Do written action plans improve patient outcomes in asthma? An evidence-based analysis

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KEY POINTS FOR CLINICIANS

- Most studies of asthma self-management do not permit retrospective isolation of the independent effects of a written action plan or peak flow meter use.
- Studies designed to isolate the effect of these self-care activities are generally underpowered or prone to systematic bias.
- Available evidence suggests that peak flow meters and written action plans do not have a large impact on outcomes when applied to the general population of asthmatics.
- These interventions are most likely to have beneficial effect when applied to selected populations, particularly patients with high baseline utilization.

■ OBJECTIVE Current guidelines recommend use of written action plans and peak flow monitoring as key components of asthma care. Our study assesses whether written action plans, with or without peak flow monitoring, have an independent effect on outcomes when used as a component of asthma self-management.

■ STUDY DESIGN This was a systematic review of published studies. Two independent reviewers followed a prospective protocol for study selection and data abstraction. Outcome data were synthesized qualitatively; they were not appropriate for quantitative meta-analysis. Our comprehensive literature search used MEDLINE, Embase, the Cochrane Library, and a hand search of recent bibliographies. The search was limited to full-length, peer-reviewed articles with abstracts in English. The studies were randomized controlled trials that compared the outcomes of an asthma self-management intervention with and without the use a written action plan. The primary outcomes of interest are utilization measures, such as hospitalizations and ER visits. Other outcomes of interest include measures of symptom control and lung function

■ POPULATION There were 1501 evaluable patients with asthma; 1410 adults and 91 children.

■ OUTCOMES MEASURED We measured the frequency of waiting and examination room companions, the reasons for accompaniment, the influence on the encounter, and the overall helpfulness of the companion as assessed by patients and companions. We also determined the physician's assessment of the companion's influence, helpfulness, and behavior during the encounter.

■ RESULTS Nine randomized controlled trials enrolling a total of 1501 patients met selection criteria. The majority of comparisons in these studies do not demonstrate improved outcomes associated with a written action plan. There are notable methodologic limitations: studies reporting negative findings lack sufficient power, and studies reporting positive findings demonstrate systematic bias.

■ CONCLUSIONS Although written action plans are widely used, there is insufficient evidence to determine whether their use, with or without peak flow monitoring, improves outcomes.

■ KEY WORDS Asthma, self-management, peak flow meter, written action plan. (*J Fam Prac 2002;51:842–848*)

Self-management skills are widely promoted by health plans and specialty societies with the expectation that they will improve care. The 1997 National Heart, Lung, and Blood Institute guidelines

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TABLE 1

Study characteristics

Study	Patient poupltation	Study Arms	Intervention components	Outcomes reported	Asthma quality indicators met
Optimal medical management vs. optimal medical management + PFM action plan					
Jones 1995[14]	Inclusions: patients using ICS < 1000 mcg per day for at least 1 month Exclusions: patients on oral steroids or using peak flow meters at home Mean age: 29.5 years Severity level: Mild–moderate	Usual care	SxD, FU	Ut, LF, Sx	Pow, Med
		PFM action plan	AP, PF, SxD, FU		
Drummond 1994 (GRASSIC)[15]	Inclusion: FEV1 reversibility 20% or greater Exclusions: patients who already owned a PFM Mean age: 50.8 years Severity level: Mild–severe	Usual care	FU	Ut, LF, Med Ex	Pow, Rev
		PFM action plan	AP, PF, FU		
Ayres 1995[16]	Inclusions: maximum PEF variability, 0.15%; minimum nights/week with symptoms, 3; minimum use of ICS or sodium cromoglycate, 3 months Mean age: 45 years Severity level: Moderate–severe	Usual care	SxD, FU	LF, Sx, Ex	Pow, Med
		PFM action plan	AP, PF, SxD, FU		
Cowie 1997[13]	Inclusions: treatment for an exacerbation of asthma in an ER asthma clinic; history of receiving urgent treatment for asthma in the previous 12 months Mean age: 37.8 years Severity level: Mild–severe	Usual care	Ed, SxD, FU	Ut, PF, Med, Ex	None
		PFM action plan	AP, PF, Ed, SxD, FU		
Cote 1997[17]	Inclusions: FEV_1 postbronchodilator 85-100 % of predicted; PEF, at minimum, 85 % of predicted; minimum PEF variability, 0%; Methacholine Exclusions: patients having previously taken an asthma educational program Mean age: 36.5 years Severity level: Mild	Usual care	Ed	Ut, LF, Med	Exc, Rev, Com
		PFM action plan	Ed, Cn, AP, PF		
Usual care + PFM use alone vs. usual care + PFM action plan					
Ignacio-Garcia 1995[18]	Inclusions: patients from outpatient asthma clinic with asthma for 2 years Mean age: 41.9 years Severity level: Mild–severe	Usual care + PFM	PF, SxD, FU	Ut, LF, Med	None
		Usual care + PFM action plan	PF, AP, Ed, SxD, FU		
Charlton 1994[19]	Inclusion: patients with inpatient or outpatient visit for asthma Mean age: 6.5 years Severity level: Mild–moderate	Usual care + PFM	PF, Ed, SxD, FU	Ut, Sx, Med, Ex	None
		Usual care + PFM action plan	PF, AP, Ed, SxD, FU		
PFM action plan vs. Symptom action plan					
Turner 1998[20]	Inclusions: Maximum methacholine PC_{20}, 7.9; using ICS Exclusions: previous PFM use; significant comorbid conditions Mean age: 34.1 years Severity level: Mild–severe	Symptom action plan	AP, Ed, SxD, Cn BM, EM	Ut, LF, Sx, Med	Exc, Com
		PFM action plan	PF, AP, Ed, SxD, Cn BM, EM		
Charlton 1990[21]	Inclusions: patients on repeat prescribing register Mean age: NR Severity level: Mild–severe (?)	Symptom action plan	AP, Ed, FU	Ut, Med	None
		PFM action plan	PF, AP, Ed, FU, Cn	Ut, PF, Med, Ex	None
Cowie 1997[16]	Inclusions: treatment for an exacerbation of asthma in an ER, or asthma clinic; history of receiving urgent treatment for asthma in the previous 12 months	Symptom action plan	AP, Ed, SxD, FU		
		PFM action plan	AP, PF, Ed, SxD, FU		
Cote 1997[17]	Inclusions: FEV_1 postbronchodilator, 85-100 % of predicted; PEF, at minimum, 85 % of predicted; minimum PEF variability, 0%; Methacholine Exclusions: previous enrollment in an asthma educational program	Symptom action plan	Ed, AP	Ut, LF, Med	Exc, Rev, Com
		PFM action plan	Ed, Cn, AP, PF		

Eligibility criteria: ICS = inhaled corticosteroid; FEV1 = forced expiratory volume in 1 second; PEF = peak expiratory flow; PFM = peak flow meter; ER = emergency room; PC20 = 20% fall in FEV1 Intervention components: PF = Peak flow meter; AP = Written Action Plan; Ed = Education; SxD = Symptom diary; FU = Follow-up visits; Cn = Counseling; BM = Behavior modification; EM = Environmental modification
Outcomes: Ut = Utilization measures; LF= Lung function measurements; Sx = Symptom=based measurements; Med = Medication use; Ex = Exacerbations of asthma Asthma Quality Indicators: Exc = Accounted for excluded patients; Pow = Reported power calculations; Rev = Established reversibility of airway obstruction; Med = Controlled for other medication use; Com = Reported compliance; Sea = Addressed seasonality.

TABLE 2

Power calculations for hospitalizations per patient per year

Assumed control mean	Possible treatment mean	% decrease	N needed per study arm
0.10	0.075	25	3077
0.10	0.05	50	770
0.10	0.025	75	342
0.20	0.015	25	770
0.20	0.10	50	193
0.20	0.05	75	86
0.30	0.225	25	342
0.30	0.15	50	86
0.30	0.075	75	38

Studies were identified that contained baseline rates on hospitalizations/patient/year, or information that allowed calculation of this parameter (Drummond, Abdalla, Beattie et al., 1994; Cote, Cartier, Robichaud et al., 1997; Cowie, Revitt, Underwood et al., 1997; Ignacio-Garcia and Gonzalez-Santos, 1995). Baseline rates of hospitalization varied in these studies from 0.04-0.29/patient/year. Standard deviations for this outcome were available only in two studies; Cote, Cartier, Robichaud et al. (1997) reported an SD of 0.30 for this variable, and an SD of 0.35 was calculated from the confidence intervals reported in GRASSIC (Drummond, Abdalla, Beattie et al., 1994). For the calculations, the more conservative 0.35 estimate for SD was used.
Number of patients per study arm were estimated for 80 percent power at the 5 percent significance level using control arm means of 0.10, 0.20, and 0.30 hospitalizations/patient/year. The expected reduction in this variable was tested along a spectrum from 25-75 percent.

on treating asthma emphasize self-management,[1] although they do not recommend specific programs. To maximize therapeutic effectiveness, it would be useful to know which components of patient self-management improve outcomes. Written action plans and peak flow meters are commonly used in asthma self-management programs. While these are simple, low-cost interventions for an individual, the aggregate cost for the entire population of asthmatics may be high.[2]

Much literature has accumulated on the effectiveness of providing asthma education alone and on programs that actively engage patients in their own care.Several systematic reviews have found that providing educational information alone has had little effect on asthma outcomes.[3–5] There is evidence, though, that self-management activities are more effective than educational information alone. A recent Cochrane review of 24 trials found that self-management with regular practitioner review reduces hospitalizations and emergency room visits.[6] This review did not identify specific components contributing to improved outcomes. In contrast to the aforementioned studies on patient education, a large case-control study of children in the Kaiser Permanente System,[7] found that written action plans were associated with lower rates of hospitalization and emergency room use. However, such observational studies often include confounding factors and are not sufficient to establish a cause-effect relationship between written action plans and improved outcomes.

We report on a systematic review that attempts to isolate the independent effect of a written action plan on asthma outcomes. We address two key questions:

1. Compared with medical management alone, does the addition of a written asthma action plan (with or without peak flow meter use) improve outcomes?
2. Compared with a written action plan based on symptoms, does a written action plan based on peak flow monitoring improve outcomes?

METHODS

This study is part of a broader evidence report on the management of chronic asthma prepared for the Agency of Health Care Research and Quality[8]. Complete details of the methodology are available in the full report[8] (http://www.ahcpr.gov/clinic/epcix.htm).

Literature search and study selection

We performed a comprehensive literature search from 1980 to August 2000 using MEDLINE, Embase, the Cochrane Library, and a hand search of recent bibliographies. The search was limited to full-length, peer-reviewed articles with an English abstract. Two independent reviewers carried out each step of study selection and data abstraction. Disagreements were resolved by consensus of the two reviewers or, if necessary, by the decision of a third reviewer.

Initial study selection was limited to comparative full-length reports or abstracts in peer-reviewed medical journals, with at least 25 evaluable children or adults per arm, treated for at least 12 weeks. Relevant comparisons included a written action plan and no written action plan; a written action plan based on peak flow readings and a written action plan based on symptoms. Study designs varied: clinical trials, cohort comparisons, case-control analyses, cross-sectional evaluations, and before-after comparisons. Specific components of the management plan had to be described.

Relevant outcomes included measures of inpatient and outpatient utilization, lung function, symptoms, rescue medication or oral steroid use, and quality of life. Outcomes of greatest interest were utilization

parameters, as the goals of self-management usually focus on improving these outcomes.

These initial selection criteria yielded many studies that were confounded by multiple asthma management interventions and thus did not isolate the comparisons of interest. Therefore, the research team collectively determined the study design features that would best isolate the effects of written action plans and used them as new criteria in a second round of study selection.The studies thus selected satisfied 4 criteria: 1) randomization of patients; (2) delivery of the same interventions to experimental and control groups, except that the experimental group also received a written action plan; (3) delivery of the same interventions to experimental and control groups, except that one group received a written action plan based on peak flow meter readings, and the comparison group received a written action plan based on symptom monitoring; and 4) inclusion of a written action plan that met our specified definition.

A written action plan, by our definition, had two components: an algorithm that identified specific clinical indicators signaling the need for adjustments in medication; and specific instructions on how to adjust medications in response to such indicators. Many publications lacked sufficient detail on the written plan, so a brief survey was sent to the primary author of each of the 36 studies. If no response was obtained (36%), the article was excluded only when it was clear from the publication that our definition was not met.

Assessment of study quality

High-quality studies were randomized controlled trials that met the 3 domains of study quality that have been demonstrated empirically to impact effect size: concealment of treatment allocation; double-blinding; and minimization of exclusion bias.[9,10] However, we doubted the feasibility of double-blinding a written asthma plan intervention, and so relaxed this requirement. We considered exclusion bias to be minimized when a study either reported intent-to-treat analysis or excluded fewer than 10% of subjects from analysis, with the ratio of subjects excluded from each arm being less than 2:1.

To more fully evaluate study design issues that may be particularly important in asthma research,[11,12] we constructed asthma-specific quality indicators in consultation with an expert panel. Controls for potential confounders of treatment effect included establishing reversibility of airway obstruction, controlling for other medication use, reporting compliance, and addressing seasonality. In addition, *a priori* reporting of power calculations and accounting for exclusions and withdrawals were judged to be study quality characteristics pertinent to this body of evidence.

Data analysis

We constructed evidence tables for the outcomes of interest, and performed a qualitative synthesis of the data. Meta-analysis was not appropriate due to wide discrepancies in the patient populations studied, the interventions employed, and measurement and reporting of outcomes.

RESULTS

Our literature search yielded a total of 4578 citations. Of these, 36 studies met the initial selection criteria. Many of these qualifying studies, however, were confounded by multiple asthma management interventions applied inconsistently across treatment arms. For example, a common confounder was review of and change in long-term medication use in the treatment group, but not in the control group. This necessitated a refinement in our selection criteria to focus on studies that largely isolated the effect of written action plans.[13–21] This step yielded a final evidence base of 9 randomized controlled trials with a total enrollment of 1501 patients.

Table 1 summarizes the characteristics, interventions, and outcomes of the 9 studies. Two studies were 3-arm trials,[16,17] which raised the total number of comparisons among the 9 studies to 11. The largest study was the Grampian Asthma Study of Integrated Care (n=569),[14] a community study conducted in the UK. Enrollment in the other 8 studies ranged from 43 to 64 patients per arm. Treatment duration ranged from 24 to 52 weeks.

None of the studies met our definition of high quality. In fact, no study met any of the generic quality criteria—none was blinded, none described concealment of allocation, and all excluded more than 10% of subjects. Furthermore, none reported an intention-to-treat analysis. Thus these trials were prone to withdrawal bias as well as overestimation of treatment effect due to lack of allocation concealment.

No study met the majority of asthma-specific indicators (Table 1). Of the 9 studies, only 5 met any asthma-specific indicator. Three reported prospective power calculations,[13–15] but 2 of these substantially overestimated the expected effect.[13,15] Two studies established reversibility;[14,17] 2 controlled for other medication use;[13,15] and 2 reported compliance.[17, 21] Thus, the studies were also prone to a type II error (failing to detect a true effect) and to potential confounding of outcomes.

We performed sample power calculations for hospitalizations (Table 2), derived from baseline

rates reported in 4 studies[14,16–18] and standard deviations reported in 2.[14,17] A study with 250 patients per arm could detect a reduction of 50% or more in hospitalization, given a control rate of at least 0.2 hospitalizations/patient/year. In actuality, GRASSIC,14 which is the largest available trial (N=569), had baseline hospitalization rates of 0.12 and 0.13. With this baseline rate, over 700 patients per arm are required, higher than the actual enrollment in GRASSIC. The other studies in this review would be adequately powered to detect a 50% difference only in the setting of even higher baseline utilization (eg, 0.30 hospitalizations/patient/year).

Table 3 displays utilization outcomes for the 11 comparisons in the 9 trials. In 5 studies (N=1019), medical management with a written action plan was compared with medical management without a written action plan.[13–17] Two trials (N=185) compared a peak flow meter plus a written action plan with a peak flow meter and no written action plan[18,19] In 4 studies (N=393), a written action plan based on peak flow monitoring was compared with a written action plan based on symptoms.

Written action plan versus no written action plan

All 5 studies used a peak flow meter based written action plan. All reported utilization outcomes, but the types and units of measurement were not consistent across studies (Table 2). Additionally, 4 studies reported on symptoms,[13–16] and 3 reported lung function outcomes.[13–15]

With one notable exception, there were no statistically significant differences in outcomes among groups. Cowie et al[16] reported an 11-fold decrease in total emergency room visits for the group using a peak-flow action plan (5 vs 55, P = .02), and also reported a reduction in hospitalizations of a similar magnitude (2 vs 12) that did not reach statistical significance. However, this study suffers from notable flaws that diminish confidence in the results. It is a post-intervention comparison among groups, which does not compare change from baseline, or incorporate baseline values as covariates in the analysis. Moreover baseline utilization data were provided by patient recall and not corroborated by medical records. There was a substantially larger variability in the baseline utilization rates for the peak flow group compared with the control group. This suggests that a subset of very high frequency users may have been over-represented in the peak flow group, and the reduction in emergency room visits may be concentrated in this subset.

Peak-flow meter-based written action plan versus peak flow meter with no written action plan

Two studies[18,19] addressed the independent effect of a written action plan when added to peak flow self-monitoring (Table 3). Charlton[19] reported no significant group differences for main outcomes, while Ignacio-Garcia[18] reported large and statistically significant differences in most of the outcomes, favoring the group that used the written action plan.

The Ignacio-Garcia study, however, suffers from notable flaws suggesting the results may be attributable to bias. The sole participating physician, not blinded to treatment assignment, was highly involved in all phases of patient assessment, monitoring, and treatment. There was evidence of baseline differences between the two groups. A total of 25% of patients were withdrawn after randomization, and an unexplained decline in lung function occurred in the control group. Thus, the potential for selection bias, withdrawal bias, and ascertainment bias limits confidence in the results of this study

Symptom-based written action plan compared with peak flow-based written action plan

In 4 studies,[16,17,20,21] reported outcomes were generally equivalent between groups and comparisons were not statistically significant, with one exception (Table 3). The 3-arm study by Cowie et al[16] reported a striking reduction in the total number of emergency room visits with a peak flow meter-based written action plan compared with a symptom-based written action plan (5 versus 45, $P < 0.002$). However, confidence in the validity of these results is limited, as discussed previously.

DISCUSSION

The objective of this systematic review was to assess the independent effects of 2 specific components commonly included in asthma self-management plans—a written action plan and a peak flow meter. Few studies, however, are designed to permit reviewers to isolate the effects of these components. Moreover, the studies we reviewed did not clearly identify the population expected to benefit from interventions or specify the primary outcomes of interest; nor was the level of clinically meaningful improvement prospectively defined.

Most of the trials we reviewed, including the largest community study of 569 patients, did not demonstrate improved outcomes. The 2 trials that reported statistically significant results favoring a peak flow-based written action plan suffer from

TABLE 3

Utilization outcomes reported

Study/Duration of Treatment	Study arm	#Enrolled #evaluable	Office visits Measure	Office visits Result	ER visits Measure	ER visits Result	Hospital visits Measure	Hospital visits Result	Missed days of work/school Measure	Missed days of work/school Result
Usual care vs PFM action plan										
Jones 1995[13] (24 weeks)	UC	64/39	% of patients with any office visit(s)	62%	NR	—	NR	—	% of patients with any missed work days	54%
	PFM AP	63/33		52%[1]		—		—		55%
Drummond 1994 (GRASSIC)[14] (52 weeks)	UC	284/260	Mean office visits/patient	2.2	NR	—	Mean hospitalize -tions/patient	0.12	NR	—
	PFM AP	285/250		2.6[1]		—		0.13[1]		—
Ayres 1995[15] (24 weeks)	UC	64/64	NR	—	NR	—	NR	—	NR	—
	PFM AP	61/61		—		—		—		—
Cowie 1997[16] (24 weeks)	UC	48/NR	NR	—	Total ER visits for entire group	55	Total hospitaliz- ations for entire group	6	NR	—
	PFM AP	46/NR		—		5[3]		2[1]		—
Cote 1997[17] (52 weeks)	UC	54/NR	NR	—	Decrease in ER visits /patient	-1.5 ± 2.9	Decrease in hospital visits /patient	0.04 ± 0.3	Decrease in days missed /patient	5.2 ± 12.5
	PFM AP	50/NR		—		-1.6 ± 2.8[1]		0.04 ± 0.3[1]		2.2 ± 12.7[1]
Usual care + PFM use alone vs usual care + PFM action plan										
Ignacio-Garcia (28 weeks)	UC + PFM use	44/35 1995[18]	Mean office visits/patient	4.5 ± 4.0	Mean hospitaliz- ations/patient	1.9 ± 2.8	Mean hospitaliz- ations/patient	5	Mean missed days/patient	20.0 ± 28.9
	UC + PFM AP	50/35		1.5 ± 1.1[3]		0.65 ± 0.7[4]		0[1]		4.9 ± 6.6[3]
Charlton 1994[19] (52 weeks)	UC + PFM use	43/37	Median office visits/patient	2	NR		Median hospitaliz- ations/patient	1	Median missed days/patient	4.7
	UC + PFM AP	48/42		2.3[1]				5[1]		2.1[1]
PFM action plan vs Symptom action plan										
Turner 1998[20] (24 weeks)	Symptom AP	48/48	% of patients with any office visit(s)	25%	% of patients with any ER visit(s)	4%	% of patients with any hospital	1	% of patients with any missed day(s)	17%
	PFM AP	44/44		39%[1]			13%[1]	visit(s)	0[1]	20%[1]
Charlton 1990[21] (52 weeks)	Symptom AP	64/	% of patients with any office visit(s)	53%	NR	—	NR	—	NR	—
	PFM AP	51/NR		66%[1]		—		—		—
Cowie 1997[16] (24 weeks)	Symptom AP	45/NR	NR	—	Total ER visits for entire group	45	Total hospital- izations for entire group	2	NR	—
	PFM AP	46/NR		—		5[3]		2[1]		—
Cote 1997[17] (52 weeks)	Symptom AP	45/NR	NR	—	Decrease in ER visits/ patient	-1.2 ± 2.7	Decrease in hospital visits/patient	0.09 ± 0.3	Decrease in missed days/ patient	2.9 ± 12.7
	PFM AP	50/NR		—		-1.6 ± 2.8[1]		0.04 ± 0.3[1]		2.2 ± 12.7[1]

UC = Usual care; NR = Not reported; AP = Action Plan; [1]*P* = not significant; [2]*P* < .05; [3]*P* < .01.

notable flaws suggesting the results may be attributable to bias. In the other 7 trials, there was little difference in outcomes between groups. However, these studies had insufficient power to detect group differences or confidently conclude equivalence between groups.

Thus, available evidence is insufficient to demonstrate that asthma outcomes are improved by use of a written asthma action plan, with or without peak flow monitoring. While this body of literature does not establish that these interventions are ineffective, it suggests they will not have a large effect on outcomes when applied to the general asthmatic population. The application of written action plans to all asthmatics indiscriminately may be a wasteful use of resources. This

systematic review also questions the validity of written action plans as an indicator of asthma quality of care, or as a means to achieve quality improvement.

This analysis also highlights several obstacles to assessing the effects of disease management interventions. First, while the impact of whole intervention programs can be evaluated in controlled trials, it may be unfeasible to isolate each component of such programs and subject it to a rigorous analysis. Furthermore, as a behavioral intervention, the general principle of engaging patients in self-management may be more important that the specific components of these programs. Finally, regarding the optimization of medications (most obviously initiation of inhaled steroids) the impact of written action plans is likely to be relatively small, particularly on lung function or symptom control.

Future clinical trials should be done selectively, aimed at producing rigorous results that can improve the effectiveness of self-management interventions. Further study is warranted for specific subpopulations, such as those with higher baseline severity of illness or those with high baseline utilization rates. Available data suggest that, if there is benefit to be gained from self-management interventions, it will most likely be seen among these patients. Specific components of self-management that might be tested individually are those that are relatively high-cost, resource intensive, or risky for the patient.

Existing trials have tended to over-estimate the effects of action plan-based interventions, thus having invested resources for results inadequate for optimizing self-management strategies. Careful consideration needs to be taken in future trials to realistically estimate the expected impact of each intervention, and to specify the primary outcomes of interest and their baseline frequencies. Future trials should be large enough to detect a difference if one exists, or to confidently conclude that the intervention is ineffective.

Attention to these principles will help to advance our knowledge in this area most efficiently and to ultimately improve the quality of care for the entire population of patients with asthma.

ACKNOWLEDGMENTS · We acknowledge Kathleen Ziegler, Pharm.D, and Claudia Bonnell, RN, MSL, for their assistance in the research and preparation of this manuscript.

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