Participant Study No

(for completion by co-ordinating centre in Aberdeen)

The REFLUX Trial

ANNUAL FOLLOW-UP QUESTIONNAIRE

A questionnaire for people participating in the REFLUX trial, which aims to find out whether taking medication or having an operation is the best form of treatment for gastro-oesophageal reflux disease

CONFIDENTIAL

This study is funded by the NHS Research and Development Health Technology Assessment Programme

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in the study. The responses you give in this questionnaire will help us find out if the treatments you get are helpful for your condition.

The information you provide will be completely confidential.

HOW TO FILL IN THE QUESTIONNAIRE

For each section please put a cross in the appropriate box like this:

Do you drive a car? **Yes** ☐

No ☒

If you make any errors while completing this questionnaire, shade out the incorrect box completely and put a cross in the correct box like this:

Do you drive a car? **Yes** ☒

No ☒

The intended answer above is No.

PLEASE USE A BLUE OR BLACK PEN TO FILL IN YOUR ANSWERS

REFLUX QUESTIONNAIRE

For the questions in section A - F, please put a cross in the box which best describes how often your symptoms have occurred and the effect they have had on your quality of life.

SECTION A - HEARTBURN

A1. In the last two weeks, how often have you experienced heartburn (a burning sensation which moves up from your chest to your throat)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A2. In the last two weeks, how often have you experienced any discomfort or pain in your chest?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A3. In the last two weeks, how much has the heartburn or discomfort/pain in your chest affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

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SECTION B - ACID REFLUX

B1. In the last two weeks, how often have you experienced acid reflux and/or had an acid taste in your mouth?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

B2. In the last two weeks, how often have you been sick (vomited)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

B3. In the last two weeks, how often have you regurgitated (brought up) quantities of liquid or solids into your mouth?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

B4. In the last two weeks, how often have you experienced a feeling of nausea (without actually being sick or regurgitating)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

B5. In the last two weeks, how often have you wanted to be sick but physically been unable to?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

B6. In the last two weeks, how much have these acid reflux symptoms affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION C – WIND

C1. In the last two weeks, how often have you experienced a lot of wind from the lower bowel?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

C2. In the last two weeks, how often have you experienced a lot of burping/belching?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

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C3. In the last two weeks, how often have you experienced bloatedness and/or a feeling of trapped wind, in your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

C4. In the last two weeks, how often have you experienced loud gurgling noises from your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

C5. In the last two weeks, how much have these wind problems affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION D - EATING AND SWALLOWING

D1. In the last two weeks, how often have you experienced difficulty swallowing food or have you actually choked on food?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

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D2. In the last two weeks, how often have your eating habits been restricted because of your condition? Examples might be eating more slowly, having smaller portions or eating different foods.

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

D3. In the last two weeks, how much have these problems with eating affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION E – BOWEL MOVEMENTS

E1. In the last two weeks, how often have you experienced diarrhoea and/or loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

E2. In the last two weeks, how often have you experienced constipation and/or hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

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E3. In the last two weeks, how often have you had a feeling of an urgent need to have a bowel movement?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

E4. In the last two weeks, how often have you had a feeling of not emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

E5. In the last two weeks, how much have these bowel problems affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION F – SLEEP

F1. In the last two weeks, how often have you experienced difficulty in lying down to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

F2. In the last two weeks, how often have you experienced difficulty getting to sleep because of your reflux symptoms?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

F3. In the last two weeks, how often have you been woken up because of your reflux symptoms?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

F4. In the last two weeks, how much have these sleep related problems affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

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SECTION G – WORK, PHYSICAL AND SOCIAL ACTIVITIES

For the following section, please put a cross in the box which best applies to you.

G1. In the last two weeks, have your reflux symptoms affected you at work (paid or voluntary)?

Not applicable (I do not do paid or voluntary work) ☐

No, my symptoms do not affect me ☐

Yes, my symptoms have affected me but I still work ☐

Yes, I have worked less often because of my symptoms ☐

Yes, I have not worked in the last two weeks because of my symptoms ☐

I no longer work because of my symptoms ☐

G2. In the last two weeks, have your reflux symptoms affected your ability to perform less strenuous activities (such as going for a gentle walk, shopping or housework)?

Not applicable (I do not perform these activities, though this is not due to my reflux symptoms) ☐

No, my symptoms do not affect me ☐

Yes, my symptoms have affected me but I still perform these activities as often as ever ☐

Yes, I perform these activities less often because of my symptoms ☐

Yes, I have not performed these activities in the last two weeks ☐

I no longer perform these activities at all because of my symptoms ☐

G3. In the last two weeks, have your reflux symptoms affected your ability to perform strenuous activities (such as brisk walking or swimming)?

Not applicable (I do not perform these activities, though this is not due to my reflux symptoms) ☐

No, my symptoms do not affect me ☐

Yes, my symptoms have affected me but I still perform these activities as often as ever ☐

Yes, I perform these activities less often because of my symptoms ☐

Yes, I have not performed these activities in the last two weeks ☐

I no longer perform these activities at all because of my symptoms ☐

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G4. In the last two weeks, have you found that your reflux symptoms have affected any of your social activities (such as going out for meals, going out for drinks or socializing with other people)?

- ☐ Not applicable (I do not perform these activities, though this is not due to my reflux symptoms)
- ☐ No, my symptoms do not affect me
- ☐ Yes, my symptoms have affected me but I still perform these activities as often as ever
- ☐ Yes, I perform these activities less often because of my symptoms
- ☐ Yes, I have not performed these activities in the last two weeks
- ☐ I no longer perform these activities at all because of my symptoms

G5. In the last two weeks, how much has the effect of your reflux symptoms on your work, physical or social activities affected your quality of life?

- ☐ Not at all
- ☐ A little
- ☐ Moderately
- ☐ A lot
- ☐ Extremely

SECTION H – DESCRIBING YOUR OWN HEALTH TODAY

By placing a cross 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	☐
Self-care	I have no problems with self-care	☐
	I have some problems washing or dressing myself	☐
	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	☐
Pain/Discomfort	I have no pain or discomfort	☐
	I have moderate pain or discomfort	☐
	I have extreme pain or discomfort	☐
Anxiety/Depression	I am not anxious or depressed	☐
	I am moderately anxious or depressed	☐
	I am extremely anxious or depressed	☐

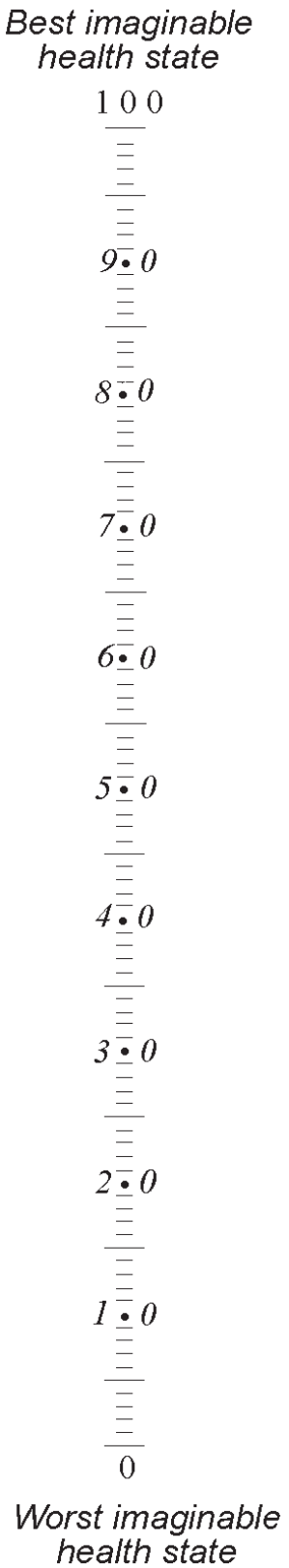
SECTION H - DESCRIBING YOUR OWN HEALTH TODAY

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box below to the point on the scale that best indicates how good or bad your health state is today.

Your own health state today



SECTION I – GENERAL HEALTH

Please fill in all the questions again by putting a cross in the relevant box of the answer that applies to you.

These questions ask for your views about your health and how you feel about life in general. Do not spend too much time in answering as your immediate response is likely to be the most accurate.

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

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. Compared to one year ago, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐	☐	☐	☐	☐

3. 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
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sport	☐	☐	☐
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
c) Lifting or carrying groceries	☐	☐	☐
d) Climbing **several** flights of stairs	☐	☐	☐
e) Climbing **one** flight of stairs	☐	☐	☐
f) Bending, kneeling or stooping	☐	☐	☐
g) Walking **more than one mile**	☐	☐	☐
h) Walking **several hundred yards**	☐	☐	☐
i) Walking **one hundred yards**	☐	☐	☐
j) Bathing or dressing yourself	☐	☐	☐

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 your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Cut down on the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Were limited in the **kind** of work or other activities	☐	☐	☐	☐	☐
d) Had **difficulty** performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

5. 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 <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Cut down on the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Did work or other **activities less carefully than usual**	☐	☐	☐	☐	☐

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with the family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
☐	☐	☐	☐	☐	☐

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

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. 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…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Did you feel full of life?	☐	☐	☐	☐	☐
b) Have you been very nervous?	☐	☐	☐	☐	☐
c) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d) Have you felt calm and peaceful?	☐	☐	☐	☐	☐
e) Did you have a lot of energy?	☐	☐	☐	☐	☐
f) Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g) Did you feel worn out?	☐	☐	☐	☐	☐
h) Have you been happy?	☐	☐	☐	☐	☐
i) Did you feel tired?	☐	☐	☐	☐	☐

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. How TRUE or FALSE is each of the following statements for you?

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a)	I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b)	I am as healthy as anybody I know	☐	☐	☐	☐	☐
c)	I expect my health to get worse	☐	☐	☐	☐	☐
d)	My health is excellent	☐	☐	☐	☐	☐

SECTION J - HEALTH CARE RELATED QUESTIONS

In the following questions, we are trying to find out about some of the costs you incurred over the last 12 MONTHS as a result of your health problems.

If you are not sure or cannot remember exact details, please give the best answer you can.

1. CURRENT EMPLOYMENT

Please tick the box, which best describes your current employment status.

Full time employment	☐	Housework	☐
Part time employment	☐	Seeking work	☐
Student	☐	Other	☐
Retired	☐		

2. TIME AWAY FROM WORK, DUE TO ILLNESS

If you are in paid employment, how many days off work have you had in the past 12 MONTHS because of health problems?

☐☐☐ Days in total ☐☐☐ Days because of reflux symptoms

3. VISITS TO NHS HEALTH CARE FACILITIES

a) How many times in the past 12 MONTHS have you personally visited your GP? Do not include visits made on behalf of others, or if you are a woman attending routine visits because of your pregnancy.

☐ Total number of visits ☐ Visits because of your reflux symptoms

b) How many times in the past 12 MONTHS have you personally had a visit from your GP?

☐ Total number of visits ☐ Visits because of your reflux symptoms

Please give details of the visits that you have had TO or FROM your GP in the spaces below
(continue on a separate sheet if necessary).

Visit 1

Date of visit Month | | | Year | 2 | 0 | | |

Reason for visit

Visit 2

Date of visit Month | | | Year | 2 | 0 | | |

Reason for visit

Visit 3

Date of visit Month | | | Year | 2 | 0 | | |

Reason for visit

Visit 4

Date of visit Month | | | Year | 2 | 0 | | |

Reason for visit

c) How many times in the past 12 MONTHS have you personally had to attend the outpatients or casualty department of a hospital?

☐ Total number of visits

☐ Visits because of your **reflux** symptoms

d) How many times in the past 12 MONTHS have you personally been admitted to a hospital as a day case (do not stay overnight)?

☐ Total number of day case admissions

☐ Admissions because of your **reflux** symptoms

Please give details of the day case admissions you have had and approximate date, in the spaces below *(continue on a separate sheet if necessary)*.

Admission 1

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Reason for day case admission

Admission 2

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Reason for day case admission

Admission 3

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Reason for day case admission

Admission 4

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Reason for day case admission

e) How many times in the past <u>12 MONTHS</u> have you personally been admitted to a hospital for treatment as an inpatient (overnight or longer)?

☐ Total number of **inpatient** admissions

☐ Admissions because of your **reflux** symptoms

Please give details of the inpatient stays you have had, in the spaces below. (continue on a separate sheet if necessary)

Admission 1

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Number of nights ☐☐

Reason for admission and details of any procedures

Admission 2

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Number of nights ☐☐

Reason for admission and details of any procedures

Admission 3

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Number of nights ☐☐

Reason for admission and details of any procedures

Admission 4

Date of admission Day ☐☐ Month ☐☐ Year 2 0 ☐☐

Number of nights ☐☐

Reason for admission and details of any procedures

4. PRESCRIBED MEDICATION FOR REFLUX

Are you currently being PRESCRIBED medication for reflux symptoms?

YES ☐ **NO** ☐ → *If NO, please go to question 5 on page 29*

If YES, please put a cross in the box against the current dose you are being prescribed and write in the number of tablets you have taken in the last two weeks.

(Please note the dose can be found on the side of your tablet bottle or packet)

	Dose (mg)						Number of tablets taken in the last 2 weeks
Omeprazole (Losec)	10mg ☐	20mg ☐	40mg ☐				☐
Lansoprazole (Zoton)	15mg ☐	30mg ☐					☐
Pantoprazole (Protium)	20mg ☐	40mg ☐					☐
Rabeprazole (Pariet)	10mg ☐	20mg ☐					☐
Esomeprazole (Nexium)	20mg ☐	40mg ☐					☐
Ranitidine (Zantac)	150mg ☐	300mg ☐					☐
Famotidine (Pepcid)	20mg ☐	40mg ☐					☐
Nizatidine (Axid)	150mg ☐	300mg ☐					☐
Cimetidine (Tagamet)	400mg ☐	800mg ☐					☐
Domperidone (Motilium)	10mg ☐	20mg ☐					☐
Metoclopramide (Maxolon)	10mg ☐	20mg ☐					☐

If you are prescribed any other medication (tablets or liquid) for your reflux symptoms that are not listed above, please list below the name(s) of the medicine(s) and include the number of times you have taken it in the last two weeks.

Names of medication	Number of times taken in last 2 weeks
e.g. Gaviscon	

5. NON PRESCRIBED MEDICATION FOR REFLUX

Please list below the names of any NON PRESCRIBED (over the counter) medication (tablets/liquid) you take for your REFLUX symptoms and include the number of times you have taken it in the last two weeks.

Names of medication	Number of times taken in last 2 weeks
e.g. Rennies	

IF YOU HAVE ANY OTHER COMMENTS about your gastro-oesophageal reflux symptoms, your reflux treatment or this study, please write them below.

THANK YOU FOR YOUR HELP IN COMPLETING THIS QUESTIONNAIRE

Once you have completed the form, please return it in the pre-paid envelope provided or to the following address:

REFLUX Trial Office
Health Services Research Unit
Polwarth Building
Foresterhill
Aberdeen AB25 2ZD
Tel: 01224 XXXXXX
Fax: 01224 XXXXXX
E-mail: reflux@hsru.abdn.ac.uk