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## RESEARCH ARTICLE

# Formation of a conceptual framework during the development of a patient-reported outcome measure for early gastrointestinal recovery: phase I of the PRO-diGi study

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## Abstract

**Aim:** Patients admitted to hospital for abdominal surgery often experience gastrointestinal dysfunction. Many studies have reported outcomes following gastrointestinal dysfunction, yet there is no unified definition of recovery or a validated patient-reported outcome measure (PROM). The first stage of PROM development requires formation of a conceptual framework to identify key themes to patients. The aim of this study was to utilize semistructured interviews to identify core themes and concepts relevant to patients to facilitate development of a conceptual framework.

**Method:** Adult patients admitted to hospital for major gastrointestinal, urological or gynaecological surgery, in an emergency or elective setting, were eligible to participate. Patients treated nonoperatively for small bowel obstruction were also eligible. Interviews were conducted by telephone, audio-recorded, transcribed, coded and analysed using NVivo software by two researchers and reviewed by lay members of the steering group. Interviews continued until data saturation was reached. Ethical approval was gained prior to interviews (21/WA/0231).

**Results:** Twenty nine interviews were completed (17 men, median age 64 years) across three specialties (20 gastrointestinal, six gynaecological, three urological). Two overarching themes of 'general recovery' and 'gastrointestinal symptoms' were identified. General recovery included three themes: 'life impact', 'mental impact', including anxiety, and 'physical impact', including fatigue. Gastrointestinal symptoms included three themes: 'abdominal symptoms' such as pain, 'diet and appetite' and 'expulsory function', such as stool frequency. A total of 18 gastrointestinal symptoms were identified during patient recovery—many of which lasted several weeks following discharge.

**Conclusion:** This study reports a range of gastrointestinal and nongastrointestinal symptoms experienced by patients during early gastrointestinal recovery. Identified symptoms have been synthesized into a conceptual framework to enable development of a definitive PROM for early gastrointestinal recovery.

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## KEYWORDS

gastrointestinal recovery, ileus, intestinal obstruction, qualitative

## INTRODUCTION

Acute gastrointestinal dysfunction is a pathology frequently managed by the general surgeon. It commonly takes the form of postoperative ileus, which is an adynamic gastrointestinal state following surgery, with multiple theorized aetiologies. The other condition commonly treated by general surgeons is intestinal obstruction, where a mechanical obstruction impedes gut function. Both syndromes classically present with nausea, vomiting, distension and obstipation, and meet the criteria for type 1 intestinal failure [1].

There is no clear consensus on how to define 'recovery' from these conditions. For example, the trial literature for ileus includes 73 different definitions of recovery from ileus, the majority of which are clinical, with an emphasis on flatus [2]. Recently developed core outcome sets for ileus and small bowel obstruction have highlighted the need for patient-reported outcomes (PROs) in this field, as the symptoms solicited by surgeons do not reflect the whole patient experience [3, 4].

Patient-reported outcomes or patient-reported outcome measures (PROMs) are of increasing relevance in surgical research. These outcomes are reported by patients either as a single outcome (PRO) or across a number of outcomes to give an overall measure (PROM). The substantial bodies of literature on ileus and small bowel obstruction use multiple different outcome measures, the majority of which are clinician reported [2, 5]. Where quality of life is measured, generic quality-of-life tools are utilized rather than a disease-specific measure. A disease-specific outcome measure is preferable to generic measures as it provides specific information that might not otherwise be captured within a generic tool [6]. Studies have demonstrated how disease-specific PROMs including quality-of-life measures are useful predictors of mortality and postoperative complications [7]. There is currently a lack of PROMs in acute gastrointestinal failure and recovery [8].

A disease-specific PROM utilizes a conceptual framework to measure key relationships and overlapping concepts in the area of interest—in this case gastrointestinal recovery. A conceptual framework is a map of concepts relevant to an idea or experience. It incorporates physical functioning in the form of patient symptoms but also includes psychological and social functioning to provide an integrated framework. This is essential in PROM development to allow integrated and holistic reporting of patient outcomes. Development of a framework is a two-stage process, involving a systematic review to establish key themes and supplemented by qualitative interviews to ensure all key patient outcomes are encompassed [9, 10]. The development of a detailed conceptual framework is key in the development of a PROM to ensure outcomes are accurately represented for the desired condition [11].

Two systematic reviews of the relevant literature have already been published by members of our research team [2, 5]. The aim of this study was to utilize semistructured interviews to identify core

### What does this paper add to the literature?

This paper reports a conceptual framework for gastrointestinal recovery following abdominal surgery. It allows clinicians to appreciate which aspects of gut dysfunction are important to patients, to better understand recovery. This is the first stage in the development of a patient-reported outcome measure for gastrointestinal recovery.

themes and concepts relevant to patients to facilitate development of a conceptual framework. This framework will be utilized to inform a disease-specific PROM for early gastrointestinal recovery.

## METHOD

## Reporting and approvals

The study is reported in line with COREQ guidelines (Appendix S1) [12]. Approvals were secured from the Health Research Authority and Wales Research Ethics Committee prior to commencement (REC ref: 21/WA/0231). Sponsor greenlight was given to each participating site to commence recruitment upon receipt of their confirmation of capacity and capability.

## Participant sampling

A purposive sampling strategy was used to identify potential participants who met the eligibility criteria and to ensure variation in patient characteristics, operations and operating centre. Participants were eligible for inclusion if they were adult patients (18 years of age and over) with conversational English, and were admitted to hospital for one of the following reasons:

1. major elective gastrointestinal surgery (e.g. colorectal resection, gastric resection, liver or pancreatic resection)
2. emergency laparotomy
3. intra-abdominal surgery for nongastrointestinal indications, for example cystoprostatectomy, prostatectomy, nephrectomy, hysterectomy or oophorectomy
4. a diagnosis of intestinal obstruction (small or large bowel).

Sample size in qualitative research is often guided by the concept of data saturation—whereby no new themes emerge from the data despite an increase in sample size. Data saturation does not occur at a set number of interviews but can be achieved at fewer than 10

interviews [9]. We aimed for a sample size of more than 20 to reach saturation given the desired variability in included participants. If saturation was not reached at 20 interviews, we planned to conduct further interviews until saturation was achieved.

## Recruitment

Participants were recruited from five hospital sites across England (Sheffield Teaching Hospitals NHS Foundation Trust, Royal Devon and Exeter NHS Trust, University Hospitals Birmingham NHS Foundation Trust, Norfolk and Norwich University Hospitals NHS Foundation Trust, Doncaster and Bassetlaw Hospitals NHS Trust). Potential participants were eligible for inclusion following their acute treatment, and at a time close to discharge, and invited to express an interest in involvement in the study. Those expressing an interest met with a member of the local research team and were given a participant information leaflet. After at least 30 min to consider participation, they were approached again by the research team to receive consent for inclusion.

Participants were made aware that the interviewers would be a member of the central research team and were independent of their clinical team. It was explained during recruitment that the goal of this research was to develop an outcome measure which included the views of patients who experienced the condition in question. It was assumed with the interviewers being independent of participants' clinical teams would result in unconstrained expression of participants' experiences.

Following successful recruitment to the study, participants' contact details were passed on to the central research team to arrange interview. All included participants were assigned a study ID after they consented, which was used during the collection of demographic data, reporting of data and identification of transcripts.

## Data collection

Participants' baseline characteristics including age, gender, type of operation and type of gastrointestinal failure were recorded anonymously during their hospital stay on the secure Research Electronic Data Capture (REDCap) servers at the University of Sheffield [13].

Interviews were conducted the week following participants' discharge from hospitals via telephone, video software (e.g. Google Meet) or in person. Given the timing of the interviews during the COVID pandemic, and also the wide geographical distribution of participants, it was anticipated that the majority would be completed remotely. We planned for only the interviewer and participant to be present during interview.

## Research team and reflexivity

Interviews were carried out by BDT and BJT, both of whom are male researchers at the School of Health and Related Research at

the University of Sheffield. Both have extensive experience of conducting interviews across a range of clinical settings. Neither had a preexisting relationship with the interviewees, were clinical at time of interview or had preexisting interests in recovery after surgery.

## Interview schedule

Candidate items to inform qualitative interview design were drawn from two systematic reviews published by the research team [2, 5]. Additional searches of the grey literature were undertaken to identify PROMs for gastrointestinal function, and identified two relevant PROMs: the Gastrointestinal Symptom Rating Scale (GSRS) [14] and the Gastrointestinal Quality of Life Index (GIQLI) [15]. The interview schedule was developed by the research team, which included experts and patients in the clinical field. This expert group was drawn from attendees at the Association of Coloproctology Gastrointestinal Recovery Group. Patient input was secured through lay members of our central research team (RA and SB). Interview schedules were piloted on two initial interviews before a debrief meeting was held to identify areas requiring addition to the schedule. Our aim was for the interview to last as long as required to extract participant experiences; however, we expected them to last no longer than 75 min. All interviews were audio-recorded and transcribed verbatim by an independent typist. Transcripts were not returned to participants for comment.

The aim of the interview schedule was to encourage participants to explore disease-specific information related to early gastrointestinal recovery. Questions were included at the start of the interview to explore participants' characteristics and their preconceptions about what they would classify as good gut health. These questions were included to aid in establishing rapport and ease participants into interviews. This formed part of the overarching project in development of the PROM, but was not part of developing an initial conceptual framework and is not reported in this paper.

## Data analysis

Anonymized interview transcripts were uploaded independently by two researchers (DB and ML) into NVivo software for qualitative analysis (QSR International, Australia). Data were analysed using the principles of thematic content analysis [9, 16]. Both researchers individually coded five interviews before discussing emergent initial codes, followed by naming and merging of similar codes to create an initial coding framework. This was reviewed with patient representatives on the steering committee. This framework was utilized to code a further five interviews before refining the framework further. Further additions to the conceptual framework were discussed on an ad hoc basis. This method of conceptual framework development has been employed previously in the literature in a similar setting for creation of a disease-specific PROM [17]. The team did not plan to ask participants to provide feedback on findings due to the presence of lay members in the central research team.

## RESULTS

A total of 43 participants were consented between October 2021 and January 2022, and 29 interviews were completed. Of those who did not complete interviews, one no longer had capacity to consent, one declined participation as they were still recovering from surgery and the remainder did not respond to telephone contacts to arrange interviews. The characteristics of participants are presented in [Table 1](#). Approximately nine patients required a stoma postoperatively. Data saturation was achieved after 25 interviews, with a further four interviews demonstrating no new themes. Interviews were completed at a median of 22 days following surgery (range 9–58 days). Interview length ranged from 20 to 71 min (median 32 min).

Two overarching themes related to early gastrointestinal recovery were identified. These were 'general recovery' ([Theme 1](#)) and 'gastrointestinal symptoms experienced during recovery' ([Theme 2](#)). Each overarching theme had three major themes identified which included a number of subthemes. A summary of the conceptual framework is presented in [Figure 1](#). [Table 2](#) is a data saturation table

illustrating the number of references to each subtheme. Example quotes for each subtheme can be found in [Table S1](#).

### Theme 1: general recovery

#### Life impact

Three subthemes were identified in this group, addressing activities of daily living, general well-being and quality of life.

*Daily living:* participants described the impact of their experiences on their ability to conduct their regular activities of daily living. This included a negative impact on simple activities of self-care such as cooking and cleaning. This was attributed to the surgery itself, presence of a new stoma or altered bowel function.

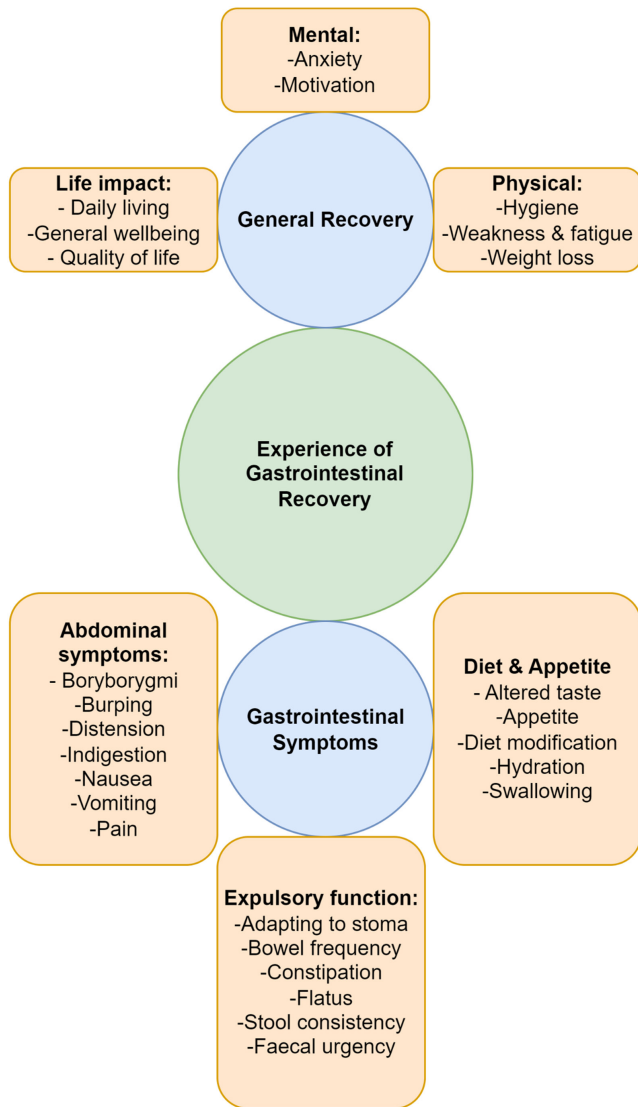
*General wellbeing:* participants made general observations on their general physical status. These often referred to how different they felt from normal. This included statements related to 'starting to feel alive again', and how their recovery stopped them living a 'normal' life.

Characteristic	Hospital site				
	A (N=5) <sup>a</sup>	B (N=6) <sup>a</sup>	C (N=7) <sup>a</sup>	D (N=5) <sup>a</sup>	E (N=6) <sup>a</sup>
Sex					
Female	1 (20)	3 (50)	1 (14)	5 (100)	2 (33)
Male	4 (80)	3 (50)	6 (86)	0 (0)	4 (67)
Age (years)	64 [57, 67]	64 [52, 78]	56 [30, 62]	67 [61, 70]	72 [70, 75]
Ethnicity					
Asian–Indian	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)
Black African	1 (20)	0 (0)	0 (0)	0 (0)	0 (0)
None stated	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)
White	4 (80)	6 (100)	6 (86)	4 (80)	6 (100)
Type of presentation					
Elective	4 (80)	1 (17)	5 (71)	5 (100)	3 (50)
Emergency	1 (20)	5 (83)	2 (29)	0 (0)	3 (50)
Surgical approach					
Minimally invasive	2 (40)	3 (50)	0 (0)	1 (20)	3 (50)
Open	3 (60)	2 (33)	7 (100)	3 (60)	2 (33)
Conservatively managed small bowel obstruction	0 (0)	1 (17)	0 (0)	1 (20)	1 (17)
Speciality					
Gastrointestinal	4 (80)	6 (100)	6 (86)	0 (0)	4 (67)
Gynaecology	0 (0)	0 (0)	1 (14)	5 (100)	0 (0)
Urology	1 (20)	0 (0)	0 (0)	0 (0)	2 (33)

**TABLE 1** Participant demographics.

Note: A–E are anonymised recruiting hospital.

<sup>a</sup>n (%) or median [interquartile range].



**FIGURE 1** Patient experiences of gastrointestinal recovery.

*Quality of life:* participants often talked about their quality of life, describing the impact of their surgical admission and recovery on this. This often crossed over with issues related to pain, and ability to complete activities of daily living.

## Mental

*Anxiety:* many participants reported feeling anxious about different aspects of their recovery. Some reported anxiety related to faecal urgency or potential problems with a stoma, such as leakage. Others reported anxiety related to their inability to perform their activities of daily living. Participants also discussed their anxiety around bowel function deteriorating during recovery due to actions they took, such as eating or exercise.

*Motivation to recover:* two participants discussed their motivation to recover. This addressed concepts such as how a positive attitude can help recovery, particularly when translated into action. The idea

of encouraging recovery by eating and light activity was discussed by another participant.

## Physical

*Hygiene:* physical hygiene during recovery was addressed by three participants. Highlighted issues included poor oral hygiene during a period of ileus due to lack of enteral intake of fluid eventually manifesting into oral thrush. The other two participants discussed feeling dirty due to soiling related to urge incontinence or leakage of the stoma appliance.

*Weakness and fatigue:* weakness and fatigue were commonly reported. During their recovery, participants reported excessive sleeping and becoming easily fatigued. This was particularly challenging for participants who reported being quite active preadmission. They referred to diminished energy levels and an inability to focus for long periods of time. This was still present when interviews were conducted around a month following admission.

*Weight loss:* this was a commonly reported experience among participants and was viewed negatively as it included both body fat and muscle. Participants linked this to issues such as periods of starvation and difficulty digesting food during gastrointestinal recovery. They also reported that impaired appetite or changes to sense of taste were linked to this. Weight loss was suggested as a cause of diminished energy and feelings of fatigue.

## Theme 2: gastrointestinal symptoms

### Abdominal symptoms

*Borborygmi:* participants referred to rumbling noises in their gut as a marker of gut recovery of function. They particularly noted this after eating.

*Burping:* participants discussed an increased frequency of burping during their recovery. This was typically noted as being significantly more frequent than normally experienced. This was not viewed with strong positive or negative connotations, and was attributed directly to their operation.

*Distension:* bloating was frequently discussed, and typically in negative terms. This was discussed as causing marked discomfort. Participants noted that this often improved with the passing of wind or stool. Some participants noted that distension persisted for several weeks following surgery.

*Indigestion:* 19 participants discussed the occurrence of indigestion, both during admission and following discharge. Participants often associated this with subsequent vomiting. One participant noted worsening indigestion and was readmitted to hospital with ongoing ileus.

*Nausea:* nausea was a commonly reported symptom. This was often reported as an early symptom of gut dysfunction, and was associated with vomiting. Participants also described

TABLE 2 Data saturation table.

Case	General recovery								Gastrointestinal symptoms				
	Life impact			Mental		Physical			Abdominal symptoms				
	Daily living	General well-being	Quality of life	Anxiety	Motivation	Hygiene	Weakness and fatigue	Weight loss	Borborygmi	Burping	Distension	Indigestion	Nausea
1							X				X		X
2	X						X		X			X	X
3	X		X	X		X	X	X			X	X	X
4	X	X		X	X	X	X		X		X		X
5											X		X
6	X		X	X									
7	X		X	X							X		X
8	X				X		X	X					X
9	X			X				X			X		
10	X		X	X				X		X			X
11	X						X	X		X		X	X
12		X					X	X			X		X
13							X					X	X
14	X	X	X				X	X			X		X
15	X										X		X
16													X
17	X		X				X			X	X	X	
18			X	X									X
19			X									X	X
20	X	X	X										X
21	X		X							X			
22			X				X				X	X	X
23													X
24	X		X				X	X			X	X	X
25			X								X		X
26		X										X	
27											X		
28							X				X		X
29				X			X	X					
Total	15	5	13	8	2	2	14	10	2	4	15	9	22

the negative impact of nausea on appetite and the desire for food. Most participants reported resolution of this within a few days; however, some participants reported symptoms lasting for 2 weeks or more.

**Vomiting:** this was a commonly reported symptom. The majority of participants reported multiple episodes of this. They often noted related symptoms of nausea, indigestion and pain related to this. Participants discussed this as being an outcome of food or drink 'building up in the stomach'. This lasted up to a week for some participants.

**Pain:** pain was a commonly discussed symptom. This was sometimes described as general pain, associated with symptoms such as distension. At other times it was localized to the abdominal wound.

## Diet and appetite

**Altered taste:** participants frequently reported an altered sense of taste, which persisted for 6 weeks for some. Several participants reported that this led to disappointment when eating their first meal after surgery, with absent or muted taste. One participant noted particular changes in aspects of their sense of taste, with sweet flavours being less prominent.

**Appetite:** comments highlighted the absence of appetite in the immediate postoperative period, describing a lack of interest in food even though they recognized the importance of eating. Many participants reported that this returned soon after surgery with the resolution of other symptoms such as vomiting and nausea. A small





the regular activity of the stoma, and how timing and frequency of meals could influence output. They also highlighted dietary modifications needed for some types of stoma. Participants highlighted benefits, including avoiding the need to use the toilet frequently in states of high activity as this could be controlled with the bag.

**Bowel frequency:** participants often commented on their inability to pass stool in the early postoperative period, and this was viewed negatively. Different recovery trajectories were reported. These included return to normal patterns of passing stool, less frequent motions than baseline or increased frequency with changed consistency. Symptoms of increased frequency often resolved a few weeks after surgery.

**Constipation:** this was reported by several participants, and typically referred to the early phases of gut recovery and inability to pass stool. Symptoms of pain and difficulty in evacuation were described. Some participants reported the need to use laxatives to aid evacuation, and this persisted beyond discharge.

**Flatus:** participants indicated that the passage of flatus following surgery was felt to be a positive thing. Many remarked on excessive passage of flatus in the initial phases of recovery. Some participants noted ongoing increased frequency of flatus lasting for a few weeks postsurgery.

**Stool consistency:** stool consistency was discussed by several participants, almost all describing a consistency which was looser than they normally experienced. This wasn't always associated with increased frequency. Most participants who had experienced this reported resolution within weeks of discharge.

**Faecal urgency:** some participants described the need to run to the toilet to open their bowels. This was typically in the early stages of recovery, and was associated with loose motion. The symptoms were felt to be distressing, and led to soiling in some cases.

## DISCUSSION

This study has developed a thematic conceptual framework which represents patient experiences of early gastrointestinal recovery, across a range of surgical specialities. It has highlighted symptoms and changes during recovery related to the gastrointestinal tract, as well as more systemic symptoms.

The 'GI-2' outcome measure is commonly used in early gastrointestinal recovery. This includes tolerance of diet and passage of stool [18]. Whilst this may be favoured as an easily measured binary outcome, this does not reflect the experiences of patients reported in this study. Whilst it captures the event of passing stool, it does not consider aspects of defaecation such as frequency, consistency and urgency. Participants reported these as ongoing symptoms with negative impact on their well-being for several weeks after surgery. These downstream and out-of-hospital aspects of gastrointestinal recovery are important for patients.

One of the key findings of this study is the range of symptoms experienced by patients across gastrointestinal functions. Previous work has demonstrated that studies largely focus on ability to pass flatus or stool and/or tolerate diet [2]. From this study, it is clear that

these do not adequately relate to the symptoms and experiences that matter to patients. Recently developed core outcome sets for ileus and small bowel obstruction have highlighted the importance of recording multidimensional aspects of gastrointestinal recovery [3, 4]. Development of a PROM for gastrointestinal recovery will also aid the multidimensional reporting of gastrointestinal recovery, as well as demonstrating how these changes affect patients beyond discharge.

This qualitative work also highlights that those with the formation of a new stoma as part of their care may have different gastrointestinal recovery trajectories from those with intestinal continuity. It demonstrates ongoing adaptation of diet and lack of control over stoma function as negative aspects of gastrointestinal recovery. These do reflect early experiences which may change overtime.

This study does have limitations. The findings of this study would need further assessment in a larger population to influence further approaches to early gastrointestinal recovery. Patient outcomes such as anastomotic leak were not collected, nor were data on whether surgery was for benign or malignant disease. We accept it is plausible that this could have an impact on the themes during recovery; however, we felt this would add excessive detail to a qualitative study that was designed to be broad. Efforts were made to sample across acuity and speciality of surgery, meaning a rounded experience of recovery is presented. Additionally, we achieved data saturation within our study and this will be validated in a larger population during subsequent PROM development. Qualitative methodology was chosen for this study as it provides an in-depth assessment of a small number of subjects. It is designed to be exploratory and allows the generation of theoretical frameworks around gastrointestinal recovery which can later be employed in a larger population as part of the development of a PROM [11].

However, the study has many strengths. Interviews were conducted by experienced interviewers and supported by experienced qualitative researchers. Patient representatives were involved in the design of the study and also in the generation of the framework. Participants were sampled across a range of abdominal conditions, and from a range of centres, increasing the variation of experience and limiting bias.

This study forms part of the NIHR funded PRO-diGI study, which aims to develop a PROM for early gastrointestinal recovery. The findings are therefore subjected to subsequent development. Despite this, the results of this substudy provide useful insights for those caring for patients with ileus or intestinal obstruction. These include considering how changes in taste and appetite may persist long after surgery and may need further attention at follow-up, including referral for dietetic input. Clinicians should also consider that the classical definition of recovery of 'passage of stool and tolerance of diet' fails to take into account the variations in bowel function during recovery and neglects several symptoms which are troublesome to patients, such as frequency. These symptoms should be considered and explored with patients during gastrointestinal recovery—with appropriate treatment if clinically indicated.

In conclusion, the patient experience of recovery from acute gastrointestinal failure in this study contains numerous previously unreported symptoms within the interventional literature. The results of this study have enabled development of a conceptual framework which will provide the basis for the development of a new PROM specific to early gastrointestinal recovery after surgery or transient gastrointestinal failure.

## AUTHOR CONTRIBUTIONS

**Daniel M. Baker:** data curation, formal analysis, visualization, writing – original draft, methodology. **Stephen J. Chapman:** analysis, writing, methodology. **Benjamin D. Thomas and Benjamin J. Thompson:** data collection, writing – revisions. **Robert Arnott and Sue Blackwell:** formal analysis, visualization, writing – revisions, methodology. **Deena P. Harji:** visualization, writing – original draft, methodology. **Gabrielle Thorpe and Georgina L. Jones:** formal analysis, writing – original draft, methodology. **Matthew J. Lee:** data curation, formal analysis, visualization, writing – original draft, methodology.

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## CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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