

**USER MANUAL FOR
THE PANCREATIC
EXOCRINE
INSUFFICIENCY
QUESTIONNAIRE
(PEI-Q) CLINICAL
PRACTICE VERSION**



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TABLE OF CONTENTS

1	Purpose of the questionnaire	3
1.1	What is this questionnaire?	3
1.2	Why measure PEI symptoms and impacts using a questionnaire?	3
1.3	What is the purpose of this questionnaire?	3
1.4	What is the purpose of this manual?	3
2	Authors and contact	4
3	Overview of the PEI-Q	5
3.1	Development and validation	5
3.2	Domains	5
3.3	Recall period	5
3.4	Response options	5
3.5	Available translations	5
3.6	Copyright and licensing	5
4	Administration guidelines	6
4.1	Mode of administration	6
4.2	Context of use	6
4.3	Administration instructions	6
5	Scoring and interpretation of scores	7
5.1	Scoring of domains and total score	7
5.2	Missing data	8
5.3	Interpretation of scores	8
6	Pancreatic Exocrine Insufficiency Questionnaire (PEI-Q)	9
7	References	12

1. PURPOSE OF THE QUESTIONNAIRE



1.1 What is this questionnaire?

The Pancreatic Exocrine Insufficiency Questionnaire (PEI-Q) is an 18-item Patient-Reported Outcome (PRO) questionnaire designed to be completed by patients with pancreatic exocrine insufficiency (PEI) to assess their PEI symptoms and associated impact on health-related quality of life (HRQoL). A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation by a clinician or anyone else.

1.2 Why measure PEI symptoms and impacts using a questionnaire?

Currently there are no known PRO questionnaires that are specific to PEI. Due to the subjective nature of PEI symptoms (e.g. pain), they are best measured via patient self-report. A PRO questionnaire can be utilised in routine clinical practice to guide treatment decisions and monitor patients' symptom severity, thus helping ensure patients' symptoms are adequately controlled and aid patient-clinician communication.

1.3 What is the purpose of this questionnaire?

The purpose of this questionnaire is to quantify and potentially track changes in PEI symptoms and associated impact on HRQoL. In doing so, this questionnaire aims to:

- Aid identification and diagnosis of PEI alongside other diagnostic tests and methods;
- Assist in the management of patients already diagnosed with PEI, ensuring correct and optimum treatment dosage;
- Monitor the impact of PEI on patients' lives;
- Facilitate patient-clinician communication.

Of note, this questionnaire is designed to complement and improve current best practice and inform discussions around treatment rather than replace standard clinical methods of diagnosing PEI and assessing PEI symptoms.

1.4 What is the purpose of this manual?

This manual provides information regarding the administration, scoring and interpretation of the PEI-Q scores.

2. AUTHORS AND CONTACT



The PEI-Q was developed and validated by Adelphi Values UK in partnership with Abbott.

For information and inquiries, please contact:

Gwendolyn Janssen-van Solingen, Global Medical Director

Abbott Products Operations AG

Hegenheimerweg 127

4123 Allschwil

Switzerland

Email: gwendolyn.janssen@abbott.com

3. OVERVIEW OF THE PEI-Q



The 18-item PEI-Q is comprised of three domains: abdominal symptoms (7 items), bowel movements (6 items) and impacts (5 items).

3.1 Development and validation

The PEI-Q has demonstrated good content validity via the conduct of qualitative concept elicitation (n=61) and cognitive debriefing interviews (n=37) with PEI patients in three countries (UK, Germany and France).¹⁻³ The questionnaire has also shown to have good reliability and validity in a psychometric validation study of 162 PEI patients in the UK, Germany, France and Spain.^{4,5}

3.2 Domains

Abdominal symptoms are assessed by 7 items of the questionnaire. The **abdominal symptoms domain** is comprised of 7 items assessing the following concepts: stomach pain (n=1), bloating (n=1), stomach noises (n=1), passing gas (n=2), nausea (n=1) and appetite (n=1).

Bowel movement symptoms are assessed by items 8-13 of the PEI-Q. The **bowel movement symptoms domain** is comprised of 6 items assessing the following concepts: diarrhea (n=1), stool colour (n=1), stool odour (n=1), fat or oil in the stool (n=1) and needing to rush to get to a toilet (bowel urgency, n=1) or be close to a toilet (n=1).

The **impacts domain** consists of 5 items of the questionnaire. The domain is comprised of 5 items assessing the impact on each of the following: avoiding fatty foods, concentration, embarrassment, worry and social activities. Of note, this domain should only be completed by patients who have been diagnosed with PEI, confirmed by a doctor.

3.3 Recall period

A recall period is the time frame which should be considered when answering the questions in a PRO questionnaire. The PEI-Q was developed with a recall period of the past seven days for all domains/items. Patients are instructed to consider the **past seven days** when selecting a response to each item. This is clearly stated and written in bold in each item, and respondents should only consider their circumstance from the past seven days.

3.4 Response options

Different verbal descriptor response scales are used throughout the PEI-Q. Despite the variation in the wording of response options, all items are responded to on a five-point verbal descriptor scale that is scored from 0-4 for each item. A numerically higher response indicates more severe PEI symptoms.

3.5 Available translations

The PEI-Q was simultaneously developed and cross-culturally validated in UK-English, French, German and Spanish and each of those language versions are available for use.

AB6699A v2_0 Page 6 of 14 17th April 2018

3.6 Copyright and licensing

To protect the integrity of the questionnaire, the PEI-Q including the user manual, scoring algorithm and any versions or translations of the above, and all associated the intellectual property rights, are owned by Abbott. The questionnaire may not be used or altered in any way without prior written permission from Abbott. The PEI-Q is available for use by contacting Mapi Research Trust.

4. ADMINISTRATION GUIDELINES



4.1 Mode of administration

The PEI-Q was developed for completion using pen/paper. It is recommended to also administer the Bristol Stool Form Scale (BSFS) alongside the PEI-Q, although the BSFS does not form part of the PEI-Q. The BSFS is used to assess stool consistency and can provide further useful insights into respondents' experience.

The PEI-Q should be administered in paper format. The PEI-Q is designed as a PRO measure and should be completed by the patient on their own, without help from anyone else.

4.2 Context of use

The PEI-Q is intended to assess self-reported PEI symptom severity and impacts in adults and adolescents aged 12 years and older, with a clinical diagnosis of PEI or who are suspected of having PEI. The PEI-Q can be used with newly-diagnosed or untreated PEI patients, to aid screening of PEI and monitoring of symptoms and impacts. The PEI-Q could also be used as an endpoint in PEI clinical trials, to examine symptom severity and impact of PEI.

4.3 Administration instructions

The questionnaire is designed to be completed independently by the patient without assistance or guidance from the healthcare team or any caregiver(s).

Instructions for administration:

1. Patients willing to complete the PEI-Q should be provided with a blank copy of the PEI-Q to complete in the waiting room before their clinic appointment.
2. The questionnaire is designed to be self-completed. However, should the patient seek any clarification it should be suggested that they use their own interpretation of the questions in providing a response.
3. If a patient asks for help any clinician or observer should simply read the item aloud and suggest that the patient chooses the response that s/he thinks is most appropriate.
4. If a patient is having difficulty choosing between two adjacent response options s/he should be instructed to choose the higher/more severe response option.
5. Once the patient completes the questionnaire the administrator or clinician should check the questionnaire carefully for completeness and point out to the patient any missed responses. If the patient still does not wish to select a response then this should be noted and initialled by the patient and administrator. If any missed responses are not addressed at the time of completion they should just be left as missing – retrospective completion of items (i.e. several hours later or more than a day later) is not appropriate.
6. The scoring sheet is for completion by the healthcare professional or researcher who administered the PEI-Q. Patients should not attempt to score the questionnaire themselves.

5. SCORING AND INTERPRETATION OF PEI-Q SCORES



5.1 Scoring of domains and total score

Separate scores are calculated for each PEI-Q domain (e.g. abdominal symptoms, bowel movement symptoms and impacts). Two total scores can also be calculated; a total summary score of all domains and a total symptom score of the PEI-Q symptom domains. A scoring sheet is provided with the PEI-Q (see section 6) and this should be completed by the healthcare professional or researcher who has administered the questionnaire.

Each item is assigned a score from 0-4 based on the response selected by the patient. Each domain score is then calculated by taking a mean (average) of all the items included within that domain (Table 1). It is expected that the domain scores will primarily be used for research purposes; they are expected to have limited value in clinical practice to monitor symptoms or guide treatment decisions.

Table 1. Items with each domain used to calculate individual domain scores and total score

DOMAIN (MEAN)	ITEM	CALCULATION FORMULA
Abdominal symptoms	1. In the past 7 days, did you have stomach pains?	$A = \frac{\text{Sum of scores of items 1 to 7}}{7}$
	2. In the past 7 days, did you feel bloated?	
	3. In the past 7 days, did your stomach make noises?	
	4. In the past 7 days, did you pass gas?	
	5. In the past 7 days, when you passed gas did smell very bad?	
	6. In the past 7 days, did you feel sick?	
	7. In the past 7 days, did you have a lack of appetite?	
Bowel movements	8. In the past 7 days, did you have diarrhoea?	$B = \frac{\text{Sum of scores of items 8 to 13}}{6}$
	9. In the past 7 days, did you feel the need to rush to the toilet to have a bowel movement?	
	10. In the past 7 days, did your poo look lighter or orange in colour?	
	11. In the past 7 days, when you had a poo did it smell very bad?	
	12. In the past 7 days, did you see or have fat or oil in your poo or on the toilet paper?	
	13. In the past 7 days, did you feel you needed to be close to a toilet because of your enzyme problem?	
Impacts	14. In the past 7 days, did you avoid fatty foods?	$C = \frac{\text{Sum of scores of items 1 to 7}}{5}$
	15. In the past 7 days, did your enzyme problems affect your ability to concentrate?	
	16. In the past 7 days, did you feel embarrassed going to the toilet because of your enzyme problems?	
	17. In the past 7 days, did you feel worried, anxious or stressed because of your enzyme problems?	
	18. In the past 7 days, did your enzyme problems affect your social activities?	



A **total summary score** for the PEI-Q is calculated by taking a mean of the domain scores. The total summary score will be of more value in clinical practice, to potentially help support diagnosis, aid management of PEI symptoms and facilitate patient-clinician communication.

Total summary score (PEI patients only)	$\frac{(\text{Abdominal symptoms domain score (A)} + \text{bowel movement symptoms domain score (B)} + \text{impacts domain score (C)})}{3}$
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It is also possible to calculate a **total symptom score**, by taking a mean of the two averaged symptom domains (abdominal symptoms and bowel movements).

Total symptom score	$\frac{(\text{Abdominal symptoms domain score (A)} + \text{bowel movement symptoms domain score (B)})}{2}$
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5.2 Missing data

The >50% rule will be employed for missing data. This means you can only calculate a score if data for more than half of the items in a given domain are available. If more items are missing, you cannot calculate a domain score. This will have to be considered as missing data. Furthermore, if more than one domain is missing, it is not possible to calculate the total symptom score or the total summary score.

5.3 Interpretation of scores

The domain and total scores range from 0-4, with higher scores indicating more severe PEI. During the psychometric validation of the PEI-Q, analyses identified suitable cut-points which are indicative of a patient being a PEI patient rather than a healthy control participant (Table 2). These cut-points should be considered for the domain score only, and not for each individual item.

These cut-points represent a threshold, where any score above this threshold indicates that the patient will likely have PEI. As Table 2 highlights, the cut-points are quite low, particularly for the bowel movements domain. For example, a patient who has a bowel movement domain score greater than or equal to 0.4 is more likely to have PEI than to be a healthy control.

Table 2. Domain and total score cut-points Domain/total score

DOMAIN/TOTAL SCORE	CUT POINT
Abdominal symptoms domain	≥0.80
Bowel movements domain	≥0.40
TOTAL SYMPTOM SCORE	≥0.60

6. PANCREATIC EXOCRINE INSUFFICIENCY QUESTIONNAIRE (PEI-Q)



This questionnaire asks about problems you may experience if you do not produce enough enzymes to digest your food.

ABDOMINAL SYMPTOMS		NO NOT AT ALL	YES, A LITTLE BIT	YES, SOME	YES, QUITE A BIT	YES, ALOT	SCORE
1.	In the past 7 days, did you have stomach pain ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
2.	In the past 7 days, did you feel bloated (your stomach feeling tight and full)?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
3.	In the past 7 days, did your stomach make noises?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
4.	In the past 7 days, did you pass gas ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
5.	In the past 7 days, when you passed gas did it smell very bad ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
6.	In the past 7 days, did you feel sick (but didn't actually vomit/throw up)?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
7.	In the past 7 days, did you have a lack of appetite ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
Sum of abdominal symptom scores:							<input type="checkbox"/>
Mean abdominal symptom domain score (A):							<input type="checkbox"/>

BOWEL MOVEMENT SYMPTOMS		NO NOT AT ALL	YES, A LITTLE BIT	YES, SOME	YES, QUITE A BIT	YES, ALOT	SCORE
8.	In the past 7 days, did you have diarrhoea (watery poo) ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
9.	In the past 7 days, did you feel the need to rush to the toilet to have a bowel movement (have a poo) ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
10.	In the past 7 days, did your poo look lighter or orange in colour?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
11.	In the past 7 days, when you had a poo did it smell very bad ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
12.	In the past 7 days, did you see or have fat or oil in your poo or on the toilet paper ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
		NO NOT AT ALL	YES, A LITTLE BIT	YES, MODERATELY	YES, QUITE A BIT	YES, EXTREMELY	SCORE
13.	In the past 7 days, did you feel you needed to be close to a toilet because of your enzyme problems?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
Sum of bowel movement symptom scores:							<input type="checkbox"/>
Mean bowel movement symptom score (B):							<input type="checkbox"/>
MEAN TOTAL SYMPTOM SCORE ((A+B)/2):							<input type="checkbox"/>



Only complete if you have been diagnosed with Pancreatic Exocrine Insufficiency (PEI)

IMPACTS		NO NOT AT ALL	YES, A LITTLE OF THE TIME	YES, SOMETIMES	YES, MOST OF THE TIME	YES, ALL OF THE TIME	SCORE
14.	In the past 7 days, did you avoid fatty food ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
15.	In the past 7 days, did your enzyme problems affect your ability to concentrate ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
16.	In the past 7 days, did your enzyme problems affect your social activities ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
		NO NOT AT ALL	YES, A LITTLE BIT	YES, MODERATELY	YES, QUITE A BIT	YES, EXTREMELY	SCORE
17.	In the past 7 days, did you feel embarrassed going to the toilet because of your enzyme problems ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
18.	In the past 7 days, did you feel worried, anxious or stressed because of your enzyme problems ?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>
Sum of impact scores:							<input type="checkbox"/>
Mean impact domain score (C):							<input type="checkbox"/>
MEAN TOTAL SUMMARY SCORE (PEI PATIENTS) $([A+B+C]/3)$:							<input type="checkbox"/>



PEI-Q scoring sheet [for administration use only]

- Each item is assigned a score from 0-4 based on the response selected by the patient.
- Each domain and total score is calculated by taking an average (mean), as shown in the table below.
- The **total symptom score (mean)** can be calculated for all respondents to provide information to help doctors to determine a diagnosis of PEI, while the **total summary score (mean)** should only be calculated for respondents who have been diagnosed with PEI.
- Domain scores can only be calculated if more than 50% of items are completed within each domain (i.e. four or more items in the abdominal symptoms domain, three or more items in the bowel movement symptoms domain, and three or more items in the impacts domain).
- Total scores can only be calculated if two or more domain scores are present for each patient.
- If more items/domains are missing, the domain/total score cannot be calculated and will be considered missing.
- Evidence suggests that patients with a **total symptom score (mean)** of greater than or equal to **0.60** is consistent with a diagnosis of PEI, if the individual does not have a diagnosis of another gastrointestinal condition such as irritable bowel syndrome with diarrhoea.
- Evidence also suggests that a **total symptom score (mean)** of greater than or equal to **1.8** is indicative of severe or poorly controlled PEI, scores of **1.4-1.8** are indicative of **moderate** PEI symptoms and scores of **0.60-1.4** are indicative of minimal or **mild** PEI symptoms.

Scoring

DOMAIN (MEAN)	FORMULA	PLEASE WRITE THE PATIENT'S SCORE HERE
Abdominal symptoms (A)	$A = \frac{\text{Sum of scores of items 1 to 7}}{7}$	A =
Bowel movement symptoms (B)	$B = \frac{\text{Sum of scores of items 8 to 13}}{6}$	B =
Total symptom score	$\frac{(\text{Abdominal symptoms domain score (A)} + \text{bowel movement symptoms domain score (B)})}{2}$	(A+B)/2 =
Impacts (C)	$C = \frac{\text{Sum of scores of items 1 to 7}}{5}$	C =
Total summary score (PEI patients only)	$\frac{(\text{Abdominal symptoms domain score (A)} + \text{bowel movement symptoms domain score (B)} + \text{impacts domain score (C)})}{3}$	(A+B+C)/3 =



7. REFERENCES

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To protect the integrity of the instrument, the PEI-Q including the user manual, scoring algorithm and any versions or translations of the above, and all associated intellectual property rights, are owned by Abbott.