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Assessment of quality of life in adolescents with allergic rhinoconjunctivitis: Development and testing of a questionnaire for clinical trials

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Background: The objectives of the study were to evaluate impairment in quality of life in 12- to 17-year-old patients with seasonal allergic rhinoconjunctivitis and to develop and test a questionnaire suitable for evaluating change in quality of life during clinical trials.

Methods: Patients were asked to identify physical and emotional impairments associated with allergic rhinoconjunctivitis. The resultant questionnaire was tested for responsiveness and validity in a clinical trial in which fluticasone nasal spray and loratadine were compared for treatment of ragweed pollen-induced rhinoconjunctivitis. Eighty-three patients, 12 to 17 years of age, with grass- or ragweed-induced hayfever participated in the instrument development phase. They were recruited for the study from an allergy clinic and local schools and recreational organizations. Two hundred forty patients with ragweed hayfever participated in the clinical trial and provided quality of life data.

Results: The survey showed that in addition to local symptoms, patients experienced impairment of quality of life because of systemic symptoms, activity limitations, and emotional and practical problems. The resultant questionnaire has 25 items in six domains. In the clinical trial responsiveness was demonstrated by the questionnaire's ability to detect change over time and differences between treatments. Construct validity was demonstrated by moderate to strong relationships between changes in diary symptom scores and quality of life.

Conclusions: The items identified by 12- to 17-year-old patients were not identical to those previously identified by adults. This suggests that impairment of quality of life may not be the same in the two groups and that it is appropriate to have a questionnaire specifically designed for adolescent rhinoconjunctivitis clinical trials. (*J ALLERGY CLIN IMMUNOL* 1994;93:413-23.)

Key words: Rhinoconjunctivitis, quality of life, adolescents

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TABLE I. Instrument development phase: Subject characteristics

Number	83
Gender male/female	44/39
Age (yr) (mean:SD)	15.1:1.54
Medication required for control of hayfever the previous summer	
No medication	7.2%
Antihistamines alone	45.8%
Antihistamines + eye drops	13.3%
Antihistamines + nasal steroids	6.0%
Antihistamines + eye drops + nasal steroids	6.0%
Other combinations or medications	21.7%

The usual outcomes measured in clinical trials in rhinoconjunctivitis are symptoms, rescue medications, clinical observations, measurements of nasal patency, and cytology.^{1, 2} Although each is important for determining the effectiveness of medications, the overall impact of rhinoconjunctivitis on the day-to-day lives of the patients has not been assessed. Recognition that patients must both feel better and be able to function better with a new medication has led to the development of quality of life questionnaires for clinical trials, which are capable of measuring within-subject change over time.³⁻⁵

We have recently developed and validated such a questionnaire for assessing quality of life in adults with allergic rhinoconjunctivitis.⁶ Because expectations and lifestyles are different in younger patients, it was not known whether the adult questionnaire would capture impairments that adolescent patients consider important. In this study we have used well-established principles⁷ and methods⁸ to determine the areas of impairment in quality of life that are important to adolescents with hayfever and to develop and test a quality of life questionnaire for use in clinical trials with these patients.

PRINCIPLES OF INSTRUMENT DEVELOPMENT

The development process was determined by the characteristics that were considered to be essential in the final questionnaire.

1. Both physical and emotional function should be included.
2. Items included should be those that are important to adolescent patients with allergic rhinoconjunctivitis.
3. Summary scores for each domain should be amenable to statistical analysis.
4. The questionnaire should be responsive to clinically important changes even if those changes are small.

5. The questionnaire should be valid; that is, it should actually measure quality of life in patients with allergic rhinoconjunctivitis.
6. The questionnaire should be short.

METHODS

Instrument development phase

The purpose of the instrument development phase was to identify the items of quality of life impairment that are most important to adolescent patients with rhinoconjunctivitis and to construct the questionnaire.

Initially, a list of 75 items that represent rhinoconjunctivitis-specific quality of life impairment was generated from unstructured interviews with adolescent patients, a review of the literature, the adult rhinoconjunctivitis questionnaire, and the experience of the investigators. Particular care was taken to use wording familiar to the patients. The aim was to generate a list that would capture all possible areas of rhinoconjunctivitis-related quality of life impairment.

The next step was to identify which of these 75 items are most important to adolescent patients with rhinoconjunctivitis. Eighty-three young persons (12 to 17 years old), who had experienced symptoms of rhinoconjunctivitis during the grass or ragweed pollen seasons the previous summer, participated in this phase. They were recruited from an allergy clinic, from notices in the local media, and from local schools and recreational organizations. Their characteristics are presented in Table I.

Each subject was asked to complete a structured questionnaire about his or her hayfever and about impairment of quality of life during the hayfever season. Subjects were asked which of the 75 items of impairment they had experienced as a result of their hayfever, and for each positive item, they were asked to indicate its importance in their day-to-day lives. Each positive item was scored from 1 (bothers me a little) to 4 (bothers me very much).

We first calculated the percentage of patients who identified the item as a problem. The possible range of percentages was 0% to 100%. We refer to this as the frequency. We then calculated the mean importance attributed to the item by those subjects for whom it was a problem, scored on a scale of 1 to 4 in which, as

TABLE II. Item frequency and importance

Domain (item)	Frequency* (%)	Mean importance†	Overall importance‡
Sleep			
Lack of a good night's sleep	78.3	2.26	1.77
Unable to get to sleep	74.7	2.00	1.49
Wake up during the night	63.9	2.06	1.31
Difficulty lying flat	49.4	2.05	1.01
Emotions			
Irritable	86.7	2.36	2.04
Restless	79.5	2.23	1.77
Frustrated	74.7	2.21	1.65
Embarrassed by how you look	67.5	2.21	1.49
Embarrassed by symptoms	68.7	2.16	1.48
Impatient	69.9	2.09	1.46
Upset	60.2	2.06	1.24
Self-conscious	62.7	1.83	1.15
Angry	53.0	2.14	1.13
Tense	55.4	1.85	1.02
Depressed	48.2	1.85	0.89
Helpless	45.8	1.71	0.78
Weepy/want to cry	37.3	1.84	0.69
Embarrassed to take medications in public	27.7	1.70	0.47
Nose symptoms			
Stuffy nose	92.8	3.42	3.17
Sneezing	88.0	3.03	2.66
Runny nose	89.2	2.80	2.66
Itchy nose	79.5	2.85	2.27
Postnasal drip	67.5	2.54	1.71
Sore nose	69.9	2.41	1.68
Nose bleeds	27.7	2.26	0.63
Eye symptoms			
Itchy eyes	88.0	3.21	2.82
Watery eyes	88.0	2.81	2.47
Swollen eyes	73.5	2.74	2.01
Red eyes	78.3	2.54	1.99
Stinging eyes	66.3	2.73	1.81
Sore eyes	74.7	2.39	1.78
Eyes stuck closed in the mornings	43.4	2.33	1.01
Other hayfever symptoms			
Itchy throat/mouth	66.3	2.55	1.69
Dry throat	71.0	2.32	1.65
Loss of taste	54.2	2.56	1.39
Itchy ears	39.0	1.97	0.77
Nonhayfever symptoms			
Thirst	81.9	2.65	2.17
Can't concentrate	86.7	2.46	2.13
Tired	84.3	2.35	1.99
Worn out	78.3	2.43	1.90
Generally don't feel well	78.3	2.32	1.82
Headache	74.7	2.34	1.75
Food tastes different	69.9	2.38	1.66
Eat less	47.0	2.18	1.02
Weak	54.7	1.85	1.01
Can't eat certain foods	28.9	2.21	0.64
Eat more	21.7	2.17	0.47

*Percentage of patients experiencing item as a result of their hayfever.

†Mean importance score in patients experiencing an item.

‡Frequency × mean importance ÷ 100.

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TABLE II. Item frequency and importance—cont'd

Domain (item)	Frequency* (%)	Mean importance‡	Overall importance‡
Practical problems			
Need to rub eyes/nose	94.0	3.26	3.06
Need to blow nose repeatedly	86.7	3.40	2.95
Always having to carry tissues	81.9	2.78	2.28
Having to take medications	73.5	2.28	1.67
Troubled by bright lights	57.8	2.19	1.26
Having to be in air-conditioning	49.4	2.20	1.08
Difficulty with make-up	25.3	2.00	0.51
Social activities			
Limited participation in activities with friends	43.3	2.03	0.88
Don't go out with friends so often	30.1	1.80	0.54
Unable to attend parties and dances	20.5	2.24	0.45
Friends come to visit less	20.5	1.94	0.40
Work/school activities			
Unable to do your work (school work) as well as usual	78.3	2.26	1.77
Difficulty concentrating on problems	74.7	2.32	1.73
Get less accomplished	69.9	2.36	1.65
Interaction with school/work friends difficult	44.5	2.02	0.90
Have to take time off work/school	37.3	1.74	0.65
Earn less money	19.3	2.63	0.51
Recreational activities			
Outside activities	81.9	2.56	2.10
Sports	65.1	2.37	1.54
Eating outside	62.7	2.44	1.53
Swimming	55.4	2.39	1.32
Biking	61.4	2.08	1.28
Reading	49.4	2.15	1.06
Going to the movies	37.3	2.32	0.87
Watching TV	33.7	2.00	0.67
Indoor activities	33.7	1.89	0.64
Dancing	25.3	2.10	0.53
Playing video games	20.5	2.12	0.43

described above, 1 represented the least importance and 4 the most importance. For instance, if three subjects identified an item as a problem and their importance scores were 2, 3, and 4, the mean importance would be 3 ($[2 + 3 + 4]/3 = 3$). The range of the importance score is therefore 1 to 4. We refer to this as the "mean importance." We then calculated the total impact of the item, which is the product of the frequency and the mean importance divided by 100. We refer to this product as the "overall importance." The range of the overall importance is therefore 0 to 4.

Instrument testing phase

Evaluation of the characteristics of the questionnaire took place in a randomized, double-blind, parallel-group trial of two active medications during the ragweed pollen season. A full report on the study design and results may be found elsewhere.⁹ In summary, 240 patients between the ages of 12 and 17 years, who had

experienced symptoms of rhinoconjunctivitis during the ragweed pollen season the previous year and who had a positive skin prick test result to ragweed pollen extract, were recruited from five centers. They were randomized to take either 200 µg of fluticasone propionate aqueous nasal spray daily or 10 mg of loratadine daily for a 4-week period that encompassed the height of the ragweed pollen season. Patients completed the quality of life questionnaire before and after 2 and 4 weeks of treatment. Throughout the study, patients kept daily diary cards in which they recorded nasal blockage, sneezing, nasal itchiness, runny nose, and eye watering or irritation.

Responsiveness. Responsiveness is the ability of the instrument to detect clinically important within-subject change even if that change is small. Conceptually, it can be thought of as the ratio of the smallest change in instrument score that is clinically significant (the minimal important difference) to the variability in instru-

TABLE III. Instrument testing phase: Subject characteristics

	Fluticasone	Loratadine
Number	121	119
Age (yr)		
12-13	45	46
14-15	36	30
16-17	40	43
Gender male/female	64/57	71/48
Severity of rhinitis during previous ragweed season		
Nasal blockage		
Mild	23	28
Moderate	64	69
Severe	34	31
Sneezing		
Mild	31	22
Moderate	46	54
Severe	41	39
Nasal itching		
Mild	44	47
Moderate	47	39
Severe	14	18
Runny nose		
Mild	28	34
Moderate	60	54
Severe	26	27
Eye symptoms		
Mild	35	30
Moderate	42	41
Severe	36	36

ment score over time in stable subjects.¹⁰ In the absence of an estimate of the minimally important difference, one can use the ratio of the change in score observed in a group of patients in whom one believes true change has occurred to the variability in that group of patients or the variability in a group of stable patients.

Alternatively, rather than generating a quantitative estimate of responsiveness, one can ask two questions: (1) Can the instrument demonstrate statistically significant differences in score in a group of patients whose status one believes has changed? (2) Can the instrument demonstrate statistically significant differences between two treatments? In the present investigation we have taken this latter approach to responsiveness.

Validity. To explore construct validity, we examined the relationship between the conventional symptom diary and the quality of life questionnaire. Because the questionnaire examines different components of the condition, we would not expect high correlations with the diary symptom score; on the other hand, there should be a loose relationship between the two outcomes. Before starting the analysis, we (E. F. J. and G. H. G.), two physicians, and a statistician predicted correlation coefficients that we would expect to find if

each domain of the questionnaire were really measuring the intended area of quality of life. We examined the relationships between variables by calculating Pearson's correlation coefficient.¹¹

RESULTS

Instrument development phase

Table II shows the results of the instrument development phase study. It shows the percentage of patients who experienced each item as a result of their rhinoconjunctivitis, the mean score for importance, and the overall importance. Items included in the final questionnaire were those that scored highest in overall importance. Other criteria for inclusion in the final questionnaire were adequate representation of both physical and emotional limitations and a minimum of three items per domain. Two high-scoring items (tired and worn out) were highly correlated ($r = 0.83$) and appeared to be measuring the same symptoms. They have been combined into one item in the final questionnaire.

Although many patients reported experiencing

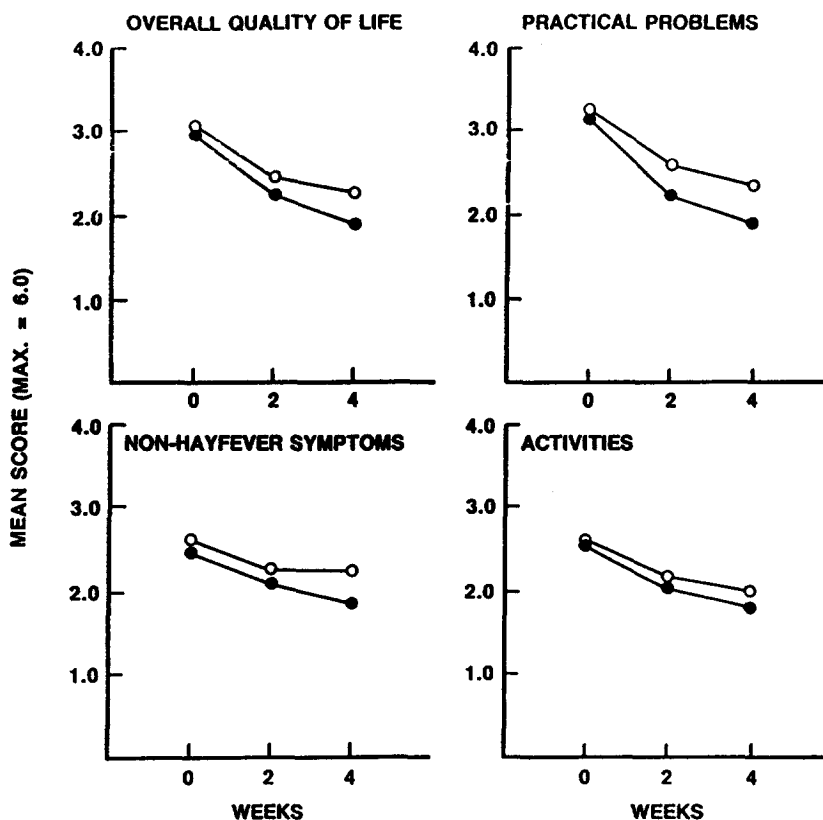


FIG. 1. Quality of life measured before and after 2 and 4 weeks of treatment. Open circles, loratadine; filled circles, fluticasone. Overall quality of life, practical problems, nonhayfever symptoms, and activity limitation.

problems with recreational activities, these have not been included in the final questionnaire. The reason for this is that the activity limitations are nearly all specific to outdoor atmospheric allergens and our aim was to ensure that this instrument should be useful in all clinical trials of allergic rhinoconjunctivitis and not just limited to those carried out during pollen seasons. Therefore in the final questionnaire a domain for activities has been included, but the actual activities are not predefined and it is up to the individual patient to identify activities that are done on a regular basis, in which there is limitation and which are important to the patient. These activities are identified at the first visit of a clinical trial and remain specific for that patient throughout the trial. This allows within-subject change in patient-specific activity limitation to be assessed but does not permit between-subject comparisons.

The final questionnaire (Appendix) has 25 items in six domains (practical problems, nonhayfever symptoms, nose symptoms, eye symptoms, patient-specific activities, and emotions). Overall quality of life is expressed as the mean of the 25

items. The time specification has been set at 1 week; that is, the patient is asked to recall the day-to-day impact that rhinoconjunctivitis has had over the previous 7 days. This time specification may be altered according to the study. Seven point-response options are used for each item. This scale has been chosen because of the need to have fairly fine gradations in an evaluative instrument¹² and because this form of scale has been shown to be as responsive and as valid as a visual analogue scale, as well as being easier to interpret.¹³

Serial pretesting of the questionnaire was done to clarify issues of wording and item presentation. We found that the initial administration, when the interviewer explains the questionnaire and assists the patient in identifying activities in which they are limited, takes a maximum of 15 minutes. Follow-up administration takes a maximum of 10 minutes and usually around 5 minutes.

Instrument testing phase

The characteristics of the patients who participated in the instrument testing phase are shown in Table III.

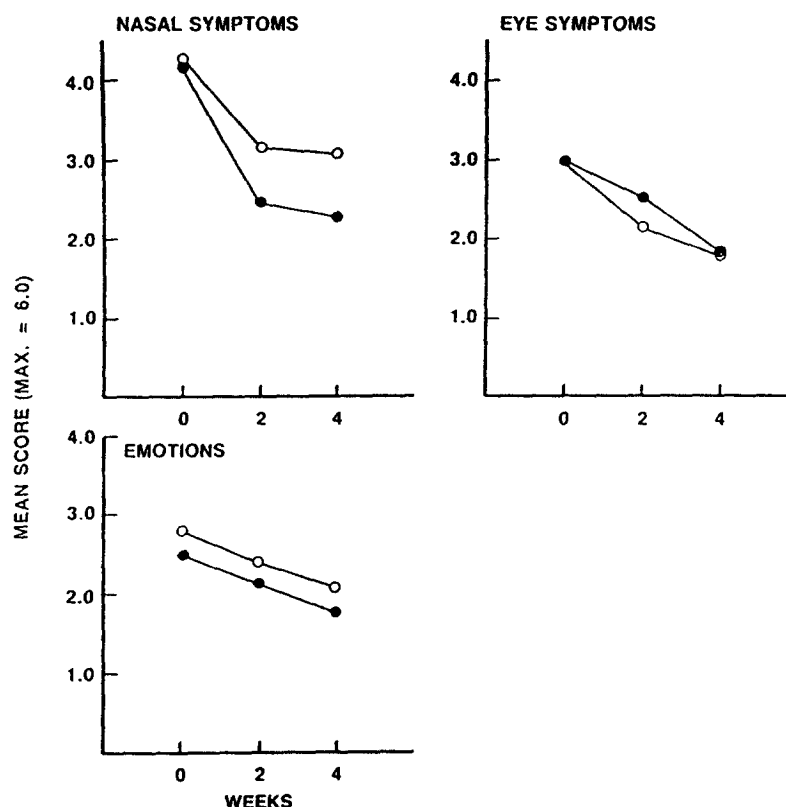


FIG. 2. Quality of life measured before and after 2 and 4 weeks of treatment. Open circles, loratadine; filled circles, fluticasone. Nasal symptoms, eye symptoms, and emotional function.

TABLE IV. Analysis of the clinical trial data: Repeated measures analysis of variance

Domain	p Values		
	Treatment*	Time†	Treatment × time‡
Practical problems	0.013	0.0001	0.18
Nonhayfever symptoms	0.062	0.0001	0.22
Nasal symptoms	0.0001	0.0001	0.007
Eye symptoms	0.38	0.0001	0.09
Activities	0.49	0.0001	0.92
Emotions	0.051	0.0001	1.00
Overall quality of life	0.049	0.0001	0.33

*Comparison of fluticasone and loratadine.

†Change in quality of life over the 4 weeks of treatment.

‡Treatment × time interaction.

The mean quality of life score over the three visits in patients receiving loratadine and fluticasone are presented in Figs. 1 and 2. To assess responsiveness a repeated measures analysis of variance was used in which the factors examined were time, treatment, and the interaction between the two.¹⁴ The first question concerning the ability of the instrument to detect change over time was examined by looking at the statistical significance

of the time effect. For every domain of the instrument, changes over time were very unlikely to have occurred by chance ($p < 0.001$) (Table IV). The second question regarding the ability of the instrument to detect differences between treatment was examined by looking at the treatment effect. Nasal symptoms was the most powerful domain in detecting treatment effects (Table IV). Practical problems also showed statistically signif-

TABLE V. Construct validation of the questionnaire*

Domains	Predicted and actual Pearson correlation coefficients	
	Symptoms (diary)	
	Predicted	Actual
Practical problems	> 0.4	0.48
Nonhayfever symptoms	> 0.3	0.39
Nasal symptoms	> 0.5	0.51
Activities	> 0.3	0.38
Emotions	> 0.4	0.39
Eye symptoms	> 0.4	0.52

*Correlations between changes in diary symptom scores and changes in quality of life.

icant differences between groups. Nonhayfever symptoms, emotions, and overall quality of life showed differences between the groups that fell around the borderline of conventional levels of statistical significance. Eye symptoms and activities failed to differentiate between the two active treatments.

Validity

The study generated the following data, which support the validity of the questionnaire.

1. In both treatment arms, quality of life scores improved with treatment.
2. The Pearson correlation coefficients between the quality of life domains and diary symptom scores were very close to those predicted (Table V).

DISCUSSION

This study has identified items of quality of life that are impaired in the day-to-day lives of 12- to 17-year-old patients with allergic rhinoconjunctivitis. From these data, we have constructed and tested a disease-specific quality of life questionnaire for use in clinical trials. We have shown that this questionnaire is responsive to within-subject change in quality of life during a clinical trial in ragweed pollen season in that it is able to measure change in impairment over time and that it is able to detect differences in effect between two active medications. We have also shown that the questionnaire is valid by demonstrating that correlations between scores on the various domains of the questionnaire and scores on conventional estimates of symptom severity are in the range that one would expect if the questionnaire were really measuring what it is intended to measure.

Although the adolescent questionnaire is fairly

similar to the adult questionnaire, there were important differences that suggested a need for a separate questionnaire. In adults several items of sleep disturbance were important and these merited a separate sleep domain, whereas in the younger patients only "lack of a good night's sleep" produced a high score, and this has been included in the practical problems domain. The young persons indicated that they experience important problems in doing their work (school work) and also that they are troubled by generally not feeling well. Both of these problems were not considered important by adults. On the practical side, words in the adult questionnaire, such as *fatigue* and *handkerchief*, were not understood by or were irrelevant to adolescents.

After the adult allergic rhinoconjunctivitis quality of life questionnaire was developed and tested, it was modified and validated for use in clinical trials of perennial rhinitis.¹⁵ For these trials, all of the questions and instructions relating to eye symptoms were removed. Perennial and non-atopic rhinitis are less common in young persons, but the present questionnaire probably could be adapted in a similar manner. However, a clinical trial should be carried out to support the validity of such a modification.

The purpose of this article has been to present the process by which the questionnaire was developed and to demonstrate that it is a responsive, valid instrument for measuring quality of life in 12- to 17-year-old patients who have rhinoconjunctivitis. It was not the intent of this article to describe, discuss, or interpret the clinical results of the trial; the trial, in this instance, was only the vehicle used to test the questionnaire. The complete results of the clinical trial are presented elsewhere.⁹

Young persons between the ages of 12 and 17 clearly experience impairment of quality of life as a result of allergic rhinoconjunctivitis, and this impairment is important to them. Although the symptoms themselves bother them, other physical and emotional areas are important too. We are not suggesting that the quality of life questionnaire should replace the conventional outcome measures of rhinoconjunctivitis but that it should be used in conjunction with the other measures in clinical trials to capture a component of the condition that is important to the patient.

We thank Ms. Penelope Ferrie for technical support and Dr. William McIlroy for statistical support.

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Appendix can be found on pages 422-3.

APPENDIX**Quality of life questionnaire for 12- to 17-year-olds with allergic rhinoconjunctivitis**

Name: _____ Date: _____ Number _____

(Visit 1: Please identify three activities that are limited or impaired by your nose/eye symptoms).

Please score every item.

Practical problems (yellow card)

How troubled have you been by each of these problems during the last week as a result of your nose/eye symptoms?

- | | | | | | | | |
|--|---|---|---|---|---|---|---|
| a. Always having to carry kleenex | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. Need to rub nose/eyes | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| c. Need to blow your nose repeatedly | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| d. Lack of a good night's sleep | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| e. Unable to do your work (school work) as well as usual | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Nonhayfever symptoms (yellow card)

How troubled have you been by each of these symptoms during the last week as a result of your nose/eye symptoms?

- | | | | | | | | |
|------------------------------------|---|---|---|---|---|---|---|
| a. Tired/worn out | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. Thirst | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| c. Can't concentrate | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| d. Generally don't feel well | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| e. Headache | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Nasal symptoms (yellow card)

How troubled have you been by each of these symptoms during the last week?

- | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|
| a. Stuffy/blocked nose | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. Runny nose | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| c. Sneezing | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| d. Itchy nose | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Eye symptoms (yellow card)

How troubled have you been by each of these symptoms during the last week?

- | | | | | | | | |
|-----------------------|---|---|---|---|---|---|---|
| a. Itchy eyes | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. Watery eyes | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| c. Red eyes | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| d. Swollen eyes | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Activities (yellow card)

How troubled have you been by each of these activities during the last week as a result of your nose/eye symptoms?

- | | | | | | | | |
|---------------------|---|---|---|---|---|---|---|
| a. Activity 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. Activity 2 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| c. Activity 3 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Emotional symptoms (green card)

How often during the last week have you been troubled by these emotions as a result of your nose/eye symptoms?

- | | | | | | | | |
|---|---|---|---|---|---|---|---|
| a. Irritable | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. Restless | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| c. Frustrated | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| d. Upset or embarrassed by others' response to your hayfever symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Scoring cards

Scoring: Yellow card

Please indicate how much you have been troubled by each item, during the last week, as a result of your nose/eye symptoms. Please use the following scale:

1. Not troubled
2. Hardly troubled at all
3. Somewhat troubled
4. Moderately troubled
5. Quite a bit troubled
6. Very troubled
7. Extremely troubled

Scoring: Green card

Please indicate how often during the last week you have been troubled by each of these items as a result of your nose/eye symptoms. Please use the following scale:

1. None of the time
2. Hardly any time at all
3. A small part of the time
4. Some of the time
5. A large part of the time
6. Most of the time
7. All of the time