Title:

The patient and clinician assessment of gastrointestinal (GI) related adverse events associated with oral disease-modifying therapies in multiple sclerosis: a qualitative study

Author order
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SUPPLEMENTAL MATERIALS

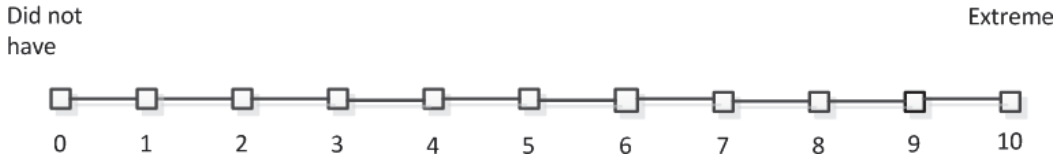
- IGISIS INSTRUMENT
- GGISIS INSTRUMENT

INDIVIDUAL GASTROINTESTINAL SYMPTOM AND IMPACT SCALE (IGISIS)

This questionnaire asks you about potential gastrointestinal symptoms you might feel after taking your study drug. For each of these symptoms, you will indicate whether or not you experienced the symptom and if you did, how intense the symptom was, how long after taking your study drug that it started, how long it lasted, and how much it affected your daily life. The gastrointestinal symptoms you will be asked about in this questionnaire include nausea, vomiting, abdominal pain (both upper and lower in location), and diarrhea. You may experience one or more of these symptoms or none at all.

You should complete this questionnaire within 9 hours after taking your study drug. As you will be taking your study drug twice a day, you will be completing this questionnaire **twice** a day as well. All questions in this questionnaire refer to the period of time **since you last completed this questionnaire** with the exception of when you complete this questionnaire for the first time. When you first complete this questionnaire, the period of time is **since your first dose**.

1. How intense has your **NAUSEA** been on a scale (shown below) from 0 (did not have) to 10 (extreme)?

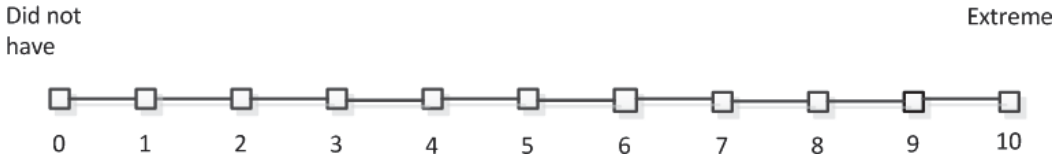


   a. When did your nausea start? _____
   b. When did your nausea stop?_____
   c. How much has your nausea INTERFERED with your ability to accomplish your regular daily activities? (choose one):

      Regular daily activities refer to the things you usually do, such as shopping, household work, taking care of a child or family member, exercising, etc.

      i. Not at all
      ii. Slightly
      iii. Moderately
      iv. Quite a bit
      v. Extremely

2. How intense has your **VOMITING** been on a scale (shown below) from 0 (did not have) to 10 (extreme)?

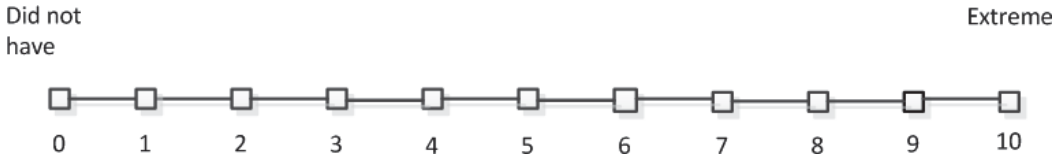


   a. When did your vomiting start?_____
   b. When did your vomiting stop? _____
   c. How much has your vomiting INTERFERED with your ability to accomplish your regular daily activities? (choose one):

      Regular daily activities refer to the things you usually do, such as shopping, household work, taking care of a child or family member, exercising, etc.

      i. Not at all
      ii. Slightly
      iii. Moderately
      iv. Quite a bit
      v. Extremely

3. How intense has your **UPPER ABDOMINAL PAIN** been on a scale (shown below) from 0 (did not have) to 10 (extreme)?

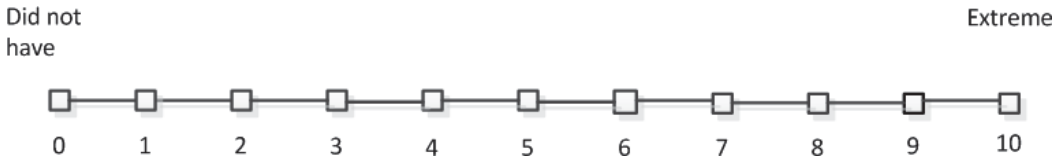


   a. When did your upper abdominal pain start? _____
   b. When did your upper abdominal pain stop? _____
   c. How much has your upper abdominal pain INTERFERED with your ability to accomplish your regular daily activities? (choose one):

Regular daily activities refer to the things you usually do, such as shopping, household work, taking care of a child or family member, exercising, etc.

i. Not at all
ii. Slightly
iii. Moderately
iv. Quite a bit
v. Extremely

4. How intense has your **LOWER ABDOMINAL PAIN** been on a scale (shown below) from 0 (did not have) to 10 (extreme)?

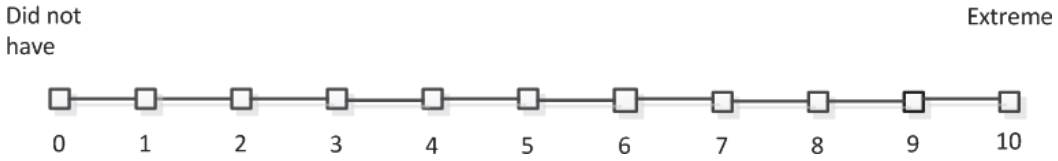


a. When did your lower abdominal pain start? _____
b. When did your lower abdominal pain stop? _____
c. How much has your lower abdominal pain INTERFERED with your ability to accomplish your regular daily activities? (choose one):

Regular daily activities refer to the things you usually do, such as shopping, household work, taking care of a child or family member, exercising, etc.

i. Not at all
ii. Slightly
iii. Moderately
iv. Quite a bit
v. Extremely

5. How intense has your **DIARRHEA** been on a scale (shown below) from 0 (did not have) to 10 (extreme)?



   a. When did your diarrhea start?_____
   b. When did your diarrhea stop?_____
   c. How much has your diarrhea INTERFERED with your ability to accomplish your regular daily activities? (choose one):

      Regular daily activities refer to the things you usually do, such as shopping, household work, taking care of a child or family member, exercising, etc.

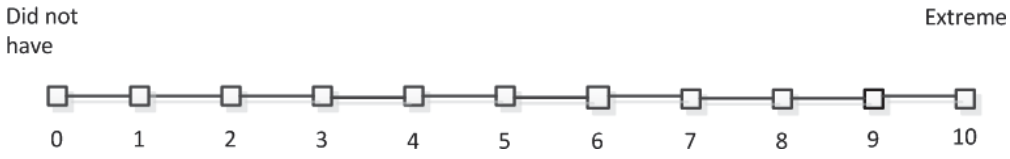
      i. Not at all
      ii. Slightly
      iii. Moderately
      iv. Quite a bit
      v. Extremely

GLOBAL GASTROINTESTINAL SYMPTOM AND IMPACT SCALE (GGISIS)

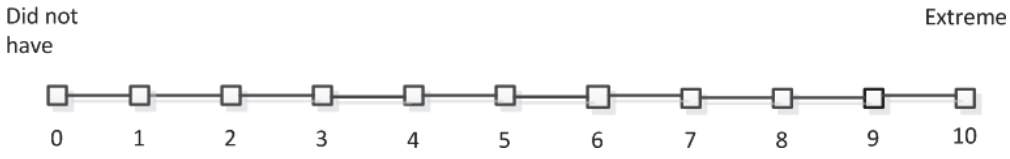
This questionnaire asks you about the overall experience of gastrointestinal symptoms you might feel after taking your study drug. The gastrointestinal symptoms to think about are nausea, vomiting, abdominal pain (both upper and lower in location), and diarrhea. You may experience one or more of these symptoms or none at all.

You should complete this questionnaire in the morning before you take your study medication. You will only complete this questionnaire **once** per day. All questions in this questionnaire refer to your experience **over the past 24 hours**.

1. Rate the **intensity** of your GI symptoms in general over the past 24 hours on a scale from 0 (did not have) to 10 (extreme) as shown below.



2. Rate how **bothersome** your GI symptoms have been in general over the past 24 hours on a scale from 0 (did not have) to 10 (extreme) as shown below.



3. How much have your GI symptoms **interfered** with your ability to accomplish your regular daily activities over the past 24 hours? (choose one):

Regular daily activities refer to the things you usually do, such as shopping, household work, taking care of a child or family member, exercising, etc.

a. Not at all
b. Slightly
c. Moderately
d. Quite a bit
e. Extremely

4. Are you currently employed (working for pay)?

If NO, check "NO" below and you have completed this questionnaire.
If YES, check "YES" below and please answer questions 5 and 6.

___NO
___YES

5. During the past 24 hours, how many hours of work did you miss because of your GI symptoms?

How many hours that you were supposed to work or were scheduled to work did you miss because of your GI symptoms? If you didn't miss any work, indicate "0" hours below. Do not include time you missed to participate in this study.
If you weren't scheduled to work during the past 24 hours, check "Not applicable" below.

___HOURS
___Not applicable

6. How much have your GI symptoms affected your productivity while you were working over the past 24 hours? (choose one)

Was there time during the past 24 hours when you were limited in the amount or kind of work you could do or you accomplished less than you usually do because of your GI symptoms?

a. Not at all
b. Slightly
c. Moderately
d. Quite a bit
e. Extremely