Measuring Asthma Control
Clinic Questionnaire or Daily Diary?

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Daily symptom, peak expiratory flow rate (PEFR), and medication diaries are often used in clinical trials of treatments for asthma on the assumption that they provide a better estimate of clinical status than does a questionnaire completed in the clinic. We conducted a study with the aim of comparing the measurement properties of the clinic-completed Asthma Control Questionnaire with those of the Asthma Control Diary. The diary is composed of questions and response options almost identical to those of the questionnaire, but uses PEFR instead of FEV_1 as the measure of airway caliber. In an observational study, 50 adults with symptomatic asthma attended a McMaster University asthma clinic at 0, 1, 5, and 9 wk to complete the Asthma Control Questionnaire and other measures of asthma status. For 1 wk before each follow-up visit, patients completed the Asthma Control Diary every morning and evening. Concordance between the questionnaire and diary was high (intraclass correlation coefficient [ICC] = 0.87). Both reliability (ICC: questionnaire = 0.90; diary = 0.86) and responsiveness (responsiveness index: questionnaire = 1.06; diary = 0.90; p = 0.005) were better with the questionnaire than with the diary. Correlations between the two instruments and other measures of clinical asthma status were similar and close to *a priori* predictions. Both the Asthma Control Questionnaire and the Asthma Control Diary are valid instruments for measuring asthma control, but the questionnaire has slightly better discriminative and evaluative measurement properties than does the diary.

It has often been assumed, in the absence of formal evidence, that more accurate and precise data may be obtained in clinical trials of treatments for asthma if patients complete daily diaries than if they are asked to recall their experiences during a clinic visit. In addition, since individual patient measurements of daily morning peak expiratory flow rate (PEFR) are considered to give a better estimate of asthma control than a single clinic measurement of FEV_1, it has been assumed that the same must be true for group data. As a result, patients participating in clinical trials of asthma treatments are often required to complete diaries and make recordings of PEFR. The assumption of the superiority of diary data over clinic questionnaire data for clinical trials involving asthma has never been tested.

The Asthma Control Questionnaire was developed and validated to measure asthma control in adults (1). It is completed in the clinic, asks patients to recall their experiences during the previous week, and includes a measure of FEV_1% predicted. In the study described here we modified the Asthma Control Questionnaire for daily completion by patients using PEFR instead of FEV_1. The Asthma Control Diary has almost identical symptom and medication questions to the questionnaire, and has the same response options. In this study we compared the measurement properties of the two instruments.

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METHODS

Subjects

Fifty adults (17 to 70 yr of age) were enrolled from previous studies, local media notices, and asthma clinics. They were required to have symptomatic asthma with an Asthma Control Questionnaire score > 0.5 at enrollment. Patients were excluded if they had evidence of fixed airway obstruction, other illnesses with symptoms similar to those of asthma, or recurrent chest infections, or were unable to communicate in English. The study was approved by the McMaster University Faculty of Health Sciences Ethics Committee. All patients signed an informed consent agreement before participating in the study.

Study Design

In this 9-wk observational study, patients were seen in the clinic at enrollment and after 1, 5, and 9 wk. At each visit, spirometry was done before and 20 min after bronchodilator administration, and patients completed the Asthma Control Questionnaire, the self-administered version of the Asthma Quality of Life Questionnaire (AQLQ) (2), and the Medical Outcomes Survey Short Form-36 (SF-36) (3).

For 1 wk before each follow-up clinic visit, patients completed the Asthma Control Diary. The day before recordings were due to start, patients were telephoned and reminded to begin filling in their diary on the next day, and to continue doing this every morning and evening until the clinic visit.

At each follow-up visit, a clinician rated change in the patient's asthma control since the previous clinic visit (+7 = a very great deal better, 0 = no change, −7 = a very great deal worse) (4). In order to do this, the clinician, blinded to Asthma Control Questionnaire and Diary scores, used spirometry, PEFR measurements, AQLQ and SF-36 data, and a consultation with the patient.

Patients whose asthma was adequately controlled continued to take their established asthma medications throughout the study. Patients whose asthma was not adequately controlled at Weeks 1 or 5 were advised to increase the intake of their medications as recommended by their asthma clinician.

Outcome Measures

Asthma Control Questionnaire (Appendix 1). The development and validation of the Asthma Control Questionnaire are described in detail elsewhere (1). In brief, we first generated a list of symptoms (n = 10) that might be used by clinicians to evaluate asthma control. Ninety-one asthma consultants from 18 countries identified the five symptoms that they considered most important for assessing asthma control, and these symptoms were included in the questionnaire. In addition, there is a question on short-acting β_2-agonist use and another on FEV_1% predicted, with information for the latter being provided by the clinic staff. Patients are asked to recall their symptoms and short-acting β_2-agonist use during the previous week. All seven questions are scored on a 7-point scale (0 = good control, 6 = poor control), and the overall score is the mean of the seven responses.

Asthma Control Diary (Appendix 2). The wording of the seven questions and response options in the Asthma Control Diary is almost identical to that used in the Asthma Control Questionnaire. The only major difference is that PEFR is recorded instead of FEV_1. Before taking any medication in the morning, patients make three measure-

TABLE 1

QUESTIONNAIRE AND DIARY SCORES AT THE END OF WEEK 1

	Questionnaire (mean ± SD)	Diary (mean ± SD)	Concordance between Questionnaire and Diary (*ICC*)	Correlation between Questionnaire and Diary (Pearson's r)	Difference between Questionnaire and Diary (*p value*)
All questions	1.49 ± 0.66	1.33 ± 0.71	0.87	0.89	0.001
Symptoms alone	1.23 ± 0.59	0.98 ± 0.72	0.84	0.89	< 0.001
Nocturnal waking	0.58 ± 1.03	0.31 ± 0.58	0.64	0.80	0.007
Morning symptoms	1.28 ± 0.95	1.15 ± 0.91	0.83	0.84	0.078
Activity limitation	1.26 ± 1.16	0.98 ± 0.91	0.78	0.83	0.004
Short of breath	1.70 ± 0.91	1.40 ± 0.89	0.78	0.83	< 0.001
Wheeze	1.34 ± 0.77	1.04 ± 0.87	0.66	0.71	0.001
FEV_1 % pred or PEFR % pred alone	2.66 ± 1.81	2.68 ± 1.71	0.54	0.54	0.93
β_2-agonist alone	1.60 ± 1.11	1.76 ± 1.02	0.93	0.94	0.004

Definition of abbreviations: ICC = intraclass correlation coefficient; PEFR = peak expiratory flow rate.

ments of PEFR and record the best value. At the same time, they score the questions about nocturnal waking and morning symptoms. At bedtime, patients score the degree of limitation, shortness of breath, and wheeze they have experienced during the day, and record β_2-agonist use during the previous 24 h. PEFR data are converted to % predicted and scored in the same manner as the FEV_1% predicted is scored in the questionnaire (as shown in APPENDIX 2). The diary is scored by adding the responses for each of the seven questions for each of the 7 d, and dividing the total score by 49 (i.e., the resultant score is between 0 = good control and 6 = poor control).

Statistical Analysis

Concordance of the questionnaire and the diary. We examined the concordance (agreement) between the questionnaire and the diary at the end of the first week through use of an intraclass correlation coefficient (ICC) and examination of bias with a paired *t* test and degree of association with Pearson's correlation coefficient (r).

Comparison of measurement properties. Testing the measurement properties of the questionnaire and the diary required defining a group of patients who remained clinically stable between clinic visits (Weeks 1 to 5 and 5 to 9) and another group who experienced change in their asthma control. For each time period, we categorized each patient with the clinician's global rating of change (stable group = scores of −1, 0 or +1; unstable group = scores −7 to −2 and +2 to +7 (4).

Discriminative properties (5). Reliability of the asthma-control instruments was determined from patients in the stable group. If a patient was stable both during Weeks 1 to 5 and Weeks 5 to 9, a single observation was selected, using a random-number generator. Reliability was estimated as the within-subject standard deviation (SD), and was related to the total SD as an ICC. For cross-sectional validity, we used data from the second clinic visit (Week 1) and made *a priori* predictions about the level of correlation we should expect to observe between the two instruments and other measures of health status based on the results of previous studies and clinical experience.

Evaluative properties (5). Responsiveness was examined in three ways. First, for patients in the unstable group, we used a paired *t* test to determine whether the instruments could detect within-patient change. Second, we used an unpaired *t* test to assess whether the instruments could detect differences between stable and unstable patients. Third, we calculated the responsiveness index ($\Delta/SD\Delta$) (6). To ensure that the contribution of two observations by some patients did not result in an overestimate of the precision of responsiveness, we inflated the variance by the quantity $1 + (n - 1)\rho$, where ρ is the ICC of the change scores and n = 2 (number of observations per subject) (7). For longitudinal validity, we once again made *a priori* predictions based on results from previous studies and clinical experience.

RESULTS

All 50 patients in the study (18 males and 32 females) completed the study and provided compete data sets. Their age was 37.1 ± 13.1 yr (mean ± SD) and FEV_1% predicted before bronchodilator administration was 77.2 ± 18.8. Twelve patients used short-acting β_2-agonists alone; 34 needed regular inhaled steroids plus short-acting β_2-agonists; three patients took inhaled steroids plus both long- and short-acting β_2-agonists; and one patient required all three medications plus oral steroids.

Concordance

Overall concordance between the questionnaire and the diary was high (ICC = 0.87). Nevertheless, mean scores were consistently higher for the questionnaire than for the diary (Table 1). This arose because both the symptoms and β_2-agonist use were scored worse (higher) in the questionnaire than in the diary; there was very little difference in airway caliber scores (FEV_1 versus PEFR). Pearson's correlations between the two instruments for overall score, symptoms, and β_2-agonist use were high, but the correlation between FEV_1 and PEFR was only moderate.

Discriminative Properties

Thirty-six patients contributed 50 sets of observations to the stable group. The within-subject SDs for the questionnaire and diary were 0.18 and 0.20, respectively. These resulted in the questionnaire having slightly better reliability (ICC = 0.90) than the diary (ICC = 0.86).

TABLE 2

CROSS-SECTIONAL VALIDITY*

	Questionnaire	Diary
Asthma Quality of Life Questionnaire		
Overall	0.76	0.75
Symptoms	0.75	0.75
Emotions	0.66	0.68
Activities	0.71	0.67
Environment	0.55	0.52
Generic Health Status (SF-36)		
Physical	0.55	0.53
Mental	0.19	0.31

Definition of abbreviations: ACD = asthma control diary; ACQ = asthma control questionnaire.

* Pearson's correlation coefficient.

A priori predictions: The ACQ and ACD should correlate with:

1. Asthma Quality of Life Questionnaire: r = 0.4 to 0.8. The highest correction should be with the symptom domain (r = 0.6 to 0.8) and the lowest with the environmental domain (r = 0.4 to 0.6).
2. Physical Health Domain of the SF-36: r = 0.4 to 0.6.

Correlations between the two instruments and the other measures of health status and quality of life are shown in Table 2. The correlations were similar for the two instruments, and matched the *a priori* predictions quite well.

Evaluative Properties

Thirty-six patients contributed 50 observations to the unstable group. Symmetry of improvements (n = 26) and deteriorations (n = 24) allowed us to combine the data by changing the sign of those who deteriorated. Both instruments showed good responsiveness (Table 3). They were able to detect changes in the patients whose asthma was unstable and to differentiate these patients from those whose asthma was stable. The responsiveness index ($\Delta/SD\Delta$) of the questionnaire (1.06) was significantly higher than that of the diary (0.90) ($p = 0.005$).

Correlations between changes in the two instruments and changes in other measures of health status and quality of life are shown in Table 4. Once again, the correlations were very similar for the two instruments, and generally agreed well with the *a priori* predictions.

DISCUSSION

Overall concordance between the Asthma Control Questionnaire and the Asthma Control Diary was high, and both cross-sectional and longitudinal construct validity were very similar for the two instruments. However, both reliability and responsiveness tended to be better for the questionnaire than for the diary. This suggests that the two instruments measure the same construct (asthma control), but that the questionnaire has slightly stronger evaluative and discriminative measurement properties than does the diary.

Although the wordings used for the symptom questions and response options were almost identical in the two instruments, both the absolute scores and the changes in scores were consistently higher with the questionnaire. There is no obvious reason for this. If it had been only the absolute scores that were higher, it could be speculated that when patients score the questionnaire, they may remember their worst experiences during the previous week. However, with change scores also being greater in the questionnaire, this explanation seems inadequate. These differences require further investigation, but in the meantime they indicate that the two instruments should not be used interchangeably. Although each in its own right is a valid instrument for measuring asthma control, one instrument should be used consistently within a given study.

A limitation of our study was that patients completed the daily diary before completing the questionnaire, and completing the diary may have influenced responses to the questionnaire. However, to compare the scores and the measurement properties of the two instruments, it was necessary for patients to be in exactly the same clinical state and to record their experiences over the same time period when completing the two instruments. To minimize the effect of confounding, we placed the Asthma Control Questionnaire in the middle of other questionnaires and measurements completed during the clinic visit, and did not review the diary until the end of the visit. Table 1 shows that there were significant differences in scores between all items in the diary and questionnaire except airway caliber, the only item measured objectively. This suggests that recall did not seriously influence the results of the study. When designing the study, we considered alternative designs, including randomizing patients into parallel groups, but judged that the errors and biases associated with alternative designs would probably be far greater than the possible influence of the diary on the questionnaire.

One of the reasons that PEFRs are collected in clinical trials is that for the individual patient, regular daily measurements often provide the clinician with a much clearer picture of the patient's clinical status than does a single measure of FEV_1 or PEFR made in the clinic. Frequent measurement of PEFR provides valuable information about diurnal variation in airway caliber and evidence of day-to-day fluctuations in the patient's status. Since PEFRs of the individual patient are of such great value, it has been assumed that group PEFR data will provide more meaningful information on clinical asthma status in clinical trials than would a single measurement of FEV_1. The data in this study suggest that this may not be a valid assumption. Therefore, those who design clinical trials should consider both the value and expense of asking volunteers to make daily PEFR measurements, especially if the trials are of substantial duration.

In clinical trials, diary data are of notoriously poor quality. Reasons for this include lost diaries, forgotten entries, omitted questions, illegal responses, illegible handwriting, and spoiled responses. In this study we endeavored to minimize these common problems. To reduce boredom and falsification of entries, we asked patients to complete the diary only for 1 wk before each clinic visit. Each patient was telephoned and reminded on the day before recording was to start. In addition, each patient was carefully trained in the use of the diary and in PEFR measurements, and these instructions were reviewed at each follow-up visit. As a result, all 50 patients provided complete diary and PEFR data at every visit. The only error we could not check was falsification of the diary entries. Nevertheless, even with this care, the measurement properties of the clinic questionnaire were still better than those of the diary. When

TABLE 3

RESPONSIVENESS*

	Patients with Stable Asthma (*n = 36*) Mean (SD)	Patients in Whom Asthma Changed (*n = 50*) Mean (SD)	Difference (*p value*)	Responsiveness Index‡
Questionnaire	0.01 (0.24)	0.73 (0.54)†	< 0.0001	1.06
Diary	−0.03 (0.27)	0.50 (0.52)†	< 0.0001	0.9

* Change in score between consecutive clinic visits.
† $p < 0.0001$.
‡ Difference in responsiveness indices, $p = 0.005$.

TABLE 4

LONGITUDINAL VALIDITY

	ΔQuestionnaire	ΔDiary
Asthma Quality of Life Questionnaire		
ΔOverall	0.73	0.77
ΔSymptoms	0.73	0.80
ΔEmotions	0.57	0.61
ΔActivities	0.62	0.64
ΔEnvironment	0.44	0.45
Generic Health Status (SF-36)		
ΔPhysical	0.15	0.11
ΔMental	0.18	0.30
Clinician's global rating of change	0.67	0.72

Definition of abbreviations: ACD = asthma control diary; ACQ = asthma control questionnaire; SF-36 = Medical Outcomes Survey Short Form 36.
* Pearson's correlation coefficient.
A priori predictions: Change in ACQ and ACD should correlate with:
1. Change in Asthma Quality of Life Questionnaire: r = 0.4 to 0.8; the highest correlations should be with the symptom domain (r = 0.6 to 0.8) and the lowest with the environmental domain (r = 0.4 to 0.6).
2. Change in Physical Health domain of the SF-36: r = 0.2 to 0.4.
3. Clinician's global rating of change: r > 0.6.

considering the use of diaries in clinical trials, and especially trials of long duration, it is also important to take into account the considerable expense of collecting diary data, the cost of data entry, the increased risk of transcription errors, and the problems of statistical analysis.

However, the advantages are not all on the side of the questionnaire. A limitation of the questionnaire is that patients must attend the clinic for data to be collected. Although patients usually attend the clinic at regular intervals throughout a clinical trial, more frequent visits will be required if one of the aims of a study is to examine the precise time course of an intervention.

When one weighs the practical advantages and disadvantages of a diary versus a questionnaire for measuring asthma control in clinical trials, we believe that the advantages of a questionnaire outweigh those of a diary. In this study we showed that the Asthma Control Questionnaire has measurement properties similar to those of the Asthma Control Diary, thus strongly challenging the assumption that a daily diary must be better for measuring asthma control than a clinic-completed questionnaire. Since the efficiency of a questionnaire is very much greater than that of a diary, we would strongly urge investigators to consider relinquishing unnecessary use of diaries in asthma clinical trials, a use based more on habit than on evidence, and to use only a validated questionnaire such as the Asthma Control Questionnaire.

In conclusion, the Asthma Control Diary is a valid instrument for measuring asthma control, it has strong measurement properties, and it is easy for patients to complete. Nevertheless, its measurement properties are not quite as good as those of the Asthma Control Questionnaire, and it is more expensive to use than the questionnaire and potentially more open to error. However, for clinicians who wish to use a diary for the assessment of individual patients, the Asthma Control Diary has been developed on the basis of recognized psychometric methods and has been thoroughly tested to provide strong evidence of good measurement properties and validity.

References

1. Juniper, E. F., P. M. O'Byrne, G. H. Guyatt, P. J. Ferrie, and D. R. King. 1999. Development and validation of a questionnaire to measure asthma control. *Eur. Respir. J.* 14:902–907.
2. Juniper, E. F., G. H. Guyatt, P. J. Ferrie, and L. E. Griffith. 1993. Measuring quality of life in asthma. *Am. Rev. Respir. Dis.* 147:832–838.
3. Stewart, A. L., R. Hays, and J. E. Ware. 1988. The MOS short-form general health survey: reliability and validity in a patient population. *Med. Care* 26:724–732.
4. Juniper, E. F., G. H. Guyatt, A. Willan, and L. E. Griffith. 1994. Determining a minimal important change in a disease-specific quality of life instrument. *J. Clin. Epidemiol.* 47:81–87.
5. Guyatt, G. H., B. Kirshner, and R. Jaeschke. 1992. Measuring health status: what are the necessary measurement properties? *J. Clin. Epidemiol.* 45:1341–1345.
6. Guyatt, G. H., S. Walter, and G. Norman. 1987. Measuring change over time: assessing the usefulness of evaluative instruments. *J. Chron. Dis.* 40:171–178.
7. Juniper, E. F., G. H. Guyatt, D. H. Feeny, L. E. Griffith, and P. J. Ferrie. 1997. Minimum skills required by children to complete health-related quality of life instruments for asthma: comparison of measurement properties. *Eur. Respir. J.* 10:2285–2294.

APPENDIX 1: ASTHMA CONTROL QUESTIONNAIRE

Please answer Questions 1–6.
Circle the number of the response that best describes how you have been during the past week.

1. On average, during the past week, how often were you **woken by your asthma** during the night?
   0 Never
   1 Hardly ever
   2 A few times
   3 Several times
   4 Many times
   5 A great many times
   6 Unable to sleep because of asthma
2. On average, during the past week, how **bad were your asthma symptoms when you woke** up in the morning?
   0 No symptoms
   1 Very mild symptoms
   2 Mild symptoms
   3 Moderate symptoms
   4 Quite severe symptoms
   5 Severe symptoms
   6 Very severe symptoms
3. In general, during the past week, how **limited were you in your activities** because of your asthma?
   0 Not limited at all
   1 Very slightly limited
   2 Slightly limited
   3 Moderately limited
   4 Very limited
   5 Extremely limited
   6 Totally limited
4. In general, during the past week, how much **shortness of breath** did you experience because of your asthma?
   0 None
   1 A very little
   2 A little
   3 A moderate amount
   4 Quite a lot
   5 A great deal
   6 A very great deal
5. In general, during the past week, how much of the time did you **wheeze**?
   0 Not at all
   1 Hardly any of the time
   2 A little of the time
   3 A moderate amount of the time
   4 A lot of the time
   5 Most of the time
   6 All the time
6. On average, during the past week, how many **puffs of short-acting bronchodilator** (e.g., Ventolin) have you used each day?
   0 None
   1 1–2 puffs most days
   2 3–4 puffs most days
   3 5–8 puffs most days
   4 9–12 puffs most days
   5 13–16 puffs most days
   6 More than 16 puffs most days

To be completed by a member of the clinic staff

7. FEV_1 prebronchodilator:	0	> 95% predicted
	1	95–90%
FEV_1% predicted:	2	89–80%
	3	79–70%
FEV_1% predicted:	4	69–60%
(Record actual values on the	5	59–50%
dotted lines and score the FEV_1% predicted in the next column)	6	< 50% predicted

APPENDIX 2: ASTHMA CONTROL DIARY

Morning Score

Please do the breathing test and fill in the questionnaire before taking your morning asthma medication.

Write in the number that best describes how your asthma has been during the night and this morning.

Peak Expiratory Flow Rate

Please record the best of three blows **before** you take any asthma medications.

How often were you **woken by your asthma during the night**?

0 not woken at all
1 once
2 a few times
3 several times
4 many times
5 a great many times
6 awake all night

How **bad were your asthma symptoms when you woke** up this morning?

0 no symptoms
1 very mild symptoms
2 mild symptoms
3 moderate symptoms
4 quite severe symptoms
5 severe symptoms
6 very severe symptoms

Bedtime Score

Please write in the number that best describes how your asthma has been during the day today.

How **limited were you in your activities** today because of your asthma?

0 not limited at all
1 very slightly limited
2 slightly limited
3 moderately limited
4 very limited
5 extremely limited
6 totally limited

How much **shortness of breath** did you experience today?

0 none
1 a very little
2 a little
3 a moderate amount
4 quite a lot
5 a great deal
6 a very great deal

How much of the time did you **wheeze** today?

0 not at all
1 hardly any of the time
2 a little of the time
3 a moderate amount of the time
4 a lot of the time
5 most of the time
6 all the time

Please **score** how many puffs of bronchodilator (Ventolin) you have used in the **past 24 hours**.

0 none
1 1–2 puffs
2 3–4 puffs
3 5–8 puffs
4 9–12 puffs
5 13–16 puffs
6 More than 16 puffs

***Scoring PEFs.** Patients record actual PEF values each day in the diary. Conversion to the scoring system below may either be done within a computer data base or by hand by the clinic staff.

0 $>$ 95% predicted
1 95–90%
2 89–80%
3 79–70%
4 69–60%
5 59–50%
6 $<$ 50% predicted