

Appendix C

Research Diagnostic
Questions for
Functional
Gastrointestinal
Disorders:

Rome II Integrative
Questionnaire

Information for Investigator

This questionnaire has been developed primarily for epidemiological surveys, though it may also be used in clinical practice. It contains the Rome II criteria in addition to other symptom-related items that can be used in clinical research.

To make a diagnosis, the questionnaire criteria must be fulfilled as indicated in the coding form. The clinician or investigator must also determine that structural disease(s) that would explain these symptoms are excluded.

Note that the Rome II criteria require that symptoms must be present for at least 12 weeks (at least one day in that week) over the past year. However, the committee accepts that for survey purposes, symptoms might only be present in the previous three months. This questionnaire will allow for 1 year and in some cases 3 months for certain categories (functional gastroduodenal, functional bowel).

Information for Respondent

The purpose of this survey is to provide a better understanding of health problems specifically related to the gastrointestinal system. Your participation is entirely voluntary. This survey will take approximately 15 minutes to complete. You may find that some questions do not apply to you. Please follow the instructions that tell you which questions require your answer and which questions you can skip.

To answer each question, you need to mark the appropriate response box. For example:

Do you have stomach pain?

- Yes
No

If you are not sure or can't remember the answer to a question, just choose your best guess. It is easy to miss questions, so please check that you haven't left any out as you go.

Copyright © 1999 by Nicholas J. Talley, Douglas A. Drossman, William E. Whitehead, W. Grant Thompson, Enrico Corazzari. Readers may photocopy this questionnaire for use in their research or practice. Major contributors to the development of this questionnaire were Nicholas Talley, Philip M. Boyce, Natasha Koloski, and Christine Burke from the University of Sydney, Australia.

Rome II Integrative Questionnaire

Section A

First, we would like to ask you some questions about any belly or abdomen pain or discomfort **in the last year.**

When we say belly or abdomen pain or discomfort, we mean any pain or discomfort in the areas labelled A, B, C or D as shown in Diagram 1 on page 692 (Please do not count cramps or pain with menstrual periods and do not count pain in your chest).

A1. In the *last year* have you had discomfort or pain in your belly or abdomen?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A2. In the *last three months* have you had discomfort or pain in your belly or abdomen?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

If you answered *Not at All or Rarely* to Question A1 or A2 please go to Question B1.

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

A3. How does the discomfort or pain you had in the *last three months* compare to what you had in the *last year*? Would you say it was ...

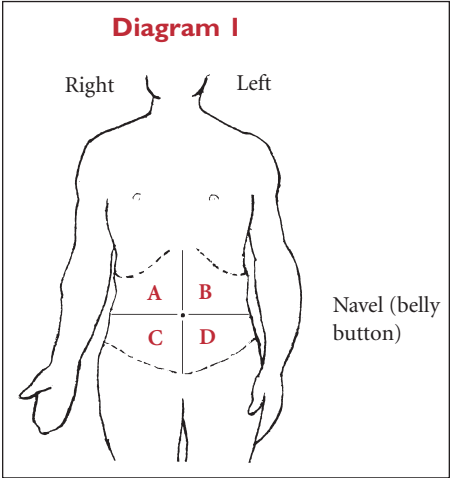
- Better in the last three months
- Worse in the last three months
- About the same.....
- Didn't have pain or discomfort in the last three months

A4. In the last year when you had this discomfort or pain in your belly or abdomen was it continuous or nearly continuous (without breaks)?

- Yes
- No

A5. How old were you when this discomfort or pain first began (as close as you can recall)?

Age in years.....



Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

A6. Where is your belly or abdomen pain located, according to the diagram on the previous page (areas A, B, C, or D)? You can mark more than one answer.

- A.....
- B.....
- C.....
- D.....

A7. If you have more than one pain, where was the location of your most troublesome pain. Choose only *one* area (A, B, C, or D) from Diagram I.

- A.....
- B.....
- C.....
- D.....

A8. In the last year, were your daily activities affected by any discomfort or pain in your belly or abdomen?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

The following questions refer to **any** belly or abdomen discomfort or pain (Areas A, B, C or D on Diagram 1) you may have had **in the last year**.

A9. In the last year, how bad was the discomfort or pain in your belly or abdomen?

- Very Mild.....
- Mild.....
- Moderate.....
- Severe.....

A10. In the last year, did this discomfort or pain in your belly or abdomen get better or stop after having a bowel movement (passing stool)?

- Not at All or Rarely.....
- Occasionally.....
- Often.....
- Very Often.....
- Almost Always.....

A11. In the last year, did you have more bowel movements (stools) than usual when this discomfort or pain began?

- Not at All or Rarely.....
- Occasionally.....
- Often.....
- Very Often.....
- Almost Always.....

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

A12. In the last year, did you have fewer bowel movements (stools) than usual when this discomfort or pain began?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A13. In the last year, did you have looser bowel movements (stools) than usual when this discomfort or pain began?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A14. In the last year, did you have harder bowel movements (stools) than usual when this discomfort or pain began?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A15. In the last year, was this discomfort or pain made better by belching?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

A16. In the last year, did this discomfort or pain occur after meals?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A17. In the last year, did this discomfort or pain ever wake you up from your sleep?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A18. In the last year, did this discomfort or pain ever spread to your back or shoulders?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A19. In the last year, was this discomfort or pain made better by bending forward?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

A20. In the last year, when you had this discomfort or pain, did it last for more than 20 minutes?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

A21. If you have discomfort or pain in the *upper* belly or abdomen (the areas marked A or B on Diagram 1) is it relieved by having a bowel movement (passing stool)?

- Yes
- Not at All or Rarely
- I do not have this pain.....

A21.1. When you had this discomfort or pain in the *upper* belly or abdomen did you have more bowel movements (stools)?

- Yes
- Not at All or Rarely

A21.2. When you had this discomfort or pain in the *upper* belly or abdomen did you have fewer bowel movements (stools)?

- Yes
- Not at All or Rarely

A21.3. When you had this discomfort or pain in the *upper* belly or abdomen did you have harder bowel movements (stools)?

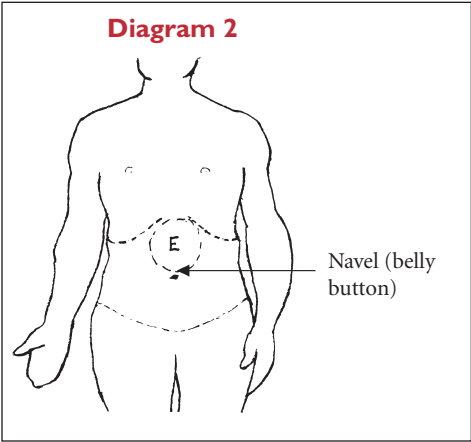
- Yes
- Not at All or Rarely

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

A21.4. When you had this discomfort or pain in the *upper belly* or abdomen did you have looser bowel movements (stools)?

- Yes
- Not at All or Rarely



A22. In the last year, when you had discomfort or pain, was it usually in a single small area that you could point to with one or two fingers? (the area marked E on Diagram 2 above).

- Yes
- No

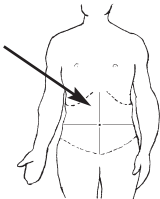
A23. In the last year, when you had this discomfort or pain was it steady and constant (it did not come and go in waves)?

- Yes
- No

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

A24. In the last year, have you been affected by episodes of steady severe pain (in the center of your upper belly or abdomen or in your right upper belly or abdomen) that lasted for 30 minutes or more?



- Not at All.....
- 1 or 2 episodes of this pain.....
- More than 2 episodes of this pain.....

A25. Have you ever had an operation where your Gall Bladder was removed?

- Yes.....
- No.....

Please check that you have answered all of the appropriate Questions in Section A. Please begin Section B.

Rome II Integrative Questionnaire

Section B

We would like to ask you some questions about other belly or abdomen problems you may have had in the last year.

B1. In the last year, did you feel uncomfortably full soon after starting to eat so that you could not finish your normal meal?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

B2. In the last year, after having normal meals, did you get an unpleasant feeling of food staying in your belly or abdomen?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

B3. In the last year, did you feel nauseated (wanting to vomit, but didn't)?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time
Very Often: more than one half of the time

Often: more than one quarter of the time

Rome II Integrative Questionnaire

B4. In the last year, have you had vomiting that was not self-induced or caused by a drug or medication?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

B5. In the last year, did you vomit on at least three separate days in a week over a three month period?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

B6. In the last year, did you have retching (heaving as if to vomit, but not vomiting)?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

B7. In the last year, have you had the feeling of abdominal fullness or bloating or swelling?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

B8. In the last year, have you seen your belly or abdomen swell up?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

B9. In the last year, what has been your *most troublesome* upper belly or abdomen symptom (areas marked A or B on Diagram I on page 692). (Choose only one answer).

- a. Belly or abdomen pain.
- b. Belly or abdomen burning
- c. Belly or abdomen discomfort (*not* pain)
- d. Bloating.
- e. Nausea.
- f. Food staying in belly or abdomen.
- g. Fullness
- h. Uncomfortably full soon after starting to eat
- i. I have no upper belly or abdomen symptoms

Please check that you have answered all of the appropriate Questions in Section B. Please begin Section C.

Occasionally: more than one tenth of the time
Very Often: more than one half of the time

Often: more than one quarter of the time

Rome II Integrative Questionnaire

Section C

We would like to ask you some questions about some other health problems you may have had **in the last year**.

C1. In the last year, have you been troubled by repeated burping or belching?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

C2. In the last year, have you swallowed excess air?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

C3. In the last year, have you had the feeling of a lump in your throat when you were not swallowing?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

C4. In the last year, have you had difficulty swallowing solids or liquids (food or drinks sticking or passing down abnormally)?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

C5. In the last year, have you had to bring up food, chew it again, and either spit it out or swallow it again?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

If you answered *Not at All or Rarely* to Question C5 please go on to Question C6.

C5.1. Did this happen at times when you felt nauseated or had been vomiting?

- Yes
- No

C5.2. Did you stop this when the food you brought up tasted acidic or sour?

- Yes
- No

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

C6. In the last year, have you had heartburn, by that we mean a burning pain or discomfort behind the breastbone rising up towards the throat? (Do not count if the pain was from angina or heart trouble)

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

C7. In the last year, have you had pain or discomfort in the center of your chest?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Please check that you have answered all of the appropriate Questions in Section C. Please begin Section D.

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

Section D

We would like to ask you some questions about any bowel problems you may have had **in the last year.**

D1. In the last year have you been troubled by any bowel problems?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D2. In the last three months have you been troubled by any bowel problems?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D3. In the last year, have you had more than 3 bowel movements each day?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

D4. In the last year, have you had fewer than 3 bowel movements each week?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D5. In the last year, have you had lumpy or hard bowel movements (stools)?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D6. In the last year, have you had loose, mushy or watery bowel movements (stools)?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D7. In the last year, have you found that after finishing a bowel movement you felt that there was still stool which needed to be passed?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time
Very Often: more than one half of the time

Often: more than one quarter of the time

Rome II Integrative Questionnaire

D8. In the last year, have you needed to strain a lot to have a bowel movement?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D9. In the last year, have you experienced an urgent need to have a bowel movement that made you rush to a toilet?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D10. In the last year, have you noticed mucus (white slimy material) in your stools?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D11. In the last year, have you had the sensation that your anus (back passage) was blocked when having a bowel movement?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

Occasionally: more than one tenth of the time
Very Often: more than one half of the time

Often: more than one quarter of the time

Rome II Integrative Questionnaire

D12. In the last year, have you needed to press your finger in or around the anus (back passage) or vagina (front passage) to help the bowel movement come out?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

D13. In the last year, have you had continual or recurring aching pain or pressure in the anus or rectal area?

- Not at All or Rarely
- Occasionally
- Often
- Very Often
- Almost Always

If you answered *Not at All or Rarely* to Question D13 please go on to Question D16.

D14. When you had this continual or recurring aching pain or pressure in the anus or rectal area, did it usually: (Choose only one answer)

- Last from seconds to minutes and disappear completely
- Last for 20 minutes or longer

D15. Were there periods of at least two weeks between episodes of pain or pressure in the anus or rectal area?

- Yes
- No

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Rome II Integrative Questionnaire

DI6. In the last year, when you had constipation or diarrhea, have you leaked or passed bowel movements (stools) or soiled yourself when you did not want to?

- Never
- One occasion in any one month.
- Two occasions in any one month
- More than two occasions in any one month

DI7. Did this (passing bowel movements when you did not want to) happen mostly when you felt constipated?

- Yes
- No

DI8. Did this (passing bowel movements when you did not want to) happen mostly when you had diarrhea?

- Yes
- No

Please check that you have answered all of the appropriate Questions in Section D.

THANK YOU.

Occasionally: more than one tenth of the time *Often:* more than one quarter of the time
Very Often: more than one half of the time

Codes for Rome II Integrative Questionnaire

The coding assumes organic disease has been excluded by appropriate testing.

A. Esophageal Disorders

A1. Globus	QC3 = often or very often or almost always, QC4 = not at all, QC6 = no
A2. Rumination Syndrome	QC5 = often or very often or almost always, QC5.1 = no, QC5.2 = yes
A3. Functional Chest Pain of presumed esophageal origin	QC7 = often or very often or almost always, QC6 = not at all, QC4 = not at all
A4. Functional Heartburn*	QC6 = often or very often or almost always, QC4 = not at all
A5. Functional Dysphagia [†]	QC4 = often or very often or almost always, QC6 = not at all

B. Gastroduodenal Disorders

B1. Functional Dyspepsia ^{††}	QA1 = often or very often or almost always + QA6 = A and/or B, QA21 = Not at all or rarely, I do not have this pain, QA21.1 = Not at all or rarely, QA21.2 = Not at all or rarely, QA21.3 = Not at all or rarely, or QA21.4 = Not at all or rarely
B1a. Ulcer-like dyspepsia	Functional Dyspepsia + QB9a or QB9b = yes
B1b. Dysmotility-like dyspepsia	Functional Dyspepsia + QB9c or QB9d or QB9e or QB9f or QB9g or QB9h = yes

*Gastroesophageal reflux must be excluded.

[†]Note, functional heartburn and functional dysphagia are mutually exclusive in the suggested algorithms. It is important to note that if both are present, neither will show up in the data.

^{††}Some of the editors prefer that 2 or more of [QA21 = Yes], or [QA21.1 = Yes, QA21.2 = Yes], or [QA21.3 = Yes, or QA21.4 = Yes] are needed to exclude these upper abdominal symptoms from the category of Functional Dyspepsia.

Codes for Rome II Integrative Questionnaire (cont'd)

- B2. Aerophagia QC1 = often or very often or almost always
 and QC2 = often or very often or almost always
- B3. Functional QB4 = often or very often or almost always,
 Vomiting QB5 = often or very often or almost always,
 QC5 = not at all

C. Bowel Disorders

- C1. Irritable Bowel QA1 = often or very often or almost always + 2 or more of
 Syndrome • [QA10 = often or very often or almost always] and/or
- [QA11 = often or very often or almost always;
 or QA12 = often or very often or almost always]
- [QA13 = often or very often or almost always or QA14 =
 often or very often or almost always].
- Diarrhea IBS + [one or more of
Predominant IBS QD3 = often or very often or almost always,
 QD6 = often or very often or almost always,
 QD9 = often or very often or almost always
+ none of
 QD4 = often or very often or almost always,
 QD5 = often or very often or almost always,
 QD8 = often or very often or almost always]
- or [two or more of
 QD3 = often or very often or almost always,
 QD6 = often or very often or almost always,
 QD9 = often or very often or almost always
+ one of
 QD4 = often or very often or almost always,
 QD8 = often or very often or almost always]
 and QD5 = not at all

Codes for Rome II Integrative Questionnaire (cont'd)

Constipation Predominant IBS	IBS + [one or more of QD4 = often or very often or almost always, QD5 = often or very often or almost always, QD8 = often or very often or almost always + none of QD3 = often or very often or almost always, QD6 = often or very often or almost always, QD9 = often or very often or almost always] or [two or more of QD4 = often or very often or almost always, QD5 = often or very often or almost always, QD8 = often or very often or almost always + not more than one of QD3 = often or very often or almost always, QD6 = often or very often or almost always, QD9 = often or very often or almost always]
C2. Functional Abdominal Bloating	QB7 = often or very often or almost always, excluding IBS and Functional Dyspepsia.
C3. Functional Constipation	Two or more of QD4 = often or very often or almost always, QD5 = often or very often or almost always, QD7 = often or very often or almost always, QD8 = often or very often or almost always, QD11 = often or very often or almost always, QD12 = often or very often or almost always, + QD6 = not at all, excluding IBS.
C4. Functional Diarrhea	QD6 = almost always + QA1 = not at all
C5. Unspecified Functional Bowel Disorder	Bowel symptoms, but not sufficient to diagnose any other functional bowel disorder.
D. Functional Abdominal Pain	
D1. Functional Abdominal Pain Syndrome	QA1 = almost always + QA4 = yes + QA9 = moderate or severe, excluding IBS and Functional Dyspepsia, QA8 = often or very often or almost always
D2. Unspecified Functional Abdominal Pain	QA1 = almost always, and failure to meet any of the other criteria for Functional Abdominal Pain Syndrome

Codes for Rome II Integrative Questionnaire (cont'd)

E. Biliary Pain

E1. Gallbladder Dysfunction

QA24 = [(1 or 2 episodes of pain) or (more than 2 episodes of pain)],
QA25 = no,
QA8 = often or very often or almost always,
QA21 = no, QA21.1 = no, QA21.2 = no,
QA21.3 = no, QA21.4 = no, QC6 = no,
QB9b = no, QB9c = no, QB9d = no,
QB9e = no, QB9f = no, QB9g = no,
QB9h = no.

E2. Sphincter of Oddi Dysfunction

QA24 = [(1 or 2 episodes of pain) or (more than 2 episodes of pain)],
QA25 = yes,
QA8 = often or very often or almost always,
QA21 = no, QA21.1 = no, QA21.2 = no,
QA21.3 = no, QA21.4 = no, QC6 = no,
QB9b = no, QB9c = no, QB9d = no,
QB9e = no, QB9f = no, QB9g = no,
QB9h = no.

F. Anorectal Disorders

F1. Functional Incontinence

QD16 = yes (1 or more occasion)
+ either QD17 or QD18 = yes

F2. Functional Anorectal Pain

F2a. Levator Ani Syndrome

QD13 = often or very often or almost always
+ QD14 = lasts for 20 minutes or longer

F2b. Proctalgia Fugax

QD13 = often or very often or almost always
+ QD14 = lasts from seconds to minutes
+ QD15 = yes

F3. Pelvic Floor Dyssynergia

Functional constipation
+ QD7 = often or very often or almost always
+ QD8 \geq often
+ QD11 \geq often