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Chest; Prepublished online August 25, 2011;
DOI 10.1378/chest.11-0574

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**The Relationship of Asthma Impairment Determined by Psychometric Tools to Future
Asthma Exacerbations**

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This study was funded by a research grant from Merck & Company. Shiva Sajjan^c, PhD, and
Felicia Allen-Ramey^c, PhD are employees of Merck and Company. None of the other authors
have conflicts of interest in relationship to this manuscript.

Word Count: 2555

22 ABSTRACT

23 **Background:** Impairment and risk are considered separate domains of asthma control, but
24 relationships between them are not completely understood.

25 **Objective:** To compare three validated questionnaires reflecting asthma impairment in their
26 ability to predict future exacerbations.

27 **Methods:** 2,680 patients with persistent asthma completed a survey that included the Asthma
28 Control Test (ACT), mini-Asthma Quality of Life Questionnaire (mAQLQ), and Asthma Impact
29 Survey (AIS-6), as well as a history of exacerbations in the prior 12 months. An exploratory
30 factor analysis was performed using the questions of the three tools, and individual patient factor
31 scores were calculated. Independent relationships between predictors (tools and factors) and
32 exacerbations the following year captured from administrative data were evaluated.

33 **Results:** Each tool was significantly related ($p < 0.0001$) to future exacerbations above and
34 beyond the risk conferred by prior exacerbations (Relative Risk [RR] = 1.3). When prior
35 exacerbations were included in the model, the three impairment tools provided similar and
36 overlapping information, such that only the mAQLQ entered the model (RR = 1.3, 95 % CI 1.1-
37 1.5). Factor analysis revealed three factors (symptoms, activity, and bother), which were each
38 significantly associated ($p < 0.0001$) with future asthma exacerbations. However, only the
39 activity factor was independently related to future exacerbations.

40 **Conclusions:** Asthma impairment is significantly related to the risk of future exacerbations, but
41 the ACT, mAQLQ, and AIS-6 do not provide independent information from each other in this
42 regard. Interference with activities is the primary subjective component of asthma impairment
43 that is related to the risk of future exacerbations.

44

45 **KEY WORDS:**

46 Asthma; Control; Quality of Life; Impairment; Risk; Exacerbations

47 **ABBREVIATIONS**

48 ACT: Asthma Control Test

49 AIS-6: Asthma Impact Survey

50 ATAQ: Asthma Therapy Assessment Questionnaire

51 ED: emergency department

52 EPR3: Expert Panel 3

53 HEDIS: Healthcare Effectiveness Data and Information Set

54 KPSC: Kaiser Permanente Southern California

55 mAQLQ: mini-Asthma Quality of Life Questionnaire

56 NAEPP: National Asthma Education and Prevention Program

57

58 **INTRODUCTION**

59 Asthma causes a spectrum of morbidity, ranging from symptoms to functional
60 impairment to exacerbations (1). Factor analysis studies have suggested that asthma
61 exacerbations represent a separate dimension from symptoms, quality of life, and pulmonary
62 function (2,3). Partly in response to these data, the new National Asthma Education and
63 Prevention Program (NAEPP) Expert Panel 3(EPR3) guidelines divide asthma severity and
64 control into two domains: impairment and risk (1). Impairment includes current symptoms and
65 functional impairment, while risk includes the risk of future exacerbations. Although considered
66 separate domains, relationships between current impairment and future risk are of interest and
67 are not completely understood.

68 Two types of validated psychometric questionnaire instruments have been developed that
69 reflect asthma impairment—control tools and quality of life tools. Both types of tools address
70 symptoms and functional impairment, but control tools typically quantify the use of rescue
71 therapy while quality of life tools tend to gauge environmental concerns and emotional impact.
72 One might expect these two types of tools to differ in their ability to predict future exacerbations.
73 Both types of tools have been shown to predict future exacerbations (4-14), but only one study
74 (5) has explored whether each type of tool provides independent information in the prediction of
75 exacerbations. It is also clear that a history of prior exacerbations increases the risk for future
76 exacerbations, so predicting future risk of exacerbations must take into account past exacerbation
77 history as well (1).

78 As part of the evaluation of a new brief quality of life tool, the Asthma Impact Survey
79 (AIS-6), we have had the opportunity to compare two quality of life tools (AIS-6 and mini-

80 Asthma Quality of Life Questionnaire [mAQLQ]) and a control tool (Asthma Control Test
81 [ACT]) for their ability to predict future exacerbations in a general population of patients with
82 persistent asthma. We have also examined whether or not each of the three tools provides
83 independent information in the prediction of asthma exacerbations. In addition, we have used
84 factor analysis to determine underlying constructs of impairment reflected by these tools and
85 determine the relationship of these constructs to future exacerbations. We were especially
86 interested in determining tools or constructs that independently predict exacerbations above and
87 beyond the history of prior exacerbations.

88

89 **METHODS**

90 This study was approved by the Kaiser Permanente Southern California (KPSC)
91 Institutional Review Board (Study number 4940). Informed consent was waived by the IRB;
92 completion of the survey was taken as consent to participate. The study patients (aged 18-56
93 with HEDIS-defined persistent asthma in 2006) have been previously described in a report
94 focusing on persistent asthma (15).

95

96 Survey

97 In November of 2007, 13,933 eligible patients were mailed a survey. The survey included a
98 validated asthma control tool [ACT (16)] and two validated asthma-specific quality of life tools
99 [mAQLQ (17) and AIS-6 (18)]. The survey also included questions regarding 1) race/ethnicity,
100 2) educational attainment, 3) smoking, 4) regular asthma controller use, and 5) a history of
101 asthma exacerbations in the prior 12 months, defined as a hospitalization, unscheduled outpatient
102 or emergency department (ED) visit, or oral corticosteroid course for asthma. The information
103 from the survey was used only for research purposes and was not made available to the clinicians
104 managing the patients.

105

106 Computerized Data

107 The following additional information was captured from KPSC administrative databases
108 for the outcome year (2008): 1) Age, 2) Sex, 3) oral corticosteroid dispensings, and 4) inpatient
109 or outpatient encounter diagnosis of asthma (ICD-9 493.xx). An *asthma exacerbation* during the

outcome year (2008) was defined as an oral corticosteroid dispensing with an asthma encounter within the prior 7 days. Although asthma-related emergency department visits and hospitalizations were also captured, the corticosteroid definition of an exacerbation was chosen since that is the definition recommended in the recent Expert Panel report (1). Linkage to an asthma encounter was included to increase the specificity of the corticosteroid dispensing as being for asthma.

Data Analysis

FACTOR ANALYSIS: The exploratory factor analysis used questions from the AIS-6 (6 questions), mAQLQ (15 questions), and ACT (5 questions) and was performed in the standard manner (19). Individual patient factor scores were calculated by adding their raw scores for questions that loaded significantly positively on that factor and subtracting raw scores that loaded significantly negatively on that factor (19,20).

RELATIONSHIPS OF TOOLS AND FACTOR SCORES TO FUTURE EXACERBATIONS.

Cut-offs for identifying low ACT (≤ 16), mAQLQ (≤ 4.7), and AIS-6 (> 60) scores were defined based on prior studies showing that these cut-offs discriminated patients with and without future exacerbations in other samples from our medical care system (4,6,21). Bivariate relationships of each tool and a history of exacerbations in the prior year to future exacerbations were evaluated by chi square analysis. Bivariate relationships of each factor to future exacerbations were evaluated by comparing mean factor scores in patients with and without future exacerbations (Student t test). Multivariable analyses were performed using robust Poisson regression to evaluate the independent relative risks of predictors to future exacerbations (22). In these

132 analyses, manual backwards stepwise regression (with p to remain < 0.05) was used to determine
133 the final models because of potential co-linearity between predictors.

134 PREDICTIVE PROPERTIES OF TOOLS FOR EXACERBATIONS. Predictive properties
135 calculated for the ability of the three tools to predict 2008 exacerbations included sensitivity,
136 specificity, positive predictive value (PPV), and negative predictive value.

137 Nominal two-tailed significance for all statistical analyses was set at the 0.05 level. All
138 analyses were conducted using SAS version 9.13 for Windows software.

RESULTS

PATIENTS: The baseline (November, 2007) survey was returned by 2,751 (20.1 %) patients, of whom 2,680 (97.4 %) had complete results for all three tools and make up the study cohort for this report. The 2680 current study patients were primarily female, well-educated non-smokers on regular asthma controller therapy, and a majority were white (Table 1). More than a third of the patients reported unscheduled asthma visits in the prior 12 months, and nearly 40 % required oral corticosteroids for asthma exacerbations in the prior year (Table 1). During 2008, 1.4 % of patients required a hospitalization for asthma; 4.4 % required an ED visit due to asthma; 4.7 % of patients required either an asthma hospitalization or ED visit; and 23.3 % received oral corticosteroids for an asthma exacerbation within 7 days of an asthma encounter, which was defined as an *asthma exacerbation* in this study.

RELATIONSHIPS OF TOOLS TO EXACERBATIONS: Each tool and a history of prior exacerbations were significantly related ($p < 0.0001$) to future exacerbations (Table 2). Impairment indicated by each tool individually was also significantly related to future exacerbations above and beyond the risk conferred by prior exacerbations (Table 2). When prior exacerbations were not considered, the mAQLQ and ACT provided independent information in the prediction of future exacerbations (Table 2). However, when prior exacerbations were included in the model, the three impairment tools provided similar and overlapping information, such that only the mAQLQ entered the model (Table 2).

FACTOR ANALYSIS (Table 3): The three final factors explained 97.8 % of the variability. Based on the questions with the highest loading on each factor, the factors were named ‘symptoms’, ‘activity’, and ‘bother’. Each factor was significantly ($p < 0.0001$) related to

161 future exacerbations in bivariate analyses (data not shown). However, only the activity factor
162 was independently related to future exacerbations, whether or not prior exacerbations were
163 considered (Table 4).

164 PREDICTIVE PROPERTIES. To be able to use the activity factor as a predictor, we
165 sought to determine the question loading on that factor most highly and uniquely related to future
166 exacerbations. A stepwise logistic regression model that included the 6 questions with the
167 highest loading on the activity factor and prior exacerbations as predictors showed that one AIS
168 question was independently related to future exacerbations: “How much of the time did your
169 asthma limit you in performing your usual work activities, including housework, work, school or
170 social activities?” Based on the distribution of the responses, a positive response to this question
171 was considered to be “sometimes”, “very often”, or “always” (32.1 % of patients) versus
172 “never” or “rarely” (67.9 % of patients).

173 Predictive properties of this activity question, the mAQLQ, and a history of exacerbations
174 in the prior year are compared in Table 5. Of these three predictors, prior exacerbations provides
175 the greatest sensitivity with only slightly less specificity. The activity question functions
176 similarly to the mAQLQ, with somewhat lower sensitivity and somewhat higher specificity. To
177 determine what a tool such as the mAQLQ or the activity question could add to the prediction
178 conferred by exacerbation history, we looked at predictive properties of prior exacerbations
179 combined with either the mAQLQ or the activity question. Considering either a prior
180 exacerbation *or* evidence of impairment increased the sensitivity by 13.7 % to 17.4 % (65.0 % to
181 73.9 % or 76.3 %) (Table 5). Considering both a prior exacerbation history *and* evidence of
182 impairment increased the specificity by 31.3-36.4 % (61.6 % to 80.9 % or 84%) (Table 5). The

183 highest PPV (40.6 %) was seen in patients with both a prior exacerbation history and a positive
184 response to the activity limitation question (Table 5)

185 **DISCUSSION**

186 Asthma impairment (including asthma control and asthma-specific quality of life) and
187 risk of asthma exacerbations are considered two separate domains, but the current study confirms
188 that these two domains are related to each other. Patients who suffered asthma exacerbations
189 during twelve months of follow-up had significantly greater baseline asthma impairment (as
190 assessed by each of the three tested tools: ACT, mAQLQ, and AIS-6) compared to patients who
191 did not experience exacerbations during the follow up period (Table 2). This finding is in
192 agreement with results of prior studies using control tools (5-9, 12,14) or quality of life tools
193 (4,5,10,11,13). It is also consistent with two prior studies showing a relationship between
194 impairment, as measured by symptoms, and prior (23) or future asthma exacerbations (24). The
195 current study provides the following novel findings: 1) The impairment domain of asthma
196 control, as measured by each of three different tools, is independent of the risk domain (history
197 of prior exacerbations) in predicting future exacerbations, 2) asthma control and asthma-specific
198 quality of life, as measured by three validated tools, are not independent of each other in their
199 prediction of future exacerbations when prior risk is considered (included in the analyses), and 3)
200 the component of these tools that measures activity limitation is primarily responsible for the
201 prediction of future exacerbations.

202 Factor analysis is a statistical technique that can be used to develop theory regarding the
203 nature of *constructs* (19)—dimensions, themes or topic areas present but not directly observable
204 in a group of observed variables. The present factor analysis (Table 3) confirmed three
205 subjective factors (symptoms, activity, and bother) found in a prior factor analysis that included
206 the mAQLQ in a separate cohort (2). The prior study included questions from a different asthma
207 control measure (Asthma Therapy Assessment Questionnaire [ATAQ]), a generic quality of life

tool (SF-12), and did not include the AIS-6. The current study shows that questions representing each of the three subjective factors are significantly related to subsequent exacerbations. However, only the activity factor provides unique information, whether or not prior risk is considered (Table 4). The three questions that loaded most strongly on this factor asked about limitations of “getting as much done at work or at home”, “usual work/school/social activities” or “work or daily activities” (Table 3). Thus, the extent to which asthma symptoms interfere with functional capacity at home or at work appears to be the best subjective impairment indicator of the risk of future exacerbations. This finding highlights the importance of going beyond symptoms assessment to additionally capture the impact of asthma on the patient’s activities and function. The current study suggests that a single specific question addressing usual work, school, or social activities may adequately provide this information, although this will need to be confirmed in further studies.

Our study provides practical clinical information for the care of both individual asthmatic patients and populations of asthmatic patients. For individual patients, the tools would probably be primarily used to assess impairment. However, patients with scores on the tools below the cut-offs used in this and prior studies would be at increased risk of experiencing exacerbations in addition to their chronic impairment and beyond the increased risk conferred by a history of prior exacerbations. Such patients should be evaluated for further trigger avoidance and medication nonadherence, considered for a step up in pharmacologic therapy if adherence is optimal, and have their action plans for increased symptoms reviewed and updated. Further studies would be necessary to show that these types of specific interventions for such patients reduce their risk of future exacerbations.

230 For population management, these questionnaires could be used as outreach tools to
231 identify patients who may benefit from targeted intervention because of their increased risk of
232 future exacerbations above and beyond the risk conferred by their prior exacerbation history.
233 The current study suggests that one can identify up to 17 % more of the patients who will
234 subsequently experience an exacerbation if one targets patients with either a history of
235 exacerbations or substantial impairment on the mAQLQ (sensitivity increased from 65 % to 76.3
236 %, Table 5). The current study also suggests that one can substantially (up to 36 %) increase the
237 specificity of the prediction, such as one might want to do with a more intensive intervention, by
238 identifying patients with both prior exacerbations *and* substantial impairment on the activity
239 question (specificity increased from 61.6 % to 84.0 %, Table 5). Although the majority of
240 patients with even both risk factors (impairment and a history of exacerbations) will not
241 experience an exacerbation in the next 12 months (PPV = maximum 40 % [Table 5]), outreach
242 and intervention would probably still be indicated for such patients to address their substantial
243 impairment.

244 This study does have some potential limitations. The surveys used for this analysis were
245 returned by only 20 % of eligible patients. As previously reported, responders differed from
246 non-responders in several ways (15), but it is not clear whether or not these differences would
247 affect the generalizability of the relationships observed in this study. Pulmonary function results
248 were not available in this cohort, and prior studies have shown that FEV₁ is independently
249 associated with future asthma exacerbations, even after accounting for other significant
250 demographic, environmental, allergic, and asthma severity risk factors (25,26). This study only
251 considered patients with persistent asthma and would not apply to patients with intermittent
252 asthma, who may also experience severe exacerbations (1). Finally, this study included only

253 adults and mostly women, and generalizability of the results to children or adult males would
254 need to be demonstrated.

255 In summary, we showed that asthma impairment as reflected by validated asthma control
256 and quality of life instruments is significantly related to the risk of future asthma exacerbations,
257 above and beyond a prior exacerbation history. In addition, our study shows that interference
258 with activities is the primary subjective component of asthma impairment which is related to the
259 risk of future exacerbations, further emphasizing the need to capture and improve this aspect of
260 the impact of asthma on patients. These tools could be used to identify high risk patients in
261 clinical practice and population management. It is hoped that interventions in these high risk
262 patients would reduce their risk of future asthma exacerbations, but further studies will be
263 necessary to confirm that hypothesis.

264 **ACKNOWLEDGMENTS**

265 Michael Schatz, MD, MS contributed to study design, data analysis, date interpretation, and
266 manuscript preparation and is the guarantor of the paper

267 Robert S. Zeiger, MD, PhD contributed to study design, data interpretation, and manuscript
268 preparation

269 Su-Jau Yang, PhD contributed to data acquisition and data analysis

270 Wansu Chen, MS contributed to study design, data acquisition, data interpretation, and
271 manuscript review

272 William Crawford, MD contributed to study design, data interpretation, and manuscript review

273 Shiva Sajjan, PhD contributed to study funding, study design, and data interpretation

274 Felicia Allen-Ramey, PhD contributed to study funding, study design, data interpretation, and
275 manuscript review

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337 **Table 1. Baseline characteristics of the 2680 patients included in the study**

Characteristic	Results
Age	44.9 (11.0)
Female	69.7
Race/ethnicity	
Caucasian	54.2
African-American	10.9
Hispanic	21.6
Asian/Pacific Islander	7.6
Other/Unknown	5.7
Education	
Less than high school	3.6
High school graduate or equivalent	18.9
Some college	35.7
College graduate	21.2
Post-graduate or professional degree	20.6
Current smokers	6.5
Regular inhaled corticosteroid therapy	73.6 %

Any asthma hospitalizations in past 12 months	4.1
Other unscheduled visits for asthma in past 12 months	31.6
Oral corticosteroid use in past 12 months	39.9
ACT score	18.7 (4.5)
mAQLQ score	5.0 (1.3)
AIS-6 score	47.9 (9.9)

338

339 Data presented as either frequency (%) or mean (SD)

340 ACT = Asthma Control Test; mAQLQ = mini-Asthma Quality of Life Questionnaire; AIS-6 =

341 Asthma Impact Survey

Table 2. Relationships of asthma control and quality of life tool scores and prior asthma exacerbations to future asthma exacerbations

A. Bivariate Analyses (all p < 0.0001)

	% Exacerbations	
Predictor	Predictor Present	Predictor Absent
ACT ≤ 16	31.4	20.0
mAQLQ ≤ 4.7	30.4	19.0
AIS-6 > 60	35.6	21.7
Prior exacerbations	33.7	14.6

B. Multivariable Analyses

	Multivariable Analyses: Relative Risks (95 % CI)		
Predictor	Each Tool/Prior Exacerbations	All Tools Only	All Tools and Prior Exacerbations
ACT ≤ 16	1.3 (1.1 - 1.5)/2.2 (1.9-2.5)	1.3 (1.1-1.5)	DNE
mAQLQ ≤ 4.7	1.3 (1.1-1.5)/2.1 (1.8-2.5)	1.4 (1.2-1.7)	1.3 (1.1-1.5)
AIS-6 > 60	1.3 (1.1-1.6)/2.2 (1.9-2.6)	DNE	DNE
Prior exacerbations	NA	NA	2.1 (1.8-2.5)

347 NA = not included in model

DNE = did not enter model

348 AC T = Asthma Control Test; mAQLQ = mini-Asthma Quality of Life Questionnaire; AIS-6 =

349 Asthma Impact Survey

350

351 **Table 3. Loading of individual survey questions on the three identified factors***

352 <u>Question</u>	<u>Factor</u>		
	<i>Symptoms</i>	<i>Activity</i>	<i>Bother</i>
354 Rating of control (ACT)	0.70	0.33	-0.29
355 Shortness of breath (ACT)	0.70	0.31	-0.18
356 Rescue inhaler use (ACT)	0.69	0.22	-0.21
357 Feeling short of breath (mAQLQ)	-0.68	-0.39	0.36
358 Chest tightness or heaviness (mAQLQ)	-0.56	-0.32	0.46
359 Experience a wheeze (mAQLQ)	-0.54	-0.29	0.48
360 Symptoms wake you at night (ACT)	0.52	0.39	-0.26
361 Interference with sleep (mAQLQ)	-0.49	-0.43	-0.45
362			
363 Limit getting as much done work/home (AIS-6)	0.29	0.80	-0.29
364 Limit usual work/school/social activities (AIS-6)	0.31	0.79	-0.31
365 Too tired to do work or daily activities (AIS-6)	0.32	0.76	-0.31
366 Limit usual activities/enjoyment (AIS-6)	0.38	0.73	-0.30
367 Limit socializing (AIS-6)	0.21	0.73	-0.30
368 Moderate activities (mAQLQ)	-0.30	-0.73	0.27
369 Work-related activities (mAQLQ)	-0.22	-0.69	0.24
370 Social activities (mAQLQ)	-0.24	-0.68	0.28
371 Limit getting as much done work/home (ACT)	0.37	0.66	-0.27
372			

373 <u>Question</u>	Factor		
374	<i>Symptoms</i>	<i>Activity</i>	<i>Bother</i>
375 Strenuous activities (mAQLQ)	-0.37	-0.63	0.27
376 Feeling fed up or frustrated (AIS-6)	0.41	0.51	-0.49
377			
378 Feeling concerned (mAQLQ)	-0.36	-0.32	0.62
379 Feeling frustrated (mAQLQ)	-0.47	-0.40	0.59
380 Bothered by avoiding dust (mAQLQ)	-0.24	-0.28	0.58
381 Bothered by avoiding going outside (mAQLQ)	-0.16	-0.44	0.58
382 Bothered by coughing (mAQLQ)	-0.38	-0.35	0.54
383 Afraid of not having medication (mAQLQ)	-0.41	-0.14	0.53
384 Bothered by avoiding smoking (mAQLQ)	-0.11	-0.20	0.50
385			
386			

387 * Exploratory Factor Analysis. Positive numbers indicate direct relationships and negative
 388 numbers indicate inverse relationships. Loading > 0.40 considered significant and bolded

389
 390 AC T = Asthma Control Test; mAQLQ = mini-Asthma Quality of Life Questionnaire; AIS-6 =
 391 Asthma Impact Survey

392

394 DNE = did not enter model

NA = not applicable

395 a. per 1 unit change in factor score

396 **Table 5. Predictive Properties of Prior Exacerbation, mAQLQ, and Activity Question for**
 397 **Future Exacerbations**

Predictor	Sensitivity	Specificity	PPV	NPV
Prior exacerbation	65.0	61.6	33.7	85.4
mAQLQ ≤ 47	49.4	65.7	30.4	81.0
Activity question positive*	44.7	71.7	32.4	81.0
mAQLQ ≤ 47 <i>or</i> exacerbation	76.3	47.0	30.1	86.9
Activity question positive <i>or</i> exacerbation	73.9	49.8	30.6	86.4
mAQLQ ≤ 47 <i>and</i> exacerbation	38.3	80.9	37.5	81.4
Activity question positive <i>and</i> exacerbation	36.4	84.0	40.6	81.5

398 PPV = positive predictive value NPV = negative predictive value

399 mAQLQ = mini-Asthma Quality of Life Questionnaire

400 * How much of the time did your asthma limit you in performing your usual work activities,
 401 including housework, work, school, or social activities (sometimes, very often, or always *versus*
 402 rarely or never)

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Chest; Prepublished online August 25, 2011;
DOI 10.1378/chest.11-0574

This information is current as of September 6, 2011

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