11. APPENDICES

Background

activity and disability.

Administering the SGRQ

Completing the SGRQ

ted the questionnaire, the coordinator should review it to

When the patient has complet

the patient without being critical.

Reference

JONES, P.W., et al. 1992. A self-complete measure for chronic 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 trying to find out which aspects of your illness cause you the most problem - rather than what the doctors and nurses think.

[illegible] anything. Answer the questions as honestly as possible. There are no right or wrong answers. Many of the questions ask you to choose [illegible] answer that best applies to you. Please read the questions carefully before answering.

Part

Describe how often your lung/respiratory problems have affected you over **the last 4** weeks. Please tick one box for each question.

	almost every day	several days a week	a few days a month	lung/ respiratory infections	not at all
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:					
4. Over the last 4 weeks, I have had episodes of wheezing					

5. Over the last 4 weeks, how many severe episodes of coughing or wheezing have you had? Please tick one box.

_____ more than 3 episodes
_____ 3 episodes
_____ 2 episodes
_____ 1 episode
_____ no episodes

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

more days

days

less than a day

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.

The most important problem I have

Causes me a lot of problems

Causes me a few problems

Causes me no problem

St. George's Respiratory Questionnaire. Reproduced and used with permission from PW Jones. UK version adapted and [illegible] with permission by Judith Garrod, Northeastern Univ, Boston MA.

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

_____ My lung/respiratory problem made me stop my job.

rom PW Jones. U.S. version adapted and
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St. George's Respiratory Questionnaire. Reproduced and used with permission f
modified with permission by Judith Barr, Sc.D., Northeastern Univ., Boston, MA

	True	False
My lung/respiratory medication does not help me very much.		
I get embarrassed using my lung/respiratory medication in public.		

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

I take a long time to get washed or dressed

I walk up one flight of stairs or walk up a hill

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

My breathing problem makes it difficult to do things such as carrying heavy loads up stairs, digging in the garden, dancing, playing golf or light sports such as horseshoes

My breathing problem makes it difficult to do things such as walking briskly, playing tennis or swimming

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

Mark

I cannot play sports or active games

I cannot go out for entertainment or recreation

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modified with permission by

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

- Going to church or places of entertainment
- Going out in bad weather or into smoky rooms
- 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:

Guide to Completing the SGRQ

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

Part 1

only with

Over the last 4 wee

coughed

had ep

_____ more than 3 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 judgement, not bad as defined by the doctor or nurse

answer:

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

de. Go to question 7 if you did not have a severe episode.

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

most severe episode of lung/respiratory problem

hould relate to item 5. If "no episodes" was the

c), "How long did the last?" This response s

lung/respiratory problems) have you had? Mark one answer only.

_____ none
_____ 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

yes

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

Part 2

Section 1:

Does not cause me problem

This item may be further explained by "is your lung/respiratory problem

naire. Reproduced and used with permission from P.W. Jones. St. George's Respiratory Questionn

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

Ensure that no response means "never employed."

True | False

Sitting

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

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

Section 3: These are more questions about your work and how your breathing affects your work.

Mark one box on each line to show your answer.

	True	False
Coughing hurts		
Coughing makes me tired		
I am short of breath whenever I move.		
My coughing or breathing disturbs my sleep.		
I become exhausted easily.		

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

Mark one box on each line to show your answer.

	True	False
My lung/respiratory problem is a nuisance to my family, friends or neighbours. *(e.g. keeps partner or household awake with coughing, relies on friends or family for rides to the hospital or for shopping)*		
My physical ability is affected by my lung/respiratory problem.		
I feel that I am not in control of my lung/respiratory problem.		
I do not expect my lung/respiratory problem to get any better.		
I feel frightened generally.		
I have become frustrated or angry because of my lung/respiratory problem.		
Exercise is not safe for me. *(e.g. feel that exercise is not safe because of lung/respiratory problem)*		
Everything seems too much of an effort.		

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

True

My lung/respiratory medication interferes with my life a lot

Section 6: These are questions a

True

These items refer to levels of activity and some patients do have

previous items in Section 1 and those in Section 2

Section 7: We would like to know how your breathing

Mark True or False

True

False

I cannot play sports or active games.

I cannot go out for entertainment or recreation.

I cannot do household chores.

St. George's Respiratory Questionnaire. Reproduced and used with permission from PW Jones. U.S. version adapted and

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

[redacted]

e garden

- Doing, or walking the dog
- Doing activities or chores at home or in th
- Having sexual intercourse

[redacted]

Parameter	Low Value of Concern	Low	High	High Value of Concern
Hemoglobin	<0.8 x LLN	[0.8 x LLN – 1 x LLN)	(1 x ULN – 1.2 x ULN]	>1.2 x ULN
Hemoglobin [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
WBC	[illegible]	[illegible]	[illegible]	[illegible]
Neutrophil (total)	[illegible]	[illegible]	[illegible]	[illegible]
Eosinophil	ND	ND	[illegible]	[illegible]
Platelet Count	<100 x 10^9/L	[100 x 10^9/L – 1 x LLN)	(1 x ULN – 600 x 10^9/L]	>[illegible] x 10^9/L
AST (SGOT)	ND	ND	(1 x ULN – 2 x ULN]	>2 x ULN
ALT (SGPT)	ND	ND	[illegible]	[illegible]
GGT	ND	ND	(1 x ULN – 2.5 x ULN]	[illegible]
Total Bilirubin	ND	ND	(1 x ULN – 1.5 x ULN]	>1.5 x ULN
[illegible] Phosphatase	[illegible]	[illegible]	[illegible]	[illegible]
Creatinine	[illegible]	[0.8 x LLN – 1 x LLN)	(1 x ULN – 1.5 x ULN]	[illegible]
BUN (SI Units)	ND	ND	[illegible]	[illegible]
[illegible] (SI Units)	ND	[illegible]	[illegible]	[illegible]
Sodium (SI Units)	≤130 mmol/L	(130 mmol/L – 1 x LLN)	[illegible]	≥[illegible] mmol/L
[illegible] (SI Units)	[illegible]	[illegible]	[illegible]	≥5.5 mmol/L
[illegible] (SI Units)	≤3.0 mEq/L	(3.0 mEq/L – 1 x LLN)	(1 x ULN – 5.5 mEq/L)	≥5.5 mEq/L
Glucose (random)	<2.0 mmol/L	[2.0 mmol/L – 1 x LLN)	(1 x ULN – 8.0 mmol/L]	>8.0 mmol/L
[illegible]	ND	[illegible]	[illegible]	[illegible]

LLN = Lower Limit of Normal, ULN = Upper Limit of Normal, ND = Not Defined

Sponsor-defined criteria for evaluating vital signs

Vital Signs	Low Concern	Low	Reference Range	High	High Concern
Systolic BP (mmHg)	<75	75-89	90-139	140-180	>180
Diastolic BP (mmHg)	[illegible]	[illegible]	[illegible]	90-110	>110
Heart rate (bpm)	<50	[illegible]	[illegible]	100-120	>120
Orthostatic change[a] in systolic BP (mmHg)	ND	ND	ND	decrease of 10-[illegible]	decrease of ≥20
Orthostatic change[a] in diastolic BP (mmHg)	ND	ND	ND	ND	decrease of ≥10
Orthostatic change[a] in heart rate (bpm)	ND	ND	ND	ND	increase of ≥10

ND = not defined

a Orthostatic change assessed as change between supine for 5 minutes followed by sitting with legs dependent for 1 minute.