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Participant study ID:

EudraCT number: 2008-001968-36



building the evidence

Post Colectomy Questionnaire

(v1-0 30Apr2012)

(for completion by patients with colectomy or reversal)

Please tick to indicate which time period this questionnaire refers to:					
On discharge					
4 weeks post discharge					
8 weeks post discharge					
12 weeks post discharge					

CONSTRUCT

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Please read all the instructions before completing this questionnaire.

Thank you for agreeing to continue participating in this study. The answers you give for this questionnaire will help us to find out whether the treatments you receive are helpful for your condition.

The information you provide will be completely confidential and will not be accessible by any third parties.

Please answer <u>all</u> the questions. Although it may seem that some questions are asked more than once, it is still important that you answer every one.

If you find it difficult to answer a question, please do the best you can. If you are unsure what the question is asking, please ask the research professional to explain it when you meet.

Please follow the instructions for each section of the questionnaire carefully as the sections ask you to think back about different periods of time.

Please return the completed questionnaire to CONSTRUCT, College of Medicine, Swansea University, FREEPOST SWC4951, Swansea SA2 8ZZ

If you have any questions about the questionnaire, please contact us on XXXX or email XXXX.

Date questionnaire started:	d	d	т	т	У	У	У	У	
Time questionnaire started:	h	h	т	т	(using 24h clock)				
Date questionnaire completed:	d	d	т	т	У	У	У	У	
Time questionnaire completed:	h	h	т	т	(using	24h clo	ck)		
Patient initials:									

Participant study ID:								
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Section A: Crohn's and Colitis Questionnaire (CCQ)

The following questions ask for your views about your bowel problem and how it has affected your life over the **last two weeks**.

The terms bowel problem or bowel condition refer to all aspects of your bowel illness and its related treatments. If you have had some bowel surgery you may wish to answer questions 1, 2, 6, 9, 24 and 26 using the "not applicable" response.

Please answer **all the questions**. If you are unsure about how to answer any question, just give the best answer you can. Do not spend too much time answering, as your first thoughts are likely to be the most accurate.

1. On how many days over the last two weeks have you had loose or runny bowel movements?



2. On how many days in the last two weeks have you noticed blood in your stools?

3. On how many days over the last two weeks have you felt tired?



- 4. In the last two weeks have you felt frustrated?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 5. In the last **two weeks**, has your <u>bowel condition</u> prevented you from carrying out your work or other normal activities?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time

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6. On how many days over the last **two weeks** have you opened your bowels more than <u>three</u> times a day?

days	Not Applicable
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7. On how many days over the last two weeks have you felt full of energy?



- 8. In the last two weeks did your bowel condition prevent you from going out socially?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time

9. On how many days over the last two weeks have your bowels opened accidentally?

days Not A	pplicable
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10. On how many days over the last two weeks have you felt generally unwell?

days

- 11. In the last two weeks have you felt the need to keep close to a toilet?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 12. In the last two weeks, has your bowel condition affected your leisure or sports activities?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time

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13. On how many days over the last two weeks have you felt pain in your abdomen?

days

14. On how many nights over the last **two weeks** have you been unable to sleep well (days if you are a shift worker)?



15. On how many nights in the last **two weeks** have you had to get up to use the toilet <u>because of</u> <u>your bowel condition</u> after you have gone to bed?



- 16. In the last two weeks have you felt depressed?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 17. In the last **two weeks** have you had to avoid attending events where there was no toilet close at hand?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 18. On how many days over the last **two weeks**, have you had a problem with large amounts of wind?



19. On how many days over the last two weeks have you felt off your food?

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- 20. Many patients with bowel problems have worries about their illness. How often during the last **two weeks** have you felt worried?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 21. On how many days over the last two weeks has your abdomen felt bloated?

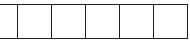
days

- 22. In the last two weeks have you felt relaxed?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 23. In the last two weeks have you been embarrassed by your bowel problem?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 24. On how many days over the last **two weeks** have you wanted to go back to the toilet immediately after you thought you had emptied your bowels?



- 25. In the last two weeks have you felt upset?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time

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26. On how many days over the last two weeks have you had to rush to the toilet?



- 27. In the last two weeks have you felt angry as a result of your bowel problem?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 28. In the last two weeks, has your sex life been affected by your bowel problem?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 29. On how many days over the last two weeks have you felt sick?



- 30. In the last two weeks have you felt irritable?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
- 31. In the last two weeks have you felt lack of sympathy from others?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time

32. In the last two weeks have you felt happy?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time
- 33. How has your quality of life changed since the last time you filled in a questionnaire? Please circle <u>one</u> of the five statements below:

1	2	3	4	5
Mucn better	Somewhat	About the	Somewhat	Much worse
now	better	same	worse	

What date did you complete the last questionnaire?

d d m	т	У	У	У	У
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Supplementary question

Do you have a stoma?

Yes Please continue with the questions below

No Please go straight to Section B on page 13

For patients with a stoma

The following questions ask for your views about your **stoma** and how it has affected your life over the **last two weeks**.

Please choose only **one** answer for each of the questions. If you are unsure about how to answer any question, just give the best answer you can. Do not spend too much time answering, as your first thoughts are likely to be the most accurate.

- 1 On how many days over the last **two weeks** have you been afraid that other people might hear your stoma?
 - a) None
 - b) On one or two days only
 - c) On three to seven days
 - d) On eight to fourteen days (i.e. more than every other day)
- 2 On how may days over the last **two weeks** have you been worried that other people might smell your stools?
 - a) None
 - b) On one or two days only
 - c) On three to seven days
 - d) On eight to fourteen days (i.e. more than every other day)
- 3 On how many days over the last **two weeks** have you been worried about possible leakage from your stoma bag?
 - a) None
 - b) On one or two days only
 - c) On three to seven days
 - d) On eight to fourteen days (i.e. more than every other day)

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- 4 On how many days over the last **two weeks** have you had problems with care for your stoma?
 - a) None
 - b) On one or two days only
 - c) On three to seven days
 - d) On eight to fourteen days (i.e. more than every other day)
- 5 On how many days over the last **two weeks** have you found the skin around your stoma irritated?
 - a) None
 - b) On one or two days only
 - c) On three to seven days
 - d) On eight to fourteen days (i.e. more than every other day)
- 6 In the last **two weeks** have you felt embarrassed because of your stoma?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time

7 In the last **two weeks** have you felt less complete because of your stoma?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

8 In the last **two weeks** have you felt less attractive as a result of your stoma?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

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9 In the last **two weeks** have you felt less feminine / masculine as a result of your stoma?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

10 In the last **two weeks** have you been dissatisfied with your body as a result of your stoma?

- a) No, not at all
- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

If you did not complete any of the questions in Section A (including the stoma questionnaire), please record the question number(s) below and, if possible, give a reason why it was not completed.

Question N°	Reason for non-completion

	-	-	-	-	-	-	-
Participant study ID:							

Section B: SF-12

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please tick the **one box** that best describes your answer.

1. In general, would you say your health is:



2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
<u>a) Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
b) Climbing <u>several</u> flights of stairs			

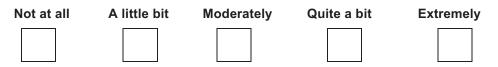
3. During the past **4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

<u>a) Accomplished less</u> than you would like	All of the time	Most of the time	Some of the time	A little of the time	None of the time
 b) Were limited in the kind of work or other activities 					

4. During the past **4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

<u>a) Accomplished less</u> than you would like	All of the time	Most of the time	Some of the time	A little of the time	None of the time
b) Did work or other activities <u>less carefully</u> than usual					

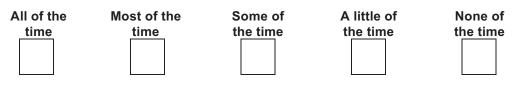
5. During the past **4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?



6. These questions are about how you feel and how things have been with you during the past **4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past **4 weeks**...

a) Have you felt calm and peaceful?	All of the time	Most of the time	Some of the time	A little of the time	None of the time
b) Did you have lots of energy?					
c) Have you felt downhearted and low?					

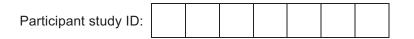
7. During the past **4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?



Section C: EQ-5D

By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today**.

Mobility I have no problems in walking about I have some problems in walking about I am confined to bed	□ A □ B □ C
Self-Care	
I have no problems with self-care I have some problems washing or dressing myself	□ A □ B
I am unable to wash or dress myself	
Usual Activities (e.g. work, study, housework, family or leisure activities) I have no problems with performing my usual activities I have some problems with performing my usual activities I am unable to perform my usual activities	□ A □ B □ C
Pain/Discomfort	
I have no pain or discomfort	ΔA
I have moderate pain or discomfort	
I have extreme pain or discomfort	L C
Anxiety/Depression	
I am not anxious or depressed	
I am moderately anxious or depressed I am extremely anxious or depressed	□ B □ C
ו מוו פאנופווופוץ מואוטעט טו עבטובססבע	



To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion.

Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

> Your own health state today

Office use only:

Health state indicated (whole number between 0 and 100).



Best imaginable health state

0

Worst imaginable health state