

Evidence Table 2. Assessment and Monitoring: Usefulness of Peak Flow Measurement

Abbreviations used in table:

BA	beta-agonist	MIC	methacholine inhalation challenge
BI	basic information	NEB	nebulizer
CI	confidence interval	NPV	negative predictive value
COPD	chronic obstructive pulmonary disease	PEF	peak expiratory flow
ED	emergency department	PEFR	peak expiratory flow rate
EI	extended information	PFM	peak flow meter/monitoring
FEV₁	forced expiratory volume in 1 sec	PL	placebo
FEF_{25-75%}	forced expiratory flow between 25% and 75% of the vital capacity	r_c	concordance correlation coefficient
FRC	functional residual capacity	ROC	receiver operating characteristic
ICS	inhaled corticosteroid	RV	residual volume
IQR	interquartile range	TLC	total lung capacity
MDI + S	metered-dose inhaler with spacer		

* indicates primary outcome

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A. Validity/Correlation of PEF

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Compliance	Morbidity	Other
Alcock et al. Symptoms and pulmonary function in asthma. <i>Respir Med</i> 1998;92(6):849–857. (National Asthma Campaign, GlaxoWellcome, Breathe North, and Duncan Flockhart)	Longitudinal descriptive study	To examine the relationship between reported symptoms, pulmonary function (expressed as best and actual/best), and therapy	824	Age >18 yr, mean = 55 yr Gender 49% male, 51% female Smoking 7.5% current smokers 40.3% never smokers	Best PEF, mean = 94.5% Actual/best PEF, mean = 87.5% Best FEV ₁ % pred., mean = 84.6% Actual/best FEV ₁ % pred., mean = 89.6 22.5% had nocturnal disturbance 46.3% had persistent daytime symptoms			Mean actual/best peak flow varied from 82% for those on oral steroids to 91% for those on low-dose ICS.			Significant correlation between symptoms score and actual function; strongest with FEV ₁ . Correlation between symptoms and actual/best function; weaker for FEV ₁ . With PEF relationship with nocturnal disturbance was similar for best (r=0.14) and actual/best (r=0.16). Using quintiles of function, symptoms were less as best function increased, but were greater in the 5th vs. 3rd and 4th quintiles of actual/best FEV ₁ .
Brand et al. Peak flow variation in childhood asthma: correlation with symptoms, airways obstruction, and hyper responsiveness during long-term treatment with inhaled corticosteroids. <i>Dutch CNSLD Study Group. Thorax</i> 1999;54(2):103–107. (Netherlands' Government Health Research Promotion Programme)	Multicenter, randomized, double-blinded trial	To assess the pattern of PEF variation over time and its relationship to changes in other parameters of disease activity	116	Age 7–14 yr, mean = 11 yr Gender 74% male, 26% female	FEV ₁ % pred., mean = 79 PD ₂₀ , geometric mean = 18.4 mcg Morning PEF, mean = 281 L/min Afternoon PEF, mean = 305 L/min Diurnal PEF variation, mean = 13.7%	Arm 1: Salbutamol 200 mcg + budesonide 200 mcg (BA+ICS) 3 times daily (n not reported; n=44 at 20 months) Arm 2: Salbutamol 200 mcg + placebo inhaler 3 times daily (BA+PL) (n not reported)	Every 2 months for 20 months	PEF improved during first 2 months for BA+ICS and was unchanged for BA+PL (95% CI for difference 17–77 L/min for morning PEF and 10–71 L/min for afternoon PEF). PEF variation decreased during first 2 months with ICS (95% CI for a difference of 6.6%–20.5%) and then remained stable (95% CI for a difference of 6.2%–19.0%).			For individuals in the BA+ICS group (n=44), positive associations were found between variation in PEF, percentage of symptom-free days, PD ₂₀ histamine, and FEV ₁ % predicted with a wide range of associations.

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Eid et al. Can peak expiratory flow predict airflow obstruction in children with asthma? Pediatrics 2000;105(2):354-358.	Observational (descriptive)	To examine whether PEF monitoring creates inaccuracies in assessment of children with moderate-to-severe asthma	244 (357 sets of pulmonary function tests)	Age 4-18 yr, mean = 10.2 yr Gender 56.1% male, 43.9% female Ethnicity 79.4% White 20.6% other	Moderate-to-severe asthma PEF, range 27-174, mean = 79.4 FEV ₁ , % pred., range 28-134, mean = 82.9 FEF _{25-75%} , range 10-158, mean = 70.3 RV/TLC, range 10.6-66.6, mean = 30.2 RV, range 38-371, mean = 136.7 FRC, range 50-192, mean = 105.3		214 pulmonary function tests on outpatients for routine asthma monitoring and 153 on inpatients just before hospital discharge	PEF, FEV ₁ , and FEF _{25-75%} correlated ranging from 0.59 to 0.73. PEF, FEV ₁ , and FEF _{25-75%} were inversely related to air trapping (RV/TLC). NPV drops for FEV ₁ (p=0.02) and for FEF _{25-75%} (p=0.008) using RV/TLC levels of ≥30 as cutoff. Sensitivity of PEF to detect abnormal pulmonary function was 76% with specificity 77%. Positive predictive value was 81%.			
Goldstein et al. Comparisons of peak diurnal expiratory flow variation, postbronchodilator FEV(1) responses, and methacholine inhalation challenges in the evaluation of suspected asthma. Chest 2001;119(4): 1001-1010. (Asthma Center Education and Research Fund; Merck & Cos., Inc.)	Prospective descriptive study	To evaluate several PEFvar indexes in a population of patients with suspected asthma and normal spirometry findings and to assess level of compliance in performing 2 to 3 weeks of home peak flow monitoring followed by a methacholine inhalation challenge (MIC)	121 (57)	Age 30% 7-18 yr, 70% >18 yr	At least 3 months with asthma-like symptoms FEV ₁ % pred. ≥80% FEF _{25-75%} ≥80% FVC % pred. ≥80%		PEF recorded 4 times daily for 2 to 3 weeks followed by an MIC 28 PEF variation indexes (PEFvar) were computed for each subject	There were no significant correlations for any of the PEFvar indexes with MICs. Specificity of the period PEFvar indexes ranged from 0 to 93.3%. MIC was the most sensitive test (85.7%) and had best negative predictive value (56.25%). MIC, post-BD FEV ₁ , and the best mean daily PEFvar index had 100% specificity and 100% positive predicted value.	Greater compliance with MIC as compared with acceptable peak flow diary (66% vs. 50.4%, p=0.012).		

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Kamps et al. Peak flow diaries in childhood asthma are unreliable. Thorax 2001;56(3):180–182.	Prospective randomized controlled trial	To examine the accuracy and reliability of peak flow diaries in White children with relatively stable asthma	40 (40)	Age 5–16 yr, mean = 9.2 yr Gender 61.5% male, 32.5% female	Moderately severe persistent asthma Clinically stable on inhaled corticosteroid (ICS), mean dose = 268 mcg FEV ₁ % pred., mean 103.5	Arm 1: Basic information (BI) that device allowed for more accurate assessment of peak flow Arm 2: Extended information (EI) given basic information plus told that peak flow values would be used in guiding adjustments to treatment	Recorded peak flow measurements in written diary for 4 weeks compared with electronically recorded data for the same period		Reported compliance did not differ between BI and EI (96.6% vs. 94.8%). Mean reported compliance was higher than actual compliance (96.6% vs. 73.4% for BI; 94.8% vs. 80.9% for EI) with no difference in actual compliance between BI and EI. There was no difference between groups in percent of correct, incorrect, missing, and self-invented PEF diary entries. Percentage of correct PEF entries decreased throughout the study in both groups. Percentage of self-invented PEF values increased from week 1 to week 4 in BI group (p=0.001), but not in EI group (p=0.28).		
Leone et al. The utility of peak flow, symptom scores, and beta-agonist use as outcome measures in asthma clinical research. Chest 2001;119(4): 1027–1033. (National Institutes of Health)	Secondary analysis of data from 2 ACRN studies: Beta ₂ -Agonists in Mild Asthmatics study and Colchicine in Moderate Asthma study	To define the operating characteristics of various self-reported measures of asthma with regard to their ability to identify a fall in FEV ₁ of ≥20% from baseline, and to identify the diary-derived measure with the best diagnostic capabilities within each of 3 measurement categories: peak flow, symptom score, and beta ₂ -agonist use	326 (313)	Age 13–58 yr, mean = 30.2 yr Gender 44% male, 56% female Ethnicity 33% minority	78% mild asthma, 22% moderately severe FEV ₁ , mean = 3.01 L FEV ₁ % pred., mean = 87 PEF, mean = 415 L PEF % pred., mean = 91	Disease-positive group: Treatment failures defined as fall in FEV ₁ ≥20% from baseline (n=71) Disease-negative group: (n=242)	Subjects recorded disease-related information daily during both source studies.	No index of PEF displayed superior discriminative capacity over any other. Changing the cutoff value to increase sensitivity resulted in increased specificity.		Areas under receiver operating characteristic (ROC) curves for tests of exacerbation ranged from 0.51 to 0.79 with no curves attaining both sensitivity and specificity of ≥80% at any cutoff value. Curves within and between groups were similar, regardless of measure employed, period analyzed, or positivity criteria used.	

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Llewellyn et al. The relationship between FEV ₁ and PEF in the assessment of the severity of airways obstruction. <i>Respirology</i> 2002;7(4):333-337. (Health Research Council of New Zealand; the Guardian Trust)	Retrospective study using medical records	To compare measurements of FEV ₁ and PEF in subjects with either asthma or chronic obstructive pulmonary disease (COPD)	101 (2,587 paired measurements)	Age 18-70 yr, mean = 38.4 yr Gender 56% male, 44% female	55% with clinical diagnosis of asthma; 45% with clinical diagnosis of chronic obstructive pulmonary disease (COPD) Number of visits to clinic ranged from 2 to 171 with median of 4 FEV ₁ % pred., range 15-124, mean = 55 at median visit	Subjects drawn from patient files at outpatient chest clinic.		Estimated mean difference (% predicted FEV ₁ minus % predicted PEF) was -10.9% (95% CI -12.8% to -8.9%). Limits of agreement from components of variance were -35.4% to 13.6%. FEV ₁ % predicted minus PEF % predicted increased as severity of airflow obstruction decreased. Weighted kappa for agreement between category of airway obstruction based on FEV ₁ and PEF was 0.59 (95% CI 0.48-0.70). Estimated mean difference of % predicted FEV ₁ and PEF was -13.9% (95% CI -11.3 to -16.4) for those with asthma.			

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<p>Reddell et al. When can personal best peak flow be determined for asthma action plans? Thorax 2004;59(11):922–924. (Asthma Foundation of NSW, the National Health and Medical Research Council of Australia, AstraZeneca Sweden and AstraZeneca Australia)</p>	<p>Secondary analysis of data from a 72-week randomized trial (high-dose budesonide study)</p>	<p>To examine the time when personal best PEF stabilizes after initiation of inhaled corticosteroids</p>	<p>61 subjects; 42,590 spirometric maneuvers</p>	<p>Age 18–75 yr Gender Not reported Smoking All nonsmokers</p>	<p>Poorly controlled asthma with ICS up to 1,200 mcg/day Reliever use, mean 3 occasions/day (IQR 1.9 to 4.4) Morning PEF, mean 340 L/min (61% predicted, 95% CI 57 to 66) Within-session PEF reproducibility 19 L/min (IQR 14–25)</p>	<p>Data from all subjects were combined for analysis. The rate of change in PEF was calculated as difference between average value for the previous 4 weeks and average for subsequent 4 weeks (2-week periods used for first 4 weeks). Plateau was determined as the week in which pairwise comparisons of 4-week averages with subsequent averages became nonsignificant.</p>		<p>Personal best PEF improved from 484 L/min (87% predicted, 95% CI 82–92) to plateau of 527 L/min (95% predicted, 95% CI 90–100; p<0.0001). Plateau reached after 3 weeks of treatment when reliever use was 0.9 occasions/day (IQR 0.3–2.9). Plateau delayed to 8 weeks if morning PEF values were analyzed. Average morning PEF improved to week 13 (467 L/min, 84% predicted, 95% CI 79–90; p<0.0001 with week 3) and reliever use to week 30 (0.1 occasions/day, IQR 0.0–0.8; p<0.0001 with week 3).</p>			

B. Peak flow versus symptoms in management

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Compliance	Morbidity	Other
Adams et al. A randomized trial of peak-flow and symptom-based action plans in adults with moderate-to-severe asthma. <i>Respirology</i> 2001;6(4):297–304. (The University of Adelaide, The Queen Elizabeth Hospital Research Foundation)	Prospective, randomized controlled trial	To compare the effect of PFM-based with symptom-based action plans in adult hospital outpatients with moderate-to-severe asthma who did not have evidence of poor perception of bronchoconstriction	172 (134)	Age >16 yr, mean = 36.5 yr Gender 39% male, 61% female	Moderate-to-severe asthma Duration of asthma, mean = 13.9 yr FEV ₁ % pred., mean = 75.7 Inhaled steroids, mean = 746 mcg/day 73% taking both ICS and bronchodilators; 22% using bronchodilators only; 5% no asthma medications 56% hospitalized in past year 60% ED visit in past year	Arm 1: Written, self-management action plan activated by a decrease in PEF (n=73 in analysis) Arm 2: Written, self-management action plan activated by an increase in symptoms (n=61 in analysis) (stratified randomization by age and gender)	Monthly assessment for 12 months	No significant changes in FEV ₁ in either group. No difference between groups in PD ₂₀ histamine.	Appropriate use of action plans was implemented in 85% of symptoms and 86% of PFM exacerbations.	*No differences between groups in health care utilization, ED visits, hospitalizations for asthma, and days absent from school or work due to asthma.	
McMullen et al. Peak flow meters in childhood asthma: parent report of use and perceived usefulness. <i>J Pediatr Health Care</i> 2002;16(2): 67–72. (National Institutes of Health)	Randomized clinical trial	To describe reported peak flow monitoring use over time and families' perceptions of its usefulness	168 (136 at 1 year)	Age 74% school-aged, 26% adolescent Gender 59% male, 41% female Ethnicity 66% White 24% Black 10% other Socioeconomic Status 51% upper 49% lower Geographic Location 34% urban 66% nonurban	Persistent asthma	Arm 1: Training in monitoring subjective symptoms (symptom monitoring) (n not reported) Arm 2: Training in peak flow monitoring at symptomatic times (symptom-time PFM) (n not reported) Arm 3: Training in daily and symptom-time peak flow monitoring (daily-PFM) (n not reported)	2-week training period and 3-month postintervention period of diary keeping and telephone contact every 2 weeks; followup contact 1 year after exiting from protocol. Overall 156 (93%) completed protocol; 136 (81%) available for 1 year contact.				At 3 months, 90% of parents perceived benefit in monitoring method; 93% planned to continue with method learned. No difference between groups. 82% of children perceived benefit and 71% continued to use assigned monitoring method: 81% of symptom-monitoring group, 73% of symptom-time PFM vs. 61% of daily PFM (p=0.05). At 1 year, there was no difference between symptom-time and daily PFM users in frequency of PFM use; 75% of school-age children continued use of PFM vs. 44% of adolescents (p=0.01). Children who reported more symptoms reported more frequent use of PFM (r=0.48, p=0.0001).

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Yoos et al. Symptom monitoring in childhood asthma: a randomized clinical trial comparing peak expiratory flow rate with symptom monitoring. Ann Allergy Asthma Immunol 2002;88(3):283–291. (National Institutes of Health)	Multisite, randomized clinical trial (11 primary care settings)	To evaluate the effect of 3 different intensities of symptom monitoring on asthma morbidity outcomes	168 (156 for postintervention, 136 for 1-year interview, 162 for chart review)	Age 74% school-aged, 26% adolescent Gender 59% male, 41% female Ethnicity 66% White 24% Black 10% other Socioeconomic Status 51% upper 49% lower Geographic Location 34% urban 66% nonurban		Arm 1: Training in monitoring subjective symptoms (symptom monitoring) (n=56) Arm 2: Training in peak flow monitoring at symptomatic times (symptom-time PFM) (n=55) Arm 3: Training in daily and symptom-time peak flow monitoring (daily PFM) (n=57) (stratified randomization based on race, age, and geographic location)	Postintervention assessment at 3 months; postexit interview at 1 year	No differences by treatment group in improvement in FEV ₁ .		*Improvement in composite severity score was greater for symptom-time PFM than for daily PFM (-0.26 vs. -0.10, p=0.002). There was no difference among treatment groups for White children, but among Black children, daily PFM showed improvement in composite severity score vs. symptom-time PFM (p=0.03). There were no differences overall among groups at 1 year, but both PFM groups showed improvement in severity score compared to symptom monitoring group for Black children (p<0.05). Symptom-time PFM group improved in number of symptom days at 3 months vs. symptom-monitoring group (0.87 days/week vs. 0.4 days/week, p=0.01).	There were no differences among groups in the change in health care utilization from pre- to postintervention.

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Wilson et al. A prospective evaluation of the 1-hour decision point for admission versus discharge in acute asthma. J Intensive Care Med 2003;18(5): 275–285. (Program for Healthcare Innovation, University of Massachusetts Medical Center)	Randomized, double-blind, placebo-controlled trial	To evaluate the 1-hour decision point for discharge or admission for acute asthma, to compare the admission recommendations of the Expert Panel Report–1 guidelines, and to develop a model for predicting need for admission in acute asthma	50 (50)	Age 6–48 yr, mean = 24 yr Gender 38% male, 62% female Smoking 32% current smokers	Presenting to ED for acute asthma or suspected asthma Duration of asthma, mean = 12 years Duration of symptoms prior to presentation, range 1 to 336 hours, mean = 72 hours	Arm 1: Albuterol by metered-dose inhaler with spacer (MDI+S) at dose of 1 puff of 90 mcg every minute for 4 puffs followed by placebo administered by updraft nebulizer (3.0 mg normal saline) (n not reported) Arm 2 Propellant gas by inhaler at 1 puff every minute for 4 puffs followed by albuterol sulfate inhalation solution 0.093% by nebulizer (NEB) (n not reported)	Treatment every 20 minutes with a minimum of 3 treatments and a maximum of 6 treatments. After 3 rounds, all received systemic corticosteroid therapy and disposition determination made.	PEFR and FEV ₁ correlated throughout the study (r=0.80 at baseline, 0.78 at 1 hours, 0.72 at 2 hours), results were more reproducible using FEV ₁ . Spirometric measurements differed between those discharged and those admitted/relapsed at baseline and after therapy, with no difference between groups across time. The maximal information content (0.161) occurred at a FEV ₁ decision threshold of ≥70% of predicted at the 120-minute time point (sensitivity 99%, specificity 41%).		22% were admitted to the hospital with no difference between MDI+S and NEB. There was no difference between those discharged and those who were admitted or had a relapse on baseline characteristics, delivery method in the ED, and serial monitoring of clinical variables during treatment.	Only the ability to lie flat without dyspnea showed a significant difference over time between those discharged and those admitted or relapsed (p=0.0164). The ability to lie flat without dyspnea and the FEV ₁ at 60 minutes produced the highest overall classification accuracy of 86% (sensitivity 97.1%, specificity 62.5%). A scoring system using these 2 variables performed better (p=0.0054) than the admission algorithm of the Expert Panel Report–2 guidelines.
Gorelick et al. Difficulty in obtaining peak expiratory flow measurements in children with acute asthma. Pediatr Emerg Care 2004;20(1): 22–26. (Maternal and Child Health Bureau, Health Resources and Services Administration, DHHS)	Prospective cohort study	To determine the frequency with which children were able to perform PEFR in the context of ED treatment of an acute asthma exacerbation and to identify factors associated with proper performance	456 (292 with attempt at PEF)	Age 6–18 yr, mean = 10.1 yr Ethnicity 100% White	Presenting at pediatric ED with acute asthma	Patients were treated using standardized, written management guidelines, based on the recommendations of the National Heart, Lung, and Blood Institute’s National Asthma Education and Prevention Program, employing a stepped approach that emphasized aggressive use of inhaled bronchodilators and early use of systemic steroids.		*65% with PEFR attempt were able to provide valid reading (95% CI 60%–71%). Patients unable to perform PEFR were younger than those able to perform (8.7 vs. 11.2, 95% CI for diff. 1.8–3.2 yr). Correlation between clinical severity score and inability to perform PEFR at start (r _s =0.52) and end (r _s =0.53) of treatment.	64% had at least 1 attempt at PEFR during the ED visit. Those with no attempt were less likely to be admitted to the hospital than those who did have attempt (18% vs. 33%, p= 0.001). 44% with mild intermittent asthma and 38% of those with persistent asthma did not have PEFR done (p=0.44).		

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Vargas et al. Underestimation of the peak flow variability in asthmatic children: evaluation of a new formula. <i>Pediatr Pulmonol</i> 2005;39(4):325-331.	Descriptive	(1) To evaluate the degree of underestimation of PEF variability in a population of children with asthma in whom circadian changes in PEF measurements were monitored and (2) to assess the accuracy of a new formula based on sinusoidal curve fitting to calculate PEF variability %variability = $200 \left \frac{PEF_{4pm} - PEF_{10am/pm}}{PEF_{10am/pm}} \right $	35	Age 8-14 yr, mean = 10.7 yr Gender 57.1% male, 42.9% female Height 115-170 cm, mean = 141.2 cm Weight 23 to 88.5 Kg, mean = 44.4 Kg Body Mass Index 15.0 to 31.2 Kg/m ² , mean = 21.7 Kg/m ²	Mild intermittent asthma	PEF measurements taken at different hours of the day or night until a total of 12 measurements at 2-hour intervals covering a 24-hour period at even hours. Children were allowed to accomplish the 12 PEF measurements in a full week. Personal peak flow meters with less than 3 months' utilization were used. Variability calculated using 5 methods: (1) actual variability, (2) sinusoidal curve variability, (3) theoretical greatest variability, (4) proposed formula variability using values obtained at 4 p.m. and either 10 a.m. or 10 p.m., and (5) examples of variability using traditional formula.		PEF varies during 24-hr period, reaching higher values during the day ($117.9 \pm 6.8\%$ predicted) and lower during night ($108.0 \pm 6.7\%$ predicted, $p < 0.0001$). According to sinusoidal curve fitting, maximal PEF observed at 16 hr 4 min and minimal PEF at 3 hr 20 min.			<u>PEF variability:</u> (1) Actual variability in PEF, median 37.3%, (2) sinusoidal curve fitting, median 21.4% ($p < 0.05$ vs. actual), (3) theoretical, median 17.8% ($p < 0.01$ vs. actual), (4) proposed formula, median 15.9% using 4 p.m. and 10 a.m. and 27.4% using 4 p.m. and 10 p.m. ($p < 0.01$ vs. actual for both), and (5) 3 examples ranged from 4% to 8.7% ($p < 0.01$ vs. actual in both cases). <u>Correlation with actual PEF variability:</u> sinusoidal curve fitting, $r_c = 0.79$; usual formula, $r_c = 0.67$; proposed formula, $r_c = 0.68$; 3 examples, $r_c = 0.18$ to $r_c = 0.38$.