 to ∞)
Wheeze severe enough to limit speech to one or two words in past 12 months†	13/71 (18)	5/95 (5)	0.2 (0.1 to 0.4)	0.0001	8 (7 to 10)
Normal activities restricted by respiratory symptoms in past 12 months†	6/71 (8)	3/95 (3)	0.4 (0.06 to 2.1)	0.3	20 (13 to ∞)
Sports or exercise activities restricted by respiratory symptoms in past 12 months†	10/71 (14)	6/95 (6)	0.4 (0.2 to 1.1)	0.08	14 (9 to ∞)
Uses preventers more than four days a week on average†	31/64 (48)	40/84 (48)	1.9 (0.8 to 4.5)	0.2	6 (3 to ∞)
Uses relievers more than four days a week on average†	19/64 (30)	8/87 (9)	0.3 (0.2 to 0.6)	0.001	6 (4 to 12)
Uses pressurised metered dose inhalers alone†	33/71 (46)	30/95 (32)	0.4 (0.2 to 1.0)	0.04	5 (3 to 150)
Uses pressurised metered dose inhalers with spacer†	27/71 (38)	59/95 (62)	2.8 (1.6 to 4.7)	0.0001	4 (3 to 8)
Uses nebuliser†	24/71 (34)	20/95 (21)	0.5 (0.2 to 1.1)	0.09	7 (4 to ∞)

NA=not applicable.

*Numbers needed to treat (benefit) (NNTB) and corresponding 95% confidence intervals derived from adjusted odds ratios (OR) and 95% confidence intervals and patient expected event rates (PEER) equal to the proportion observed for the control group. $NNTB = 1 - [PEER \times (1 - OR)] / [PEER \times (1 - OR) \times (1 - PEER)]$ for $OR < 1$ and $NNTB = 1 + [PEER \times (OR - 1)] / [PEER \times (OR - 1) \times (1 - PEER)]$ for $OR > 1$.¹¹

†Measures intervention effect taking into account baseline value of the outcome measure.

Results

Baseline demographics and participation rates

Table 2 summarises the baseline characteristics of the participating general practitioners and children. The two groups were similar, but the children in the intervention group had, on average, greater reductions in FEV₁ after cold air challenge (−2.2%) than control children (−0.7%). Four out of 69 (6%) control children and 13/92 (14%) intervention children had missing spirometric outcome data at the end of the trial

(P=0.2). Eight children were lost to follow up, 6/101 (6%) in the intervention group and 2/73 (3%) in the control group. Four of these children formally withdrew from the trial (all intervention)—one had moved interstate, and the remaining three failed to attend three scheduled visits and did not subsequently return mailed clinic questionnaires.

Outcome measures at 12 months

Table 3 shows that intervention children attended their general practitioners for asthma related consultations more often than control children, and for intervention children these consultations were significantly more likely to be proactive. Twenty eight per cent of the children in the intervention group fully completed the 3+ plan, significantly more than the 3% in the control group. An additional 20% of the intervention children partially completed the 3+ plan. The intervention group had increased use of written asthma action plans at 12 months. The number needed to treat (benefit) for one additional written asthma action plan was 5 (95% confidence interval 3 to 41) children.¹⁴ Neither symptom-free day scores nor the three components of this composite score (wheeze, night time symptoms, and restriction of activities) differed between groups (table 4). However intervention children had fewer

Table 4 Clinical and spirometric outcome measures at 12 months

Outcome measure	Mean (SD)		Mean (95% CI) treatment effect*	P value
	Control	Intervention		
Clinical measures				
Symptom-free days score†	3.9 (0.9)	4.1 (0.6)	0.1 (−0.03 to 0.2)	0.1
Spirometric measures‡				
Percentage change in FEV ₁ after cold air challenge	−2.6 (6.3)	−0.5 (5.2)	2.6 (1.7 to 3.5)	0.0001
Absolute difference (ml) in FEV ₁ after cold air challenge	−57 (159)	−9 (89)	44 (18 to 70)	0.001

FEV₁=forced expiratory volume in 1 second.

*Measures effect of intervention taking into account baseline value of the outcome measure.

†1=worst (average ≥4 days with symptom each week); 5=best (all days symptom free). Control group, n=71; intervention group, n=95.

‡Models adjusted for child's sex, height, weight, and trial entry measurement and to take account of clustering by general practitioner. Control group, n=67; intervention group, n=82.

occurrences of speech-limiting wheeze at trial end (table 3). Intervention children were more likely to use pressurised metered dose inhalers with a spacer and less likely to use relievers more than four days each week. Emergency department attendances tended to occur less often in intervention children, although the difference did not reach statistical significance. Spirometric measurements indicated that the intervention children were significantly less reactive to cold air than were control children (table 4). This persisted after further adjustment for clinic temperature and humidity and presence of an upper respiratory infection.

Discussion

The combination of the 3+ visit plan with prompts for children to attend proactive asthma appointments resulted in improved asthma management. The 3+ plan was much more likely to be completed by intervention general practitioners, with increased use of written asthma action plans among intervention children. Statistically significant, but clinically small, reductions occurred in the reactivity of intervention children's FEV₁ measurements to cold air challenge, supporting the hypothesis that the intervention group would have better controlled asthma and therefore less bronchial hyperreactivity after the challenge.¹⁵ Although some clinical measures did not show significant differences between the control and intervention groups, a marked reduction in speech-limiting wheeze occurred and intervention children's attendance at the emergency department tended to be lower than that for control children, with an odds ratio of substantial magnitude (0.4). This difference approached statistical significance and represented a number needed to treat (benefit) of 17, a clinically important finding given the burden placed on emergency departments by children with exacerbations of wheeze.^{4 16}

Study strengths and limitations

The findings are strengthened by the randomised controlled design, relatively unusual in studies looking at the organisation of healthcare delivery.¹⁷ Blinding is difficult to achieve in studies such as this,⁷ but less than half of general practitioners correctly identified their group allocation at trial end, indicating that the concealment approach used was effective. Retention rates were high. The study endpoints provided a balance between process, clinical, and spirometric data, and the study method was designed to approximate as closely as possible the "real world" of general practice. The intervention was not "forced." General practitioners, parents, and children were free to make decisions about whether a visit actually took place. Even when a practice was prompted to remind a child to return, the decision to actually recall that child was made by the doctor. If a recall was made, parents had a free choice about whether to attend. The intention to treat analyses considered all intervention children as a group regardless of how much of the 3+ plan they were exposed to. After intervention general practitioners had one face to face academic detailing session and a dinner meeting discussing the 3+ plan, 52% of the intervention children received no aspects of the 3+ plan and 20% received only parts of it. This moderate

uptake is consistent with the reported effectiveness of outreach visits and local opinion leaders as a means of influencing practice.¹⁸ The effect is important, however, given that 89% of the control children were not exposed to the 3+ plan at all.

Explanations for the limited uptake of the 3+ plan by the intervention general practitioners are speculative. They include framing the study question as general practitioners' recall rather than the 3+ plan in order to approximate blinding, the mild nature of some children's asthma being appropriately managed by less structured care, and the difficulty of implementing the 3+ plan approach for all patients despite its adoption by general practitioners. The last possibility is likely given that all but two intervention general practitioners completed the 3+ plan for at least one child in their care, yet the overall completion rate for the 3+ plan was low.

Two aspects of the study potentially reduced its power. Firstly, the study relied on survey results to identify children with moderate to severe asthma. Although we used criteria taken from existing guidelines,⁴ the children's spirometric assessments at trial entry produced mean changes in FEV₁ after cold air challenge of less than 3% in both arms, much less than the 9% identified by Nicolai et al as the 95th centile cut-off point between the reference population and children with excess bronchial hyperreactivity.⁹ Secondly, the children's asthma status changed over time: although all children satisfied the criteria in March 2000, the same questionnaires given at trial entry (May 2000), round 2 (October 2000), and round 3 (July 2001) identified 76%, 64%, and 53% of children as having moderate to severe asthma. Thus, this study is likely to have included children with mild disease who needed neither additional general practitioner visits nor completion of the 3+ plan for optimal management.

Measurement of process

Written asthma plans represent one facet of optimal asthma care and are a specific content item in the 3+ plan.² In eastern Australia 21.7% of children reported having a written asthma action plan in 1993, an increase from 16.7% in 1990.¹⁹ Here, at trial end, 44% of intervention children had a written asthma action plan, less than the 70% used to estimate sample sizes. However, this is still an important outcome, with five children needing the intervention to provide one additional written asthma action plan.

Measurement of completion of the 3+ plan was complex and needed three criteria to be satisfied. Consultations had to occur in which asthma was considered; at least one of these consultations had to be proactive; and at least two different content items from the 3+ plan had to be covered. This approach led to the apparent paradox that the 3+ plan could be completed in two visits for the purposes of this study. The 3+ plan was designed for delivery over three or more consultations to allow for a usual consultation being about 10-15 minutes long, rather than because of evidence that three or more consultations were beneficial. General practitioners may have taken more time on occasions and delivered more than one consultation's "worth" of 3+ plan materials. The 3+ plan approach was nationally promoted during the course of the trial, and this could explain the fact that

some control children received it. The idea of regular review is part of optimal asthma management, so allowing completion of the 3+ plan in a single consultation was inappropriate. Proactive consultations allowed time for observation of inhaler technique, review of a written asthma action plan, or development of a child's understanding of asthma. The measured clinical and spirometric changes reflect both full and partial exposure to the intervention. In keeping with trends in delivering primary care, the 3+ plan allows for content items to be delivered by nurses, asthma educators, or both, where such resources are available. The focus of this trial was on general practitioners undertaking proactive care, rather than on assessing the contributions made by different members of the primary healthcare team.

Several possibilities may explain the excess of reactive visits seen in the intervention group. These children may have had more symptoms as a result of chance. An imbalance between the control and intervention groups in terms of reactive care could have existed at the start of the trial. This could not be assessed, as we did no baseline audit of the general practice records. Parents of intervention children may have had a greater awareness of asthma symptoms, because of the proactive consultations, and therefore a lower threshold for presenting. The classification of consultation type is unlikely to have introduced bias, as the auditor was blind to trial group status.

Child related outcomes

Although most of the clinical outcomes showed beneficial effects in the intervention group, two important clinical indicators of childhood asthma control showed no change in the study—the symptom-free day scores and the number of days missed from school with asthma. For both these items, parents were asked to recall the information at the time of clinic visits. The approach chosen may have lacked sufficient sensitivity to detect true differences. We used the same method for speech-limiting wheeze and emergency department visits, but these dramatic events may be more likely to be accurately recalled. Alternatively, the intervention may have had a stronger impact on more severe asthma. The direction of change for all clinical measures favoured the intervention arm. Intervention children were less likely to use pressurised metered dose inhalers alone and more likely to use pressurised metered dose inhalers with a spacer device. Non-significant trends favouring the intervention children occurred: the daily use of preventer drugs increased, quality of life factors such as activity restriction because of wheeze improved,²⁰ and the frequency of episodes of wheeze decreased. Part of the reduction in symptom scores and visits to the emergency department could plausibly result from improved adherence to preventer drug regimens using optimised delivery systems.

We chose cold air spirometry as the challenge test because it is acceptable to children and represents a “natural” wintertime exposure.^{9 21} The magnitude of the reduction in reactivity to cold air was small for intervention children. The spirometric test results have little clinical importance in isolation but give useful construct validity, providing reassurance that the effect of the intervention was not just dissuading parents

What is already known on this topic

Delivering optimal health care in chronic illness requires health systems to move from a reactive to a proactive orientation

Proactive primary care and training in self management improve outcomes for adults with asthma

Active recall systems increase attendance for proactive general practice consultations

What this study adds

Proactive health care with active recall seems to be beneficial in the management of moderate to severe childhood asthma

from presenting to an emergency department or encouraging parents to under-report symptoms.

Conclusion

These results suggest that the 3+ visit plan combined with recall in children with asthma results in improved asthma management with a reduction in respiratory morbidity. Confirming the effect of the 3+ plan combined with recall on emergency department presentations and examining the effects of this approach in adolescent and adult populations are important future studies.

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Contributors: NJG was involved in all aspects of the study, including the initial idea and design, fieldwork, data management and analysis, and writing the paper. A-LP was involved in developing the initial study idea and design, data management and analysis, and writing the paper. RY was involved in the fieldwork, data management and analysis, and writing the paper. JB and PD were involved in the study design and oversight of the fieldwork and data management and contributed to analysis of results and writing of the paper. NJG is the guarantor.

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- Wagner EH, Austin BT, von Korff M. Organizing care for patients with chronic illness. *Milbank Q* 1996;74:511-44.
- Gibson PG, Coughlan J, Wilson AJ, Abramson M, Bauman A, Hensley MJ, et al. Self-management education and regular practitioner review for adults with asthma. *Cochrane Database Syst Rev* 2003;(1):CD001117.
- The International Study of Asthma and Allergies in Childhood (ISAAC) Steering Committee. Worldwide variation in prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and atopic eczema: ISAAC. *Lancet* 1998;351:1225-32.
- National Asthma Council of Australia. Asthma management handbook 2002. www.nationalasthma.org.au/publications/amh/asthma_facts.htm (accessed 13 Mar 2003).
- Fardy HJ. The 3+ plan for asthma management [correction appears in *Aust Fam Physician* 1999;28:208]. *Aust Fam Physician* 1999;28:95.
- Feder G, Griffiths C, Eldridge S, Spence M. Effect of postal prompts to patients and general practitioners on the quality of primary care after a coronary event (POST): randomised controlled trial. *BMJ* 1999;318:1522-3.
- Edwards S, Braunholtz DA, Lilford R, Stevens AJ. Ethical issues in the design and conduct of cluster randomised controlled trials. *BMJ* 1999;318:1407-9.
- Asher MI, Keil U, Anderson HR, Beasley R, Crane J, Martinez F, et al. International study of asthma and allergies in childhood (ISAAC): rationale and methods. *Eur Respir J* 1995;8:483-91.
- Nicolai T, Mutius EV, Reitmeir P, Wjst M. Reactivity to cold-air hyperventilation in normal and in asthmatic children in a survey of 5,697 school-children in southern Bavaria. *Am Rev Respir Dis* 1993;147:565-72.
- Ponsonby AL, Glasgow N, Gatenby P, Mullins R, McDonald T, Hurwitz M, et al. The relationship between low level nitrogen dioxide exposure and

- child lung function after cold air challenge. *Clin Exp Allergy* 2001;31:1205-12.
- 11 Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. *Evidence-based medicine: how to practice and teach EBM*. 2nd ed. Edinburgh: Churchill Livingstone, 2000.
 - 12 Campbell M, Grimshaw J, Steen N. Sample size calculations for cluster randomised trials. *J Health Serv Policy* 2000;5:12-6.
 - 13 Donner A, Klar N. *Design and analysis of cluster randomization trials in health research*. New York: Oxford University Press, 2000.
 - 14 Altman DG. Confidence intervals for the number needed to treat. *BMJ* 1998;317:1309-12.
 - 15 Pierce R, Johns DP. Spirometry: the measurement and interpretation of ventilatory function in clinical practice. Thoracic Society of Australia and New Zealand, 1995. www.nationalasthma.org.au/publications/spiro/index.htm (accessed 13 Mar 2003).
 - 16 Mannino DM, Homa DM, Pertowski CA, Ashizawa A, Nixon LL, Johnson CA, et al. Surveillance for asthma—United States, 1960-1995. *MMWR CDC Surveill Summ* 1998;47(1):1-27.
 - 17 Neville RG, Higgins BG. Providing better asthma care: what is there left to do? *Thorax* 1999;54:813-7.
 - 18 Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *Can Med Assoc J* 1995;153:1423-31.
 - 19 Comino EJ, Mitchell CA, Bauman A, Henry RL, Robertson CF, Abramson ML, et al. Asthma management in eastern Australia, 1990 and 1993. *Med J Aust* 1996;164:403-6.
 - 20 Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring the quality of life in children with asthma. *Qual Life Res* 1996;5:35-46.
 - 21 Ponsonby AL, Gatenby P, Glasgow N, Mullins R, McDonald T, Hurwitz M. Which clinical subgroups within the spectrum of child asthma are attributable to atopy? An epidemiological assessment. *Chest* 2002;121:135-42.