Supporting Information

Diagnostic criteria and Digestive Health and Wellbeing Questionnaires

This appendix was part of the submitted manuscript and has been peer reviewed. It is posted as supplied by the authors.

Appendix to: Potter MDE, Jones MP, Walker MM, et al. Incidence and prevalence of self-reported non-coeliac wheat sensitivity and gluten avoidance in Australia. *Med J Aust* 2020; doi: 10.5694/mja2.50458.

1. Modified Rome IV Criteria for diagnoses of irritable bowel syndrome and functional dyspepsia, including subtypes: from the Digestive Health and Wellbeing Questionnaire, 2018

Irritable bowel syndrome

Criteria fulfilled for the last 3 months

- Defined as the presence of pain anywhere in the belly or tummy (abdomen) on at least one day per week in the last 3 months, and two or more of:
    - The pain was sometimes/often/most of the time or always made better or made worse by having a bowel movement;
    - The following features were associated with the pain when it began (sometimes/often/most of the time or always); more bowel motions than usual or fewer bowel motions than usual, or harder bowel motions than usual or looser bowel motions than usual.
    - The following features were associated with the pain when it began (sometimes/often/most of the time or always); harder bowel motions than usual or looser bowel motions than usual.

Functional dyspepsia

Fulfil criteria for either the postprandial distress or epigastric pain syndrome subtypes as detailed below.

Functional dyspepsia: post-prandial distress subtype

- Defined by the presence of one of the following being present on more than one day per week) in the last 3 months;
    - Inability to finish a regular sized meal, or
    - Feeling uncomfortably full after a regular sized meal.

Functional dyspepsia-epigastric pain syndrome subtype

- Defined as the presence of pain or burning in the stomach or upper tummy (above your belly button but not in the chest) being present one day per week or more.

2. Digestive Health and Wellbeing Questionnaire (2018): validation

Methods

The updated Digestive Health and Wellbeing questionnaire was prospectively tested in of 80 randomly selected outpatients (not part of the Digestive Health and Wellbeing Study) attending outpatient gastroenterology clinics at John Hunter Hospital, who were approached by research nurses prior to their clinic appointments and asked to complete the questionnaire. They were also asked to complete a brief feasibility questionnaire (including questions about the time to complete the questionnaire and how easy the survey was to read and complete), and a subset were then asked either to fill out and return a questionnaire one week later via post to determine test–retest reliability, or complete the questionnaire again with a clinician or research nurse for concurrent validity. The subsequent full study questionnaire was slightly modified based on the findings from this pilot. Concurrent validity (n = 41) and test–re-test reliability (n = 25), undertaken after one week were analysed by calculating raw agreement (percentage) and Cohen κ statistic. Acceptable validity was defined as agreement exceeding 80% and $\kappa > 0.2$ (fair agreement).[1]

Results

Based on the pilot sample, the mean time to complete the survey was 15 minutes (range, 3–55 minutes), and 95% of participants found the survey "easy" or "extremely easy" to understand and complete. Minor modifications to two questions were made to the questionnaire in line with comments from the feasibility survey. Concurrent validity testing (n = 41) and test-retest reliability (n = 25) indicated acceptable validity aside from two questions which were identified as being problematic (low agreement or small κ) and were removed from the subsequent full study.

References

1. Viera AJ, Garrett JM. Understanding interobserver agreement: the kappa statistic. *Fam Med* 2005; 37: 360–363.

3. Digestive Health and Wellbeing Questionnaire (2015)

ID No. JHH-DHWS

DIGESTIVE HEALTH & WELLBEING SURVEY

INSTRUCTIONS: Please place a tick in the box unless otherwise specified.

1. What is your date of birth? ______/_______/________ **2. Are you?** Male ☐ *or* Female ☐

3. In the last 3 months, how often did you have heartburn (a burning discomfort or burning pain in your chest)?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

4. In the last 3 months, how often have you had any pain or burning in your stomach or upper tummy (we mean above your belly button but not in your chest)?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

5. In the last 3 months, how often did you feel uncomfortably full after a regular-sized meal?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

6. In the last 3 months, how often were you unable to finish a regular-sized meal?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

7. In the last 3 months, how often did you have a feeling of bloating?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

8. In the last 3 months, how often did you have a visible swelling of your belly or tummy?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

9. In the last 3 months, how often did you have pain or discomfort anywhere in your belly or tummy (abdomen)?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

Please use the following responses to help you answer these questions
Never/Rarely, Sometimes: About 25% of the time, **Often:** About 50% of the time,
Most of the time: About 75% of the time, **Always:** 100% of the time

10. At the time when you had ANY discomfort or pain in your abdomen, stomach, or tummy, how often would you say that:

a. the discomfort or pain was made better or stopped by having a bowel movement?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

b. you had more bowel motions (stools) than usual when the discomfort or pain began?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

c. you had less bowel motions (stools) than usual when the discomfort or pain began?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

d. you had looser bowel motions (stools) than usual when the discomfort or pain began?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

e. you had harder bowel motions (stools) than usual when the discomfort or pain began?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

11. In the last 3 months, how often did you have any of the following problems with your bowels?

a. you had less than three (0-2) bowel motions each week?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

Continued overleaf

b. you had more than three bowel motions each day?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

c. your stools been lumpy or hard?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

d. your stools been loose or watery?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

e. you needed to strain to have a bowel motion?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

f. you had been troubled by an urgent need to have a bowel movement that made you rush to a toilet?
Never/Rarely ☐, Sometimes ☐, Often ☐, Most of the time ☐, Always ☐

12. In the last 3 months, how often did you have nausea (a feeling of wanting to be sick)?
Never ☐, Less than one day a month ☐, One day a month ☐, Two to three days a month ☐,
One day a week ☐, More than one day a week ☐, Every day ☐

13. Did your tummy/bowel problems start within 3 months of gastroenteritis? No ☐ Yes ☐ N/A ☐

14. Did your tummy/bowel problems start within 3 months of a course of antibiotics? No ☐ Yes ☐ N/A ☐

15. Do you have stomach or bowel symptoms when you eat wheat based foods (e.g. bread)?
No ☐ Yes ☐

16. Have you ever been told by a doctor that you have any of the following conditions?
(You may tick more than one box)

Asthma	☐	Food allergy	☐	Rheumatoid arthritis	☐	Anxiety Disorder	☐
Scleroderma	☐	Pollen allergy	☐	Wheat (gluten) intolerance	☐	Depression	☐
Reflux	☐	Animal allergy	☐	Parkinson's disease	☐	Glaucoma	☐
Diabetes	☐	Helicobacter pylori/ulcer	☐	Psoriasis	☐	Polyps/cancer bowel	☐
Crohn's Disease	☐	Ulcerative colitis	☐	Coeliac disease	☐	Migraine	☐

17. Have you ever smoked? No ☐ (Please go to Q19), Yes ☐

18. How often do you NOW smoke?
Less often than weekly ☐, At least weekly ☐, At least daily ☐

19. During the past 4 weeks (28 days), how much of the time did you feel… (tick one box on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
…so sad nothing could cheer you up	☐	☐	☐	☐	☐
…nervous	☐	☐	☐	☐	☐
…restless or fidgety	☐	☐	☐	☐	☐
…hopeless	☐	☐	☐	☐	☐
…that everything was an effort	☐	☐	☐	☐	☐
…worthless	☐	☐	☐	☐	☐

20. How often during the past 4 weeks did you…. (tick one box on each line)	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Get enough sleep to feel rested upon waking in the morning?	☐	☐	☐	☐	☐
b. Awaken short of breath or with a headache?	☐	☐	☐	☐	☐
c. Have trouble falling asleep?	☐	☐	☐	☐	☐
d. Awaken during your sleep time and have trouble falling asleep again?	☐	☐	☐	☐	☐
e. Have trouble staying awake during the day?	☐	☐	☐	☐	☐
f. Get the amount of sleep you needed?	☐	☐	☐	☐	☐

21. Are you taking any proton pump inhibitors? (Omeprazole (Losec), Esomeprazole (Nexium), Rabeprazole (Pariet), Pantoprazole (Somac), and Lansoprazole (Zoton) No ☐ Yes ☐

22 What is your height? ___cms or ___feet ___inches **and weight?** ___kgs or ___stone ___pounds

23 If asked, would you be willing to participate in future research? No ☐ Yes ☐

Thank you very much for participating in this important research. We appreciate your time.

4. Digestive Health and Wellbeing Questionnaire (2018)

DIGESTIVE HEALTH & WELLBEING SURVEY

INSTRUCTIONS: Please place a tick in the box unless otherwise specified.

1. What is your date of birth? _______/_______/________

2. Sex: ☐ **Female** ☐ **Male**

3. In the <u>last 3 months</u>, how often: (tick one box on each line)	Never	Less than 1 day a month	1 day a month	2-3 days a month	1 day a week	2 – 3 days a week	Most days	Every day	Multiple times a day
a. Did you have heartburn (a burning discomfort or burning pain in your chest)?									
b. Did you feel uncomfortably full after a regular-sized meal so that it interfered with your regular activities?									
c. Were you unable to finish a regular-sized meal?									
d. Did you have the feeling that your abdomen, stomach or tummy was bloated?									
e. Did you have a visible swelling of your belly or tummy?									
f. Did you have pain or burning in your stomach or upper tummy (we mean above your belly button but not in your chest) which was so severe it interfered with your usual activities?									
g. Did you have pain anywhere in your belly or tummy (abdomen)?									

Please use the following responses to help you answer these questions

Never/Rarely: Less than 25% of the time**, Sometimes:** About 25% of the time, **Often:** About 50% of the time, **Most of the time:** About 75% of the time, **Always:** 100% of the time

NB: this questions relates to your answer in Question 3G **4. At the time when you had pain anywhere in your belly or tummy (abdomen), how often would you say that:** (tick one box on each line)	Never/Rarely	Sometimes	Often	Most of the	Always
a.the pain was made better or stopped by having a bowel movement?					
b. the pain was made worse by having a bowel movement?					
c. you had more bowel motions (stools) than usual?					
d. you had less bowel motions (stools) than usual?					
e. you had looser bowel motions (stools) than usual?					
f. you had harder bowel motions (stools) than usual?					

5. In the <u>last 3 months</u>, have you had discomfort (not pain) anywhere in your abdomen, stomach or tummy, more than one day a week?

Yes ☐ No ☐

6. In the <u>last 3 months</u>, how often did you have any of the following problems with your bowels?	Never/Rarely	Sometimes	Often	Most of the time	Always
a. fewer than three (0-2) bowel motions each week?					
b. more than three bowel motions each day					
c. lumpy or hard stools?					
d. loose or watery stool?					
e. a need to strain to have a bowel motion?					
f. an urgent need to have a bowel movement that made you rush to a toilet?					

7. Do you think your tummy/bowel problems (identified above) started <u>within 3 months</u> of gastroenteritis (a sudden attack of severe vomiting and diarrhoea - like food poisoning)?

Yes ☐ No ☐ Never or rarely have tummy / bowel problems ☐

8. Do you think your tummy/bowel problems (identified above) started <u>within 3 months</u> of a course of antibiotics?

Yes ☐ No ☐ Never or rarely have tummy / bowel problems ☐

9. Do you have stomach or bowel symptoms when you eat wheat or gluten based foods (e.g. bread)?

Yes ☐ No ☐ (go to question 11)

10. Which of the following symptoms do you get when you eat wheat or gluten based foods? *(You may tick more than one box)*									
Pain anywhere in the abdomen		Heartburn		Inability to finish a meal		Upper stomach pain		Nausea	
Feeling of bloating		Swollen abdomen		Constipation		Diarrhoea		Skin rash	
Headache		Anxiety		Fatigue		Mental clouding (fogginess)		Joint or muscle pain	
Other (please specify):…………………………………………………………………………………….									

11. Have you reduced gluten or wheat in your diet?

Yes (partially) ☐ Yes (completely) ☐ No ☐ (go to question 14)

12. How long have you been avoiding gluten in your diet?

Less than 6 months ☐ 6 months to 1 year ☐ More than 1 year ☐

13. Why have you reduced gluten or wheat intake? *(You may tick more than one box)*					
Abdominal symptoms		Other symptoms (e.g. tiredness, rash, headache)		General health	
Gluten free household		Weight loss		Taste preference	
Other……………………………………………………………………………………………					

14. Have you followed any of the following diets in the last 3 months due to stomach or bowel symptoms?

Yes ☐ No ☐

Please specify: *(You may tick more than one box)*

Low FODMAP		Vegan		Vegetarian		Fructose/ sugar free		Lactose or dairy free	
Food elimination diet		Five- two diet		High protein/ high energy diet		Low calorie diet (eg. Optifast)		Other? …………………	

15. Have you ever been told by a doctor that you have any of the following conditions?
Please tick all boxes relevant

Asthma		Helicobacter Pylori		Diverticular Disease/Diverticulitis		Glaucoma	
Scleroderma		Ulcerative Colitis		Barrett's Oesophagus		Migraine	
Reflux		Gut Bleeding		Anxiety Disorder		Wheat (gluten) Intolerance	
Type I Diabetes		Rheumatoid Arthritis		Depression		Coeliac Disease	
Type 2 Diabetes		Parkinson's Disease		Bowel Polyps		Liver Disease	
Crohn's Disease		Psoriasis		Bowel Cancer		Animal Allergy	
Pollen Allergy		Food Allergy		Please Specify type of food allergy ………………………………………………………			

16. Have you ever had any of the following operations? *(You may tick more than one box)*

Anti-Obesity surgery		Bowel Resection		Fistula Surgery		Perianal abscess Surgery		Gall Bladder Surgery	

17. Have you ever smoked? Yes ☐ No ☐ (Please go to Q19)

18. How often do you NOW smoke?

No longer smoke ☐ Less often than weekly ☐ At least weekly ☐ At least daily ☐

19. During the past 4 weeks (28 days), how much of the time did you feel: *(tick one box on each line)*	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. So sad nothing could cheer you up?					
b. Nervous?					
c. Restless or fidgety?					
d. Hopeless?					
e. That everything was an effort?					
f. Worthless?					

20. How often during the past 4 weeks (28 days) did you…. *(tick one box on each line)*	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Get enough sleep to feel rested upon waking in the morning					
b. Awaken short of breath or with a headache?					
c. Have trouble falling asleep?					
d. Awaken during your sleep time and have trouble falling asleep again					
e. Have trouble staying awake during the day					
f. Get the amount of sleep you needed?					

21. What is your height? ___ cms or ___feet ___inches

22. What is your weight? ___ kgs or ___stone ___pounds

23. Are you taking any proton pump inhibitors?

These include: Omeprazole (Losec), Esomeprazole (Nexium), Rabeprazole (Pariet), Pantoprazole (Somac), and Lansoprazole (Zoton)

Yes ☐ No ☐

24. Have you taken any of the following medications regularly during the past 3 months? *(tick all boxes relevant)*

Aspirin (Cartia)		Methotrexate		Ondansetron (Zofran)	
Clopidogrel (Plavix)		Infliximab (Remicade)		Loperamide (Gastrostop)	
Mesalazine (Pentasa)		Adalimumab (Humira)		Ranitidine (Rani, Zantac)	
Sulfasalazine (Salazopyrin)		Vedolizumab (Entyvio)		Domperidone (Motilium)	
Mercaptopurine (Purinethol)		Ustekinumab (Stellara)		Metoclopromide (Maxalon)	
Azathioprine (Imuran)		Predinsone (Steroids)		Creon (Pancreatic enzymes)	
Laxatives		Please Specify……………………………………………………………………			

Non-steroidal anti-inflammatory drugs *e.g. Ibuprofen (Neurofen), Celecoxib (Celebrex), Meloxicam, (Mobic), Diclofenac (Voltaren) etc.*	
Anti-coagulation or blood thinning medication *e.g. Warfarin, Dabigatran (Pradaxa), Rivaroxaban (Xarelto), Apixaban (Eliquis)*	
No (I don't take any of these) ☐	
Are you on any other medication specifically for your stomach bowel problems? Please specify ………………………………………………………………………………	

25. If asked, would you be willing to participate in future research? Yes ☐ No ☐

Date completed: ____

Thank you very much for participating in this research. We appreciate your time.

This form can be returned:

- **in the pre-paid envelope provided**

- **or scanned and emailed to - digestive.health@newcastle.edu.au**