

Background

Following major abdominal surgery, patients may experience significant gastrointestinal dysfunction, including post-operative ileus. Many clinical tools are used to measure this dysfunction, but there is no Patient-Reported Outcome Measure (PROM) specific to this group. The aim of this study was to develop a new PROM for this common condition.

Methodology

A four-phase approach was undertaken.



Stage one used semi-structured interviews with 29 patients to explore experiences of gastrointestinal recovery and develop a draft questionnaire.



Stage two solicited feedback from 18 patients and 15 clinical experts on the face validity of the proposed tool using the QQ10 (a questionnaire of questionnaires designed and validated to assess face validity).



Stage three recruited 297 patients to complete the questionnaire. Principal Component Analysis reduced the items and identified the domain structure.



Test-retest reliability and a pilot assessment of responsiveness were assessed in **stage four** in a sample of 100 and 68 patients respectively.

Results

The interviews generated 27 themes across gastrointestinal recovery and general wellbeing. An initial questionnaire containing 43 items was developed. The QQ10 demonstrated high value and low burden, supporting face validity. Tests to reduce the items, and identify the domains structure resulted in a 15-item questionnaire across four domains (nausea, eating, wellbeing, and bowel function). Test-retest reliability showed ICC values >0.7 for all domains. Pilot responsiveness was demonstrated through differences in pre- and post-surgical scores.

Conclusion

PRO-diGI is a PROM for gastrointestinal dysfunction after major abdominal surgery which shows good psychometric properties, and demonstrates face validity, reliability, and responsiveness. This now needs external validation to facilitate broader implementation.

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Items in the PRO-diGI

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Since going to hospital/your operation...

These questions are about nausea and vomiting:	Not at all	Rarely	Sometimes	Most of the time	All the time
Have you felt sick (in the stomach)?					
Have you vomited (been sick)?					
Have you felt sick (in the stomach) after eating?					
Have you vomited (been sick) after eating?					

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These questions are about fatigue:

Not at all	Rarely	Sometimes	Most of the time	All the time
Have you felt more tired than usual?				
Do you feel weaker than usual?				
Have you found it difficult to do activities to help you recover?				

These questions are about your bowel function:

Not at all	A couple of times	A few times	Quite a few times	Lots of times	Not relevant
Have you had to rush to the toilet to open your bowels (do a poo)?					
Have you had diarrhoea (watery poo)?					
Have you found it difficult to control your bowels?					

We would like to know how good your gut function is today. The scale below is numbered from 0 to 100. 100 means the best function you can imagine. 0 means the worst function you can imagine. Please put an X on the line below to show how your gut function is today, and then write the number you marked in the box below.

0 10 20 30 40 50 60 70 80 90 100

Worst imaginable Best imaginable

Taking of my gut function today (0-100)

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If you have any questions about the PRO-diGI or want to find out more about the research, please contact InSpired Health Outcomes: enquiries@inspiredoutcomes.co.uk

Alternatively, you can visit InSpired Health Outcome's website using the QR code!

