

11. APPENDICES

Appendix 11: St. George's Respiratory Questionnaire

21/1/03 Andy

Background:

The St. George's Respiratory Questionnaire (SGRQ) is a validated questionnaire for use in studies in patients with chronic airflow limitation. It has been shown to be a sensitive measure of health-related quality of life, including frequency of cough, sputum production, breathlessness and the duration and frequency of attacks of acute exacerbation. The SGRQ was developed as a measure of health-related quality of life in patients with chronic airflow limitation. It has been shown to be a sensitive measure of health-related quality of life, including frequency of cough, sputum production, breathlessness and the duration and frequency of attacks of acute exacerbation. The SGRQ was developed as a measure of health-related quality of life in patients with chronic airflow limitation. It has been shown to be a sensitive measure of health-related quality of life, including frequency of cough, sputum production, breathlessness and the duration and frequency of attacks of acute exacerbation.

Administering the SGRQ

The SGRQ will be administered once to all patients included in the study.

Completing the SGRQ

After the questionnaire, the coordinator should review it to ensure that all questions have been answered. If any question is blank, ask the patient to complete the questionnaire without being critical.

When the patient has completed the questionnaire, ensure that all questions have been answered.

By asking the patient to complete the questionnaire without being critical, the coordinator can ensure that the patient provides accurate information. It is important to avoid leading the patient or making them feel that they are being judged. The coordinator should be supportive and encourage the patient to provide the best possible answer.

Reference

JONES, P.W., ET AL. 1992. A self-complete measure for chronic airflow limitation—the St. George's Respiratory Questionnaire. *Am Rev Respir Dis* 145: 1321-1327.

The St. George's Respiratory Questionnaire

This questionnaire is designed to help us learn more about how your breathing is troubling you and how it affects your life. We are using the first six which aspects of your illness cause you the most trouble, rather than what the doctors and nurses think it is.

Answer the questions as honestly as possible. There are no right or wrong answers in this questionnaire. It is for your information only.

Part 1

problems have affected you over the last 4 weeks

Describe how often your lung/respiratory infections

almost every day
several days a week
a few days a week
no. of days a week

day
week
month
year
2 years

1. Over the last 4 weeks, I have coughed
2. Over the last 4 weeks, I have brought up phlegm (sputum):
3. Over the last 4 weeks, I have had shortness of breath:

had episodes of wheezing

more than 5 episodes

3 episodes

2 episodes

1 episode

no episodes

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6. How long did the worst episode of lung/respiratory problem last? Mark one answer only.

Go to question 7 if you didn't have a severe episode.

a week or more

3 or more days

2 or 3 days

less than a day

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6. If you wheeze, is it worse in the morning? If you don't wheeze, go to Part 2.

No
Yes

Part 2

Section 1:

How would you describe your lung/respiratory condition? Mark one answer only.

- Not an important problem. Rare
- Causes me a lot of problems.
- Causes me a few problems.
- Causes me no problem.

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If you have ever held a job, please mark one of these answers:

My lung/respiratory problem made me stop my job.

My lung/respiratory problem interferes with my job or makes me

My lung/respiratory problem does not affect my job.

Section 2 These are questions about what activity makes you breathe

Mark the box True or False and indicate how often

Sitting or lying still

Walking outside on level ground

Working at a desk

Playing sports or active games (baseball, tennis, etc.)

Other time (please specify) _____

True False

Coughing hurts

Quickly makes me tired

I am often out of breath when I am sure of breath when I talk

am short of breath when I bend over

I become exhausted easily

Section 4: These are questions about other effects that you may experience when you have your Mask or when you use your inhaler. Please answer each question as often as you can.

	True	False
I feel that I am not in control of my lung/respiratory problem.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem makes me feel embarrassed.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem makes me feel nervous.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem makes me feel shy.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem makes me feel awkward.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem makes me feel self-conscious.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem makes me feel like I am a burden on others.	<input type="checkbox"/>	<input type="checkbox"/>

Section 5: These are questions about your lung/respiratory medication, including how you are taking it and how often you are taking it. Please answer each question as often as you can.

Section 6: These are questions about your lung/respiratory medication. Please answer each question as often as you can.

	True	False
My lung/respiratory medication does not help me very much.	<input type="checkbox"/>	<input type="checkbox"/>
I get embarrassed using my lung/respiratory medication in public.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication makes me feel nervous.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication makes me feel shy.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication makes me feel awkward.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication makes me feel self-conscious.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication makes me feel like I am a burden on others.	<input type="checkbox"/>	<input type="checkbox"/>

	True	False
I have had an increase in my lung/respiratory medication.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication interferes with my work.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication interferes with my school.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication interferes with my social life.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication interferes with my family life.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication interferes with my hobbies.	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory medication interferes with my relationships.	<input type="checkbox"/>	<input type="checkbox"/>

Section 6: These are questions about how your activities might be affected by your

and if more parts occur to you

It takes long time to get washed & dressed

to rest

walk on a flat surface

slow down

difficult to do things such as

lifting, carrying, pushing, pulling, digging, dancing, playing golf or other sports such as horse-riding

in a hurry on walk, I have to stop

My breathing problem makes it difficult

My breathing problem makes it difficult to do things such as very heavy manual labor, riding a bike, running, swimming fast or

Section 7: We would like to know how your breathing now

Mark from 1 (false) to 5 (true) in the space provided

cannot play sports or active games

cannot go out for entertainment or recreation

never raise

cannot do things such as

Here is a list of other activities that your lung/respiratory problem may prevent you from

- e. Going to church or place of entertainment
- e. Going out in bad weather or into smoky rooms
- e. Visiting family or friends or playing with children

Please write in any other important activities that your lung/respiratory problem may stop you from doing:

Now would you mark the one statement which you think best describes how your

in doing one or two things I would like to do

Guide to Completing the SGRQ

This is a guide to answering questions some patients may have as they complete the

Part 1

Questions about how often you have had cough or wheezing in the weeks or months before a marker, one box for each question.

Emphasize to the patient that we are interested in how many times you coughed or wheezed.

only with

almost several a few a few times a day

ring

not

week

month

lifetimes

Over the last 4 weeks I have coughed:

Over the last 4 weeks I have

Over the last 4 weeks, I have

episodes of wheezing:

Over the last 4 weeks, I have had ep

5. How many severe or very unpleasant episodes of

5. During the last 4 weeks, how many

- more than 5 episodes
- 3 episodes
- 2 episodes
- 1 episode
- no episodes

"severe or very unpleasant episodes of lung/respiratory problems" can be further described as "Whatever is a bad episode for you in the patient's own judgment, not bad as defined as the doctor or nurse

6. How long did the worst episode of lung/respiratory problem last? Mark one only:

- a week or more
- 3 or more days
- 1 or 2 days

most severe episode of lung/respiratory problem should relate to item 5. If "no episodes" was the answer to item 5, this response should be marked "0".

7. Over the last 4 weeks, how often do you have severe or very unpleasant lung/respiratory problems? Mark one answer or "N/A"

- never
- 1 or 2
- 3 or 4
- nearly every day
- every day

The real meaning of this item is often misinterpreted because the polarity of the questions and responses is reversed compared to the

Check that the response to this item appears with a

no

yes

If the patient does not have a wheeze no response will be given. Ensure

that the response shows no wheeze by using the patient or by eyeing

the patient for any wheeze

compare in any interview in the day of night

Part 2

Section 1:

write you describe your lung/respiratory problem. mark one answer only

The most common lung problem I have

causes me a lot of problems

causes me no problem

this item may be further explained by the fact lung/respiratory problem

that cause breathing problems more than anything else

of problems. It gives some patients difficulty. Ensure that you

If you have ever held a job, please mark one of these answers.

My chest trouble interferes with my work. If I have a respiratory problem, I am usually able to do my job. If I have a respiratory problem, I am usually unable to do my job.

If a patient's response to the item "lung/respiratory problem interferes with my job" is marked "never employed" or "not applicable", this item should be omitted from the score calculation.

Ensure that no response means "never employed."

A major change in response scale occurs here. With low nations, items are marked as "never employed" or "not applicable".

Clarifying this to the patient

True False

Sitting or lying still

Washing yourself or dressing

Walking in the house

Walking outside on level ground

Walking up a flight of stairs

Walking up hills

Most patients do not engage in physical activity. However, it must be determined whether this is a genuine lack of inclination or a limitation because of chest trouble. A response should be made if patients would like to be able to play sports and games, but cannot because of their chest trouble.

Section 3: These are questions about your cough and chest and throat. Mark

	True	False
Coughing hurts	<input type="checkbox"/>	<input type="checkbox"/>
Coughing makes me tired	<input type="checkbox"/>	<input type="checkbox"/>
I become exhausted easily	<input type="checkbox"/>	<input type="checkbox"/>
My coughing or throat clearing disturbs my sleep	<input type="checkbox"/>	<input type="checkbox"/>

Section 4: These are questions about other effects that your lung/respiratory problem may have on you.

	True	False
My lung/respiratory problem has caused me to lose weight	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem has caused me to lose interest in my usual activities	<input type="checkbox"/>	<input type="checkbox"/>
My lung/respiratory problem has caused me to lose interest in my usual activities (e.g. keeps partner of household awake with coughing, relies on friends or family for rides to the hospital or for picking up)	<input type="checkbox"/>	<input type="checkbox"/>
I park longer at a fair when I go to one	<input type="checkbox"/>	<input type="checkbox"/>
I do not expect my lung/respiratory problem to get any better	<input type="checkbox"/>	<input type="checkbox"/>
I have become afraid of driving because of my lung/respiratory problem	<input type="checkbox"/>	<input type="checkbox"/>
Exercise is not so fun for me (e.g. feel that exercise is not so fun because of lung/respiratory problem)	<input type="checkbox"/>	<input type="checkbox"/>
Everything seems too much of an effort	<input type="checkbox"/>	<input type="checkbox"/>

on including

Section 5: These are questions about your lung/respiratory medication

True False

My lung/respiratory medication does not help me very much

I get on well with my lung/respiratory medication

I have any unpleasant side effects from my lung/respiratory medication (e.g. weight gain from steroids, pigmentation, shakes)

My lung/respiratory medication interferes with my life a lot

I remember to take it with me

Section 6: These are questions about how your activities might be affected by your

True False

I have a cough or phlegm that is worse than usual

I wake slower than other people in the morning

Jobs such as housework or ones that take a long time or I have to rest

If I wake up one night or stairs, I have to go slowly or stop

If I hurry or walk fast, I have to stop or slow down

My breath becomes short when I walk or go up stairs

My breath becomes short when I walk or go up stairs

I feel very tired or heavy when going in the garden or doing housework

I play competitive sports

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These items refer to levels of activity and some patients do have difficulty with the format. The first item indicates how much you are with

[Redacted]

previous items in Section 6 and those in Section 7

Section 7: We would like to know how your breathing

Mark True or False

smallly affects your daily life as it appears to you because of your lung(s) especially possible

front, upper and/or lower chest area, you may be aware of

These items are for you to mark if you think they prevent you from doing. Either mark statement

True False

I cannot play sports or active games

I cannot go out for entertainment or recreation

I cannot do household chores

Here is a list of other activities that your lung/respiratory problem may prevent you from

your shortness of breath may affect you

the garden

the weather or into smoke rooms

leaving family or friends to play with children

Being out walks or walking dog

Doing activities or chores at home or in th

Having sexual intercourse

Going to church or to religious services

neck for missing data or any incongruous responses in the case of

your response to the question in this case has been recorded as

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being omitted in the

data base in the case of the data in question with the value

of 000000

Parameter	Low Value	Low	High	High Value
Hemoglobin	<0.8 x ULN	1.0 x ULN	1.5 x ULN	>1.5 x ULN
Neutrophils	<0.5 x ULN	1.0 x ULN	1.5 x ULN	>1.5 x ULN
ASAT (SGOT)	ND	ND	2 x ULN	3 x ULN
Alanine Aminotransferase (ALT)	ND	ND	2 x ULN	3 x ULN
Gamma-GT (GGT)	ND	ND	2 x ULN	3 x ULN
Creatinine	<1.5 x ULN	1.5 x ULN	2.5 x ULN	>2.5 x ULN
Urea Nitrogen	<1.5 x ULN	1.5 x ULN	2.5 x ULN	>2.5 x ULN
Glucose (fasting)	<5.0 mmol/L	5.0 mmol/L	6.0 mmol/L	>6.0 mmol/L
Glucose (random)	<7.0 mmol/L	7.0 mmol/L	11.0 mmol/L	>11.0 mmol/L

Sponsor-defined criteria for evaluating vital signs

Vital Signs	Low		Reference		High	High Concern
	Concern	Low	Range	High		
Systolic BP (mmHg)	<75	75-89	90-139	140-180	>180	
Diastolic BP (mmHg)	<55	50-89	90-119	120-159	>160	
Heart rate (bpm)	<50	50-99	100-120	>120	>160	
Orthostatic change in systolic BP	decrease of ≥ 10	decrease of ≥ 20				
Orthostatic change in diastolic BP	decrease of ≥ 10	decrease of ≥ 20				
Orthostatic change in heart rate (bpm)	increase of ≥ 10	increase of ≥ 20				

ND = not defined

a: Orthostatic change assessed as change in 1 minute