Developing a Patient Reported Experience Measure for Gastrointestinal Procedures (ENDOPREM)

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Abstract

Background: Gastrointestinal (GI) endoscopy and computed tomography colonoscopy (CTC) are important diagnostic and therapeutic tools in the investigation and management of gastrointestinal diseases. Current measures of patient satisfaction and experience within GI endoscopy are clinician derived and measured. This study aims to develop a patient reported experience measure (PREM) specific to GI procedures, derived from the patient's perspective.

Methods: The study comprised three phases. Phase 1: This qualitative phase involved semi-structured interviews with patients who had recently undergone endoscopy/CTC. Thematic analysis identified important aspects of the patient experience. Phase 2: A questionnaire bank was developed from the thematic analysis. An iterative process of review and revision within the wider study team refined the questions. Rounds of cognitive interviews with patients who had undergone GI procedures were used to further refine the questionnaire. Phase 3: The resultant PREM was prospectively administered, for self-completion, to 1652 patients following a GI procedure. IBM® SPSS® 24 was used to investigate the psychometric properties of the instrument.

Results: Phase 1: 35 participants participated in semi-structured interviews. Six over-arching themes were identified: anxiety, expectations, information & communication, embarrassment & dignity, choice &control and comfort. Phase 2: Areas related to these themes were structured by procedural stage. Ten rounds of review and revision within the study team were conducted, followed by five rounds of cognitive interviews (total n=15). Phase 3: 799 participants completed the questionnaire (response rate= 48.4%). Of the 59 questionnaire items, a 'ceiling' effect was present in 24. No questions demonstrated 'floor' effects. Individual item completion rates were high, with only three items having >5% missing. Exploratory factor analysis identified potential scales within the questionnaire.

Conclusion: The ENDOPREM™ is a tool which assesses all aspects of the GI procedure experience. Potential future uses include assessing patient experience in routine care or comparing experience associated with different endoscopic interventions in trials.

Dedication

This thesis is dedicated to my parents, Kenneth and Lorraine, and to my sister, Lynsey. Thank you for your unfailing support and encouragement.

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Table of Contents

List of Tables

List of Figures

List of Appendices

List of Abbreviations

ADR	Adenoma Detection Rate
ANOVA	Analysis of variance
ASGE	American Society of Gastrointestinal Endoscopy
BCSP	Bowel Cancer Screening Programme
BSG	British Society of Gastroenterology
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CQC	Care Quality Commission
CTC	Computed tomography colonography
EFA	Exploratory factor analysis
ESGE	European Society of Gastrointestinal Endoscopy
EQIP	Endoscopy Quality Improvement Programme
GESQ	Gastrointestinal Endoscopy Satisfaction Questionnaire
GI	Gastrointestinal
GP	General Practitioner
GRS	Global Rating Scale
HRA	Health Research Authority
JAG	Joint Advisory Group on Gastrointestinal Endoscopy
JP	Joanne Patterson
KPI	Key Performance Indicator
LM	Lesley McGregor
LN	Laura Neilson
LS	Linda Sharp
mm	millimetres
NHS	National Health Service
NRES	National Research Ethics Service
NRS	Numerical rating scale
OECD	Organisation for Economic Co-operation and Development
OGD	Oesophagogastroduodenoscopy
PCA	Principal Components Analysis
PREM	Patient reported experience measure
PROM	Patient reported outcome measure
STDH	South Tyneside District Hospital
TNE	Trans-nasal endoscopy

UK	United Kingdom
VAS	Visual analogue scale
VRS	Verbal rating scale

Chapter One: Introduction

1.1. Overview of gastrointestinal procedures

Various gastrointestinal (GI) procedures exist to evaluate the upper and lower GI tracts. Widely performed endoscopic procedures include oesophagogastroduodenoscopy (OGD, upper GI endoscopy) and colonoscopy. 35% of the population will require a GI endoscopy at some point in their life and approximately 1.5 million procedures are performed in England alone each year (Seeff *et al.*, 2004; Department of Health Knowledge and Intelligence Team, 2010; NHS England, 2016). In England, OGD accounts for 39.0% of all endoscopic procedures and colonoscopy accounts for 32.6% (Centre for Workforce Intelligence, 2017). Most endoscopic procedures are undertaken in patients over age 35 (approximately 91%), particularly in patients aged 65-69 (Centre for Workforce Intelligence, 2017). The estimated annual number of OGDs performed in the United States of America (USA) is 6.1 million, compared with 11.0 million colonoscopies (Peery *et al.*, 2019). Most procedures in the USA are undertaken in adults aged 18-64 years, with fewer OGDs and colonoscopies undertaken in those aged over 65 years (Peery *et al.*, 2019).

Generally, GI endoscopy may be performed by consultants (gastroenterologists or surgeons), non-medical endoscopists (such as nurse endoscopists) or non-consultant grade medical endoscopists, such as associate specialists and trainees.

Other GI endoscopic procedures include flexible sigmoidoscopy, endoscopic retrograde cholangio-pancreatography (ERCP) and endoscopic ultrasound (EUS), but these are not considered further within this body of work.[1]

Computed tomography colonography (CTC) is a radiological alternative to colonoscopy for visualising the lower GI tract. Precise data for CTC are difficult to establish, however; it is estimated that 100,000 CTCs are undertaken in England annually (Obaro *et al.*, 2018). CTCs are performed by radiographers, but nursing

[1] OGD and colonoscopy are the most commonly performed procedures, with CTC the alternative to colonoscopy. For this reason, this thesis focuses on these three procedures.

staff may also be present. The images are later interpreted by a radiologist (after the patient has left the department).

Broadly, these procedures may be undertaken in symptomatic patients (for example, to exclude cancer), as surveillance procedures to monitor a disease, screening procedures or to enable therapy to be undertaken.

For the purposes of this thesis, OGD, colonoscopy and CTC will be referred to collectively as 'GI procedures.'

1.1.1. Oesophagogastroduodenoscopy (OGD)

Oesophagogastroduodenoscopy (OGD) involves passing a thin, flexible endoscope (approximately 10mm diameter) into the oesophagus, stomach and duodenum via the mouth. This allows visualisation of the upper GI mucosa and biopsies, in addition to therapeutic uses in patients with, for example, acute upper GI bleeding. OGD is considered the 'gold standard' investigation of the upper GI tract (Harris, 2013; Beg *et al.*, 2017). Indications for OGD include; suspected upper GI cancer, for example, patients presenting with dysphagia or weight loss in the context of reflux or dyspepsia; non-urgent indications such as dyspepsia or to take small bowel biopsies for the diagnosis of coeliac disease; surveillance and screening procedures, for example, surveillance of Barrett's oesophagus or 'screening' for oesophago-gastric varices in patients with portal hypertension (Harris, 2013; Fitzgerald *et al.*, 2014; Ludvigsson *et al.*, 2014; National Institute for Health and Care Excellence, 2015).

Patients may have the procedure with local anaesthetic throat spray or intravenous conscious sedation, defined by the American Society of Gastrointestinal Endoscopy (ASGE) as a "drug-induced depression in the level of consciousness" where patients are "able to make purposeful responses to verbal or light tactile stimulation" (ASGE Standards of Practice Committee *et al.*, 2018). Alternatively, deep sedation using propofol administered by an anaesthetist can be used, however, this practice is rare in the United Kingdom (UK) (Sidhu *et al.*, 2019). During OGD, carbon dioxide or air are used to distend the upper GI tract and allow both insertion of the endoscope and mucosal visualisation.

Although OGD is traditionally performed using the per-oral route, transnasal endoscopy (TNE) using an ultrathin endoscope is increasingly being used as an

alternative (Parker *et al.*, 2016). The proposed benefits of this approach are reduced need for conscious sedation, superiority over per-oral OGD in terms of reduced cardiovascular stress and reduced gagging due to less oropharyngeal irritation (Preiss *et al.*, 2003; Alexandridis *et al.*, 2014; Parker *et al.*, 2016).

1.1.2. Colonoscopy

Colonoscopy is the most well-established procedure for investigation of the lower GI tract. Following a regimen of laxative preparation to clear colonic contents, a thin, flexible colonoscope (approximately 12mm) is passed into the colon via the anus. This allows mucosal visualisation and detection of pathology, biopsy of areas of interest and therapeutic techniques such as polyp removal. During colonoscope insertion, carbon dioxide or air are blown into the colon to distend it and allow both insertion and mucosal visualisation. Various indications for diagnostic colonoscopy exist which can be grouped into three broad categories. 'Alarm symptoms' are those considered to be suggestive of cancer, for example, blood mixed in with the stool or iron deficiency anaemia in males and non-menstruating females (National Institute for Health and Care Excellence, 2015). More routine symptomatic indications include persistent diarrhoea, abnormalities seen on radiological investigation and abdominal symptoms in the context of a raised faecal calprotectin (a marker of colonic inflammation) (Harris, 2013). The third group includes surveillance and screening of patients, for example, surveillance of patients with known inflammatory bowel disease (IBD), those with previous colonic polyps or a family history of colorectal cancer (Cairns *et al.*, 2010). Colonoscopy is used within many screening programmes including the National Health Service (NHS) Bowel Cancer Screening Programme (BCSP). The English NHS BCSP sends faecal occult blood or faecal immunochemical testing kits to individuals aged 60-74 and offers colonoscopy to those who return a positive result (Public Health England, 2019). It is also performed within the English BCSP following positive flexible sigmoidoscopy where polyps are found and a 'completion' colonoscopy is performed. It may also be used as a primary screening tool, for example, in Poland and USA (Rex *et al.*, 2000; Zavoral *et al.*, 2009).

In the United Kingdom, colonoscopy is usually performed either under conscious intravenous sedation, with analgesic use of nitrous oxide or entirely unsedated (Sidhu *et al.*, 2019). Deep sedation (usually propofol) is used widely internationally

but is not commonly used for diagnostic colonoscopy in the UK and tends to be reserved for complex, prolonged endoscopic procedures (Sidhu *et al.*, 2019).

1.1.3. Computed Tomography Colonography (CTC)

Computed tomography colonography (CTC) is a relatively new radiological approach which provides cross-sectional imaging of the colon (Vining, 1996). Patients are required to drink oral contrast prior to the procedure, with or without laxative medication to clear the bowel. A thin tube is inserted into the rectum to insufflate carbon dioxide into the bowel. A CT scan is then performed with the patient in the supine and prone positions, which produces two and three dimensional images of the bowel (Rex *et al.*, 1999). Although there is no significant difference in detection rates of colorectal cancer and large polyps when compared to colonoscopy, smaller lesions may be missed by CTC (Atkin *et al.*, 2013; Halligan *et al.*, 2015). As cross-sectional images are obtained, incidental extra-colonic findings may be detected, necessitating at least further discussion with the patient if not further investigation (Hanly *et al.*, 2012). It is not possible to take biopsies or remove polyps at CTC and there is a small cancer risk due to radiation exposure (Brenner *et al.*, 2005; Steward *et al.*, 2014). The indications for CTC are similar to colonoscopy, however, due to the limitations of the test in terms of biopsies, the test tends to be favoured in patients who may tolerate colonoscopy less well, or who are at lower risk of significant pathology (Jensch *et al.*, 2010; Neilson *et al.*, 2018). CTC is also used within the NHS BCSP for patients with positive FOBt tests who are either unsuitable for colonoscopy or who have an incomplete colonoscopy (British Society of Gastrointestinal and Abdominal Radiology, 2014). CTC is seen as less burdensome by patients in terms of bowel preparation and discomfort when compared with colonoscopy (Jensch *et al.*, 2010)

1.2. Quality of care

1.2.1. Quality of care: the concept

Quality of care is a complex concept, but can be considered broadly as the ability of patients to access care and the effectiveness of care in terms of clinical outcomes and experience (Campbell *et al.*, 2000; Hanefeld *et al.*, 2017). A 2008 report into improving quality in the NHS recommended that quality of care should encompass three main domains: patient safety, effectiveness of care and patient experience (Darzi, 2008). The Francis Report detailed the outcomes and recommendations of a public inquiry investigation into an English NHS Trust with high mortality rates, concluding that loss of sight of patients at the centre of care contributed to many of the clinical quality issues raised (Francis, 2013). The report recommended that patient experience should be measured, reported and acted upon.

1.2.2. Defining patient experience

Although they are different concepts, the terms ‘patient experience’ and ‘satisfaction’ have often been used interchangeably. The use of the term ‘patient satisfaction’ in the literature is widely variable and as a concept it is complex with uncertain constructs (Williams, 1994; Gill *et al.*, 2009; Batbaatar *et al.*, 2015). Historically, surveys used to measure satisfaction have questionable validity and reliability as it is difficult to discriminate between levels of satisfaction, which is usually rated highly (Williams, 1994; Gill *et al.*, 2009). Items included in previous patient satisfaction surveys, such as hospital amenities, are seen as separate to care quality by patients (Cleary, 2016). Patient priorities with regards specific diseases or procedures may differ from overall satisfaction with care and identifying these priorities could allow more specific improvements to be made. This has led to the development of the concept of measuring patient experience.

Similarly to the concept of satisfaction, there is no single definition of ‘patient experience’ (Wolf *et al.*, 2014). The NHS Institute for Innovation and Improvement describes patient experience as “what the process of receiving care feels like for your patients” (NHS Institute for Innovation and Improvement, 2013). In contrast with satisfaction, patient experience encompasses what actually happens during a healthcare episode and to what degree patient’s needs are met (Beattie *et al.*, 2015). Experience questionnaires do not ask patients to rate their treatment/ care but

instead ask whether, or to what extent, certain processes occurred during a healthcare episode (Beattie *et al.*, 2015). The Picker Institute has defined eight principles of patient centred care and these encapsulate what are considered to be important aspects of patient experience; respect for patients' preferences; coordination and integration of care; information, communication and education; physical comfort, emotional support and alleviation of fear and anxiety; involvement of family and friends; continuity and transition; access to care (Picker Institute Europe, 2019). The Picker Institute describes the importance of examining specific events during a care episode but also notes that patients are usually asked a question regarding 'overall satisfaction' (Redding *et al.*, 2009). The rationale for this is that this question is likely to be informed by answers to the preceding experience questions and the responses can be analysed to identify which domains correlate most with overall satisfaction (Redding *et al.*, 2009).

1.2.3. Patient experience as a healthcare priority

Over recent years, increased emphasis has been placed on patient experience in healthcare. A systematic review which explored the relationship between patient experience and clinical outcomes found that overall, a positive association exists between patient experience and health outcomes, healthcare resource use, care delivery and adverse events (Doyle *et al.*, 2013). For example, overall patient experience ratings were positively associated with adherence to clinical guidelines in acute myocardial infarction. The NHS Outcomes Framework (a set of indicators used to measure health outcomes in the NHS) stresses the role of a positive patient experience, the need to measure care as perceived by patients, and the need for healthcare systems to respond to and act on such feedback (Department of Health, 2012b).

1.2.4. Measuring patient experience

Patient Reported Experience Measures (PREMs) measure patients' perceptions of their experience of healthcare. They should address aspects of care that are important to the patient (Coulter *et al.*, 2009; Hodson *et al.*, 2013). This implies that patients should be involved in the development of such measures, to ensure that all aspects of care important to patients are addressed.

PREMS are a separate entity from Patient Reported Outcome Measures (PROMs). The latter measure patients' perceptions of their health status, functional status and health-related quality of life (Higginson *et al.*, 2001; Coulter *et al.*, 2009). An example of such a measure is the EuroQol EQ-5D, which measures health related quality of life across five domains: mobility, self-care, usual activities, pain/discomfort, anxiety/depression and overall health (Herdman *et al.*, 2011). This measure is not disease or procedure specific. Within the NHS and internationally, more focused PROMs have been developed for specific conditions, e.g. patients undergoing hip and knee replacement (Feng *et al.*, 2014; NHS Digital, 2018; Prodinger *et al.*, 2018) or those with colorectal cancer (van der Hout *et al.*, 2019). These PROMs examine the effect of the condition on a patient's quality of life.

In England, the Care Quality Commission (CQC) undertakes annual surveys as part of the NHS Patient Survey programme, including: the annual inpatient survey, community mental health service surveys, cancer patient experience survey and the friends and family survey (Care Quality Commission, 2016). The Picker Institute has developed patient experience questions which can be added to patient surveys, however, these are generic and not procedure-specific (King *et al.*, 2013). These cover issues such as: whether patients' needs are assessed, patient involvement in decisions, support from social services and who to contact if the patient has questions (King *et al.*, 2013). Outpatient surveys are undertaken on a cyclical basis, including those treated for cancer (Quality Health, 2019). These surveys were designed by the Picker Institute, Europe, using a number of pilot studies to ensure that patient priorities in terms of experience were addressed (Reeves *et al.*, 2002). The surveys are used to measure and monitor patient experience both nationally and at individual healthcare institutions. However, studies analysing the impact and use of survey results suggest that their use should be extended to inform quality standards and improve patient experience (DeCourcy *et al.*, 2012; Groene *et al.*, 2015).

The realisation of the importance of measuring and acting upon patient experience is not restricted to the UK. In Europe, the Organization for Economic Cooperation and Development (OECD) has identified that patient experience should be measured as part of the Health Care Quality Indicators Project (Arah *et al.*, 2006; OECD, 2017). In the United States of America (USA), patient experience is measured using Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys, which focus

on areas such as communication, access to care and information and customer service (Agency for Healthcare Research and Quality, 2014).

1.2.5. Quality of gastrointestinal procedures

Patient experience is also becoming an increasingly recognised aspect of quality within GI procedures, however, there are no fixed standards on how this should be measured and it is suggested as a research priority (Bisschops et al., 2016; Rees et al., 2019).

In endoscopy, high quality investigations are crucial to ensure patient safety and to maximise detection of pathology. For endoscopic procedures, variation in quality has been demonstrated; for example, an audit of UK colonoscopy practice found significant variation in quality of colonoscopy procedures across 68 English endoscopy units (Bowles *et al.*, 2004). Such studies have prompted quality improvement programmes and development of key performance indicators (KPI), which are measures used to assess performance against an agreed standard (Rex et al., 2006; Gavin et al., 2013; Rutter et al., 2016; Rees et al., 2016; Bisschops et al., 2016). In the UK, the British Society of Gastroenterology (BSG) has developed an Endoscopy Quality Improvement Programme (EQIP) with the aim of raising quality across all endoscopic procedures by identifying and supporting achievement of KPIs and standardising training pathways (Rees et al., 2019). KPIs tend to be related to procedural elements, pathology detection and complication rates, however, more recently items such as ensuring the provision of patient information sheets have been included (Bisschops *et al.*, 2016; Beg *et al.*, 2017).

Within the field of colonoscopy, certain KPIs have been shown to correlate with clinical outcomes; for example, colonoscopists with low adenoma detection rates (ADR; proportion of procedures where at least one adenoma is found, expressed as a percentage) have significantly higher rates of post colonoscopy colorectal cancers (Kaminski et al., 2010; Corley et al., 2011; Wieszczy, et al., 2017). This has led to innovations aimed at improving ADR, such as new technology to aid detection of adenomas, educational sessions with feedback on performance and the implementation of evidence-based interventions into routine practice (Rajasekhar *et al.*, 2015; Wallace *et al.*, 2017; Ngu *et al.*, 2018).

Variation in practice and quality in upper GI endoscopy have been evidenced by variable rates of 'missed' cancers, that is, upper GI cancers found following a normal OGD (Menon *et al.*, 2014; Veitch *et al.*, 2015). Quality improvement initiatives and KPIs have been developed following the success of similar approaches in colonoscopy (Rees *et al.*, 2019). These KPIs include procedural aspects, such as time taken to examine the stomach, biopsy protocols, pre-procedural aspects including provision of patient information sheets and broader recommendations such as the minimum annual procedure count to maintain endoscopist competence (Park *et al.*, 2015; Bisschops *et al.*, 2016; Beg *et al.*, 2017). In addition, patient comfort is considered a performance measure and has been highlighted as a research priority area (Rees *et al.*, 2016).

The incidence of post-imaging colorectal cancers following a normal CTC is low, i.e. patients diagnosed with colorectal cancer following a normal CTC (Obaro *et al.*, 2018). Standards have been established to optimise technique and minimise missed lesions (Neri *et al.*, 2013). These standards include technical aspects of the procedure, such as patient position, but also include standards for reporting and interpreting CTC (Burling *et al.*, 2010; Neri *et al.*, 2013). Furthermore, these recommendations include provision of written information for patients and informed consent.

1.2.6. Measuring patient experience of GI procedures

A systematic review demonstrated that patient experience is linked with adherence to treatment and utilisation of preventive care (Doyle *et al.*, 2013). This may be particularly important in the context of GI procedures, as patients may require repeat tests to monitor conditions or require treatment based on the procedure findings. There is some limited evidence within GI procedures that suggests that colonoscopists who deliver high quality procedures also provide better patient experience (Ekkelenkamp *et al.*, 2013). One study, conducted in four English centres, compared polyp detection rate (PDR), sedation use and caecal intubation rate (CIR) with nurse-reported comfort scores and patient responses to a patient satisfaction question(Ekkelenkamp *et al.*, 2013). It found that colonoscopists with better pathology detection and caecal intubation tended to have better comfort and satisfaction scores.

Current practice nationally is variable in terms of measuring patient experience in endoscopy. In the United Kingdom, the Joint Advisory Group on Gastrointestinal Endoscopy (JAG) grants accreditation status to endoscopy units which meet quality assurance standards across four domains: clinical quality, quality of the patient experience, workforce and training (Joint Advisory Group on Gastrointestinal Endoscopy, 2016a). Assessment of patient experience is undertaken using the Global Rating Scale (GRS) (Joint Advisory Group on Gastrointestinal Endoscopy, 2016b). However, the GRS simply states that patient experience should be measured and advises that a range of methods may be employed, without recommending a standardised or optimal approach. This allows individual endoscopy units to choose how to measure patient experience and means that results are not comparable between units.

1.2.7. Limitations of available tools to measure GI procedure experience

A systematic review identified available tools which measure patient experience of GI procedures and found that a variety of methods are reported in the literature (Brown *et al.*, 2015). Common themes covered by questionnaires included anxiety, satisfaction and comfort or pain (Brown *et al.*, 2015). However, tools were developed from clinicians' perceptions and expert opinion. Furthermore, the timing of administering such feedback tools varied; some tools required patients to complete surveys in the endoscopy department as researchers were concerned that sedation would affect their later recall, however, others were completed once patients had left the department and had test results. Currently, no patient-derived measures specific to GI procedures exist (Brown *et al.*, 2015).

1.2.8. Current approaches to measure GI procedure experience

For colonoscopy procedures undertaken as part of the English national screening programme, data on patient experience is collected routinely by the BCSP, both for colonoscopy and CTC. A postal questionnaire sent thirty days after the procedure asks detailed questions about the screening and invitation process, followed by questions about information leaflets, comfort, follow up information and symptoms on discharge (Ghanouni *et al.*, 2016). These responses are then reviewed at regular local BCSP meetings. This tool is not suitable for use across the symptomatic service as it focuses on the screening process. Furthermore, it is not patient-derived.

Patient experience of OGD, colonoscopy or CTC in the NHS symptomatic service is not routinely measured.

Across Europe, the European Society of Gastrointestinal Endoscopy (ESGE) has set out quality standards for lower GI endoscopic procedures, which recommend measuring self-reported patient experience using a 'validated scale' (Kaminski et al., 2017). The guideline acknowledges the lack of a standardised approach.

The Gastronet is a commonly used questionnaire for assessing patient experiences of endoscopy in Europe (Hoff *et al.*, 2006; Kaminski *et al.*, 2017). This clinician-derived measure asks patients to complete a short questionnaire on the day following their colonoscopy. It includes three questions about discomfort (before and after the procedure) and one question about satisfaction with the information given about the test and results (Hoff *et al.*, 2006).

In the USA, the American Society of Gastrointestinal Endoscopy (ASGE) recommends that a general satisfaction scale, which has been modified for endoscopic procedures, is used to assess patient experience (Johanson *et al.*, 2000; Rizk *et al.*, 2015). This comprises nine questions which cover: waiting time for an appointment, waiting time in the department for the procedure, personal manner of the endoscopist and support staff, explanation, overall rating and willingness to attend for repeat procedures by the same endoscopist and at the same facility (Johanson *et al.*, 2000). The limitations of this scale are that it is not specific to GI procedures, was not developed with patient input and it has been pointed out that this does not assess comfort (Yacavone *et al.*, 2001).

Patient experience of CTC in the NHS symptomatic service (i.e. patients with symptoms who are not undergoing BCSP procedures) is not routinely measured (Hansmann *et al.*, 2013). Measurement of patient experience and satisfaction of CTC in research settings tend to focus on comfort and bowel preparation, excluding other aspects of the patient experience (Zueco Zueco *et al.*, 2012; Gareen *et al.*, 2015). Earlier studies comparing CTC with other imaging or endoscopic modalities used clinician-derived questionnaires including the above components but also asked questions regarding patient preference (Taylor *et al.*, 2003; Jensch *et al.*, 2010).

The Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ) has been described as a measure of patient experience (Hutchings *et al.*, 2015). This tool was

designed with patient input, however, questionnaire items were identified through review of literature and guidelines, rather than directly from patients themselves (Hutchings *et al.*, 2015). This means that it is not clear if all aspects of patient experience are covered by the tool.

1.2.9. Developing PREMs

The systematic development and validation of PREMs has been undertaken in a range of specialties and disease conditions, for example, cancer care, paediatric emergency care and sickle cell disease (Davies *et al.*, 2011; Department of Health, 2012a; Chakravorty *et al.*, 2018). For example, the paediatric emergency care PREM involved the Royal College of Paediatrics and Child Health collaborating with the Picker Institute, Europe to devise a questionnaire which was patient-derived and covered all aspects of the emergency care experience, as reported by patients (Davies *et al.*, 2011). The methodology involved four stages, including: literature review to identify current tools and aspects contributing to patient experience; a qualitative stage including relevant patients to identify themes important to patients which could be used to design the questionnaire; questionnaire design; and cognitive testing of the questionnaire (Jenkinson *et al.*, 2002; Davies *et al.*, 2011).

The remainder of this thesis describes the methodological approach used to systematically develop and test the Newcastle ENDOPREM™- the first patient-derived PREM for use in GI procedures. This PREM may be used in the future in routine practice to monitor experience in an individual clinical site or compare experiences between sites or in research to compare experiences of different procedures.

Chapter Two: Study Overview

2.1. Overall Study Aims

This study aimed to develop a fully patient-derived PREM - named ENDOPREM™ - specific to upper and lower GI procedures.

2.2. Study Design

This mixed methods sequential study comprised three phases. The aims and overview of each phase are described below.

2.2.1. Phase One: Describing Patient Experience of GI Procedures

The aim of this phase was to explore in depth and detail the patient experience of OGD, colonoscopy and CTC (referred to collectively as GI procedures in this work), based on accounts of patients who had undergone these procedures. Semi-structured interviews were undertaken with patients who had undergone GI procedures. Thematic analysis was undertaken to identify over-arching themes which were organised by procedure stage. This phase was used to identify the aspects of experience that matter to patients and therefore to generate initial item content as a basis for questionnaire development. Furthermore, this phase was used to identify whether it was possible to develop a PREM that would work across different GI procedures.

2.2.2. Phase Two: Developing the ENDOPREM™

The phase aimed to generate a question bank from the qualitative data and refine this into a pilot PREM. The questions were generated from the data gathered in the qualitative analysis. Several rounds of revision and review were undertaken within a wider study team. The questions were then pre-tested using cognitive interviews with patients who had undergone GI procedures. Five rounds of cognitive pre-testing were undertaken. Analysis of each round resulted in refinement of the questionnaire with the refined draft tested further in the next round of interviews. The pilot PREM generated at the end of this phase was agreed once no new issues arose in the cognitive pre-testing.

2.2.3. Phase Three: Piloting the ENDOPREM™

The final phase of the study aimed to investigate the psychometric properties of the pilot questionnaire. The pilot PREM was prospectively administered, for self-completion, to 1652 patients following a GI procedure. Statistical software (IBM® SPSS® 24) was used to investigate the psychometric properties of the instrument including: missing values, 'floor' and 'ceiling' effects, completion rates and exploratory factor analysis. Recommendations for final refinement were made on the basis of this analysis.

2.3. Thesis Structure

The methods of each phase are described together in chapter three, with three results chapters following this. Discussion of the findings and strengths and limitations of each phase is contained in each of the results chapters, with a final discussion on future uses of the ENDOPREM™ at the end of the thesis:

- Chapter 3: Methods
- Chapter 4: Results of phase one & discussion
- Chapter 5: Results of phase two & discussion
- Chapter 6: Results of phase three & discussion
- Chapter 7: Final discussion

Chapter Three: Materials and Methods

3.1. Phase One: Describing Patient Experience of GI Procedures

3.1.1. Phase One Overview

The design of this phase was a qualitative study, involving interviews with patients who had undergone different forms of GI procedures: namely OGD (per-oral or transnasal approach), colonoscopy and CTC. Semi-structured 'one to one' interviews were chosen over focus groups, which generally include three or more participants. Detailed, descriptive accounts of patient experience were required and it is accepted that semi-structured interviews best achieve this, whereas focus groups are preferred when patient's attitudes or behaviours in social context are being explored (Ritchie *et al.*, 2003; Barbour, 2014). It was also anticipated that some aspects of the interview may be sensitive and a one-to-one interview would allow participants to speak more freely (Elam *et al.*, 2003; Ritchie *et al.*, 2003). Lewis and Ritchie (2003) define interviews as unstructured, semi-structured or structured. The latter is a quantitative tool, which would not allow the depth of experience to be explored in this study. Semi-structured interviews were preferred in this study as a topic guide could be used to ensure a range of aspects of the patient experience to be covered whilst allowing flexibility with the order issues were covered and allowed probing of areas of interest.

It was initially planned that all semi-structured interviews would be undertaken face-to-face at the hospital site; however, subsequently it was decided to also allow telephone interviews. The rationale for this was to ensure that all eligible patients had access to participation in the study, including those who might struggle to attend for interview (e.g. because of work or caring commitments). Telephone interviews have historically been viewed as inferior to face-to-face interviews as it may be more difficult to build rapport, however, advantages include increased perceived anonymity for participants who may feel more able to discuss sensitive topics (Sturges *et al.*, 2004; Novick, 2008). In order to improve rapport and allow non-verbal clues to be observed, preference was for face-to-face interviews but if a patient suggested they might not be able to return to the hospital, a telephone option was offered.

3.1.2. Recruitment

Recruitment took place between February 2016 to April 2017. Patients aged 18 years and older who were referred for OGD, colonoscopy or CTC at South Tyneside District Hospital were invited to participate in an interview. For patients undergoing OGD or colonoscopy, a member of the research team (either the student- LN, or a research specialist nurse) identified and approached eligible patients on a series of endoscopy lists, in the department but prior to their procedure. The lists were not consecutive due to limited research staff availability. CTCs are scheduled throughout the week in the radiology department, rather than having dedicated lists like endoscopy. A research team member identified patients due to have a CTC in the next week and approached eligible patients prior to their procedure. Those potentially interested in participating were given a patient information leaflet (Appendix A), their details were recorded, and they were telephoned (by LN) in the week following their test. If they were still willing to take part a convenient time was arranged for the interview. Those who attended for interview at the site signed a consent form on the day of the interview. For those who underwent a telephone interview, a consent form was posted out once the interview was scheduled and the individual was asked to sign and return it; alternatively if the individual was due to attend the hospital for another reason the consent form was completed then, in advance of the interview (but at least 24 hours following their GI procedure). Verbal confirmation of consent was also sought during the telephone call, before recording commenced and any interview questions were asked.

3.1.3. Participant Selection

Purposive sampling was used to ensure a range of procedures (OGD, colonoscopy, CTC), age (<54, 55-64, >65) and sex (male/ female) amongst participants. Age and sex are known to affect both self-reported experience of GI procedures and the likelihood of the test being completed fully (McCarthy *et al.*, 1993; Hsu *et al.*, 2012; Ritvo *et al.*, 2013; Valori *et al.*, 2018). Diversity in socio-economic status was sought. As described in chapter 1, various indications exist for undertaking each GI procedure. Therefore, heterogeneity across three broad categories of procedural indication was sought: ‘alarm symptoms,’ routine symptomatic patients and surveillance procedures. ‘Alarm symptoms’ were those which indicate a high suspicion of cancer, for example, dysphagia (difficulty swallowing), haematochezia

(rectal bleeding) or weight loss (Harris, 2013). Surveillance procedures included patients attending for investigations to follow-up chronic conditions such as Barrett's oesophagus or inflammatory bowel disease, in addition to those with a strong family history of colorectal cancer. Diversity amongst participants was also sought according to whether they had previously had a GI procedure, grade of endoscopist (supervised trainee or independent endoscopist), completeness of procedure (i.e. caecum reached in colonoscopy, the second part of the duodenum reached in OGD) and result (normal examination, cancer and other abnormality). Ensuring diversity of participants in this manner was considered important to try and capture any potential variation in experience. Participant characteristics were examined as recruitment progressed, with unfilled strata then targeted.

Participants unable to give informed consent were excluded from the study. As the interviews were conducted by a researcher with a dual role as an endoscopist and clinician, patients who had had previous contact with her in her clinical role were also excluded in order to avoid the possibility that this would influence the interview.

Patients undergoing procedures as part of the National Health Service (NHS) Bowel Cancer Screening Programme (BCSP) were excluded. The English NHS BCSP sends faecal occult blood testing or faecal immunochemistry testing kits to individuals aged 60-74, with colonoscopy offered to those who return a positive result (Public Health England, 2019). The rationale for this exclusion was that the referral pathways, patient selection, pre-assessment and aftercare for the BCSP vary significantly from "routine" or other NHS referrals. Moreover, considerable research into improving uptake and experience in this patient group has already been undertaken (Morris *et al.*, 2012; Ghanouni *et al.*, 2016; Plumb *et al.*, 2017).

3.1.4. Ethical approval

Ethical approval was obtained through the proportionate review sub-committee of the NRES Committee London-Stanmore on 20th March 2014 and ongoing approval was obtained from the Health Research Authority (IRAS ID: 14869, Appendix B and C). Local Research and Development approvals were obtained, and Newcastle University ethics approval was granted on the basis that appropriate NHS ethics were already in place.

3.1.5. Data Collection

Recruitment and interviews continued until saturation was achieved (i.e. no new concepts arose in the last three interviews, identified in the iterative analysis) and no new experiences were identified, whilst ensuring at least 7-8 interviews were undertaken per procedure type. A clinician-researcher (LN) conducted the interviews having undertaken training in qualitative methodology (a qualitative methods workshop and informal face to face training). The face-to-face interviews were conducted in a non-clinical building within the hospital grounds. It was not revealed that the interviewer (LN) was an endoscopist, in case this inhibited discussion.

A topic guide was used to ensure that all "stages" of the procedure were covered, from referral to the results (Appendix D). The topic guide was used flexibly from interview to interview, to allow the interview to evolve and issues to be raised in the order that was natural for the participant. Participants were first asked their age and a little about themselves as an ice-breaker, then asked whether they had any previous GI procedures. The interviewer then asked them to describe their experience of endoscopy. The interview was generally guided by the participant's discussion but any broad areas on the topic guide not covered were probed by the interviewer. The interviews were recorded using a digital dictaphone (with the permission of the interviewee) and transcribed verbatim after each interview to allow preliminary and iterative analysis. Field notes were also made by the interviewer to enable further discussion or clarify points and to identify areas to be explored in further interviews. Using this method, emerging themes could be identified, and the topic guide could be modified if required to ensure complete description of the GI procedure experience. Throughout this process the topic guide was not substantially amended but areas requiring further exploration for clarity were noted (e.g. probing about what made the bowel preparation unpleasant). The initial interview transcripts were reviewed by LN and then by the supervisors (LS and JP), then discussed, to ensure adequate depth was being achieved.

3.1.6. Data Management

Participants were allocated a unique personal identifying number to ensure anonymity. Interviews were transcribed and anonymised prior to analysis. This transcription was performed either by a transcription company (JHTS Audio and Video Transcription Services, Birmingham, UK) or LN, depending on the scheduling

of the next interview to allow time for preliminary analysis. Where the interview was transcribed by JHTS, this was compared to the audio file by LN to ensure accuracy and clarify any queries raised by the transcription company.

3.1.7. Data Analysis

Thematic analysis was chosen to analyse the semi-structured interviews. Braun and Clarke describe thematic analysis as "a method for identifying, analysing and reporting patterns (themes) within data" (Braun *et al.*, 2006). An advantage of this method is that it produces a detailed thematic account of the data. The transcripts were read and re-read in detail and an inductive process was used to code the data for each transcript, which were then organised into categories. This approach meant that themes were derived solely from the semi-structured interview dataset, rather than from pre-existing literature or the researcher's pre-conceptions (Ritchie *et al.*, 2003; Braun *et al.*, 2006). Data-driven analysis was considered important in this study as the aim was to produce a fully patient-derived PREM. The data was initially analysed at a 'semantic' or 'explicit' level, meaning that codes were applied as a description of what was said by the participant (Boyatzis, 1998, Braun and Clarke, 2006). Word processing software was used to cut and paste coded quotes into broader themes. The sub-themes were later explored using a 'latent' level or 'interpretative' approach, by revisiting the data to identify what each sub-theme represented and to describe over-arching themes across the dataset (Boyatzis, 1998, Braun and Clarke, 2006). A member of the study team (LM, Appendix E) double coded three of the interview transcripts, one from each procedure type, to further strengthen the integrity of the analysis. Discussion with the supervisory team was undertaken throughout the process to enhance validity and reliability. Several sub-themes emerged and these were pertinent to all three modalities; therefore the results are presented together. Where an over-arching theme or subtheme was relevant to only one type of procedure (or not relevant to one type of procedure), this was identified. The sub-themes were subsequently organised into procedural "stages" to enable the findings to more directly inform the questionnaire development (i.e. before coming to the hospital for the test; preparing for the test; at the hospital,

before the test; during the test; after the test)[2]. The results (Chapter 4) are presented in terms of the over-arching themes identified (which are described at a high level) and the procedural stages (which are described in detail). Illustrative quotes are provided to supplement narrative descriptions. Each quote is followed by the relevant anonymised participant ID number, consisting of 2 letters to identify the procedure (OG= oesophagogastroduodenoscopy; CO= colonoscopy; CT= CT Colonography) and a number.

3.2. Phase Two: Developing the pilot version of the ENDOPREM™

3.2.1. Phase Two Overview

The aim of this phase was to develop a pilot PREM by (i) generating a question bank (which involved decisions on the topics to be included in the questionnaire and their order, informed by the qualitative interviews and a focused literature review); decisions about question and response format; review and revision of question wording by the study team and (ii) pre-testing the questionnaire with patients who had undergone GI procedures. An overview of this phase is shown in figure 3.1.

[2] The sub-themes were organised in this way because this was the way in which most participants described their experience (see section 4.3) and was felt to be the most logical order to inform the generation of questions for the PREM.

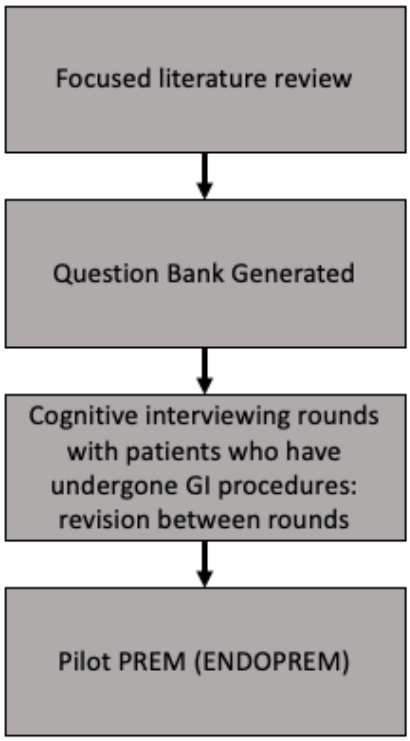

Figure 3.1: Flow chart illustrating steps in Phase 2

3.2.2. Literature Review

A focused literature review was undertaken to ensure that no areas of patient experience had been missed. This step was deliberately left until after the qualitative interviews were complete to prevent the findings biasing the interviewer (LN). Search terms included “patient experience” and “colonoscopy,” “OGD,” “upper GI endoscopy,” “CTC,” “CT colonography” or “gastrointestinal endoscopy.” Streiner & Norman (2008) suggest that when developing a questionnaire, it is important initially to ensure that the questions cover all relevant themes and topics. This describes content validity. This literature review was used to ensure no aspects of the patient experience were missed and added further content validity to the questionnaire.

3.2.3. Item Generation

In order to generate a question bank, it was first necessary to determine what topics should be addressed in the questionnaire. The themes identified within the qualitative interviews had been organised into chronological order according to the patient ‘journey’:

- Before coming for the test: the time between being told the test would happen and coming to the hospital for the test (but not including management in primary care)
- Preparing for the test: for colonoscopy/ CTC patients only, this section related to taking the bowel preparation
- At the hospital, before the test
- During the test (i.e. the procedure itself)
- After the test: immediately after the test and the days following the test

Although the initial General Practice (GP) referral process was sometimes discussed in the qualitative work, it was felt that issues pertaining to primary care consultations and time taken to refer for the investigation were out with the remit of this PREM- this stage was therefore not included.

Themes were mapped into stages (Chapter 4; Section 4.3). Item stems were then composed, where possible, using language used by participants in the qualitative interviews. It was anticipated that the question bank would contain more items than would eventually be included in either the pilot PREM or the final ENDOPREM™; and that the number of items would be reduced during the testing process. After items were generated, each one was assessed to ensure that it addressed one of the six over-arching themes identified within the qualitative phase.

The choice of the response format for items is important as it can impact on both ease of completion and subsequent analysis. Categorical scales can be used as responses to a series of questions, however, this may create significant heterogeneity between questions and restrict psychometric analyses (Fallowfield, 1995; Rattray *et al.*, 2007). A Likert scale format was chosen as the response format for the majority of the questions, as this is well suited to measuring attitudes and most of the items in the question bank were related to people's attitudes about different aspects of their experience (McColl *et al.*, 2001; Streiner *et al.*, 2008). This question style involved phrasing the question as a statement and giving a range of options for participants to indicate the extent to which they agreed/disagreed with the statement (Likert, 1932). A benefit of this response format is that scores can potentially be analysed as interval data, thus allowing the use of parametric statistical

tests (Rattray *et al.*, 2007). Using this format also improved the aesthetics and readability of the questionnaire; using the same format throughout a questionnaire limits confusion (Fallowfield, 1995). The number of response options in a Likert scale can vary, but seven is the upper limit beyond which participants may be unable to discriminate between response options (Fallowfield, 1995; Streiner *et al.*, 2008). Within the context of health surveys, it is recommended that where rating scales are used, a maximum of five response categories should be included (McColl *et al.*, 2001). Debate exists over whether a 'neutral' option should be included. Including such an option allows respondents to indicate when they neither agree nor disagree with the statement, however, people may interpret what the neutral option means differently (Streiner *et al.*, 2008; Nadler *et al.*, 2015; Simms *et al.*, 2019). Omitting a neutral response option compels respondents to choose whether they agree or disagree, however, this can cause frustration and non-response, thereby introducing bias (Rattray *et al.*, 2007; Streiner *et al.*, 2008). In this study five response options were included as this was felt to provide a reasonable number of response options and allowed a neutral option, as it was felt that people might validly feel neutral about some of the items. The response options were: strongly agree, agree, neither agree or disagree, disagree and strongly disagree.

Consideration was given to the wording of item stems, in terms of both readability and positive and negative wording. McColl et al conclude that a mixture of positive and negative items should be used in order to prevent "response set" bias, where respondents choose the same response option for each question (McColl *et al.*, 2001). This is generally accepted in the literature, however it may affect how participants respond to a question as they are more likely to agree with a positively worded question (McColl *et al.*, 2001; Locker *et al.*, 2007; Jaensson *et al.*, 2017). In this study, it was decided that both positive and negative questions would be included (i.e. some statements were phrased such that 'strongly agree' would indicate a 'positive' experience, and others were phrased so that 'strongly disagree' would indicate a 'positive' experience). Equal proportions of each were not sought and the direction of wording was determined in the first instance by the theme or subject matter and what seemed to be more 'natural' (as judged by the research team), then tested in the cognitive interview phase.

The questions were initially refined by several rounds of review and revision within the study team, which comprised a range of domain experts and questionnaire

developer specialists (Appendix E). This involved circulating questionnaire drafts via email, along with the results from the qualitative analysis, and inviting group members to comment, in addition to teleconference and email discussions. This iterative process focused on ensuring that all of the themes identified in the qualitative interviews were covered, in addition to refining the wording of questions. Team members suggested alterations in wording or variations in question style. Where there were areas of disagreement on question wording or the optimal method of assessing, the original interview transcripts were explored further or a focused literature review undertaken (for example, in the assessment of pain and discomfort). This process of circulation, review and revision continued until all team members agreed on the final question bank.

The final question bank was then compiled into questionnaire format to enable cognitive testing.

Two options were identified for timing of questionnaire distribution: giving patients the questionnaire pack on the day of their test or posting it at a later date. It was considered possible that having their test results may influence how participants would respond to the PREM. An advantage of posting the questionnaire to participants was that distribution could be delayed for a period to allow them to receive the results of their test, if they hadn't already received them. However, participants in the qualitative interviews described varying methods and timescales of receiving their test results so it would have been difficult, in practice, to ensure that all participants had their results at the time of questionnaire completion. Also, creating a delay in posting the questionnaire may affect recall of the experience. The final decision was to distribute the questionnaire on the day of the test and ask individuals to complete it after they had left the department and to return it by post.

3.2.4. Cognitive Pre-Testing

The aim of cognitive pre-testing is to ensure that intended recipients correctly understand and respond to questionnaire items (Willis, 2004). The pilot questionnaire was produced using graphic design software, with the assistance of a graphic designer. This format was tested in the cognitive interviews.

3.2.5. Cognitive Pre-testing: Participant Recruitment

Cognitive interviews took place from June 2017 to July 2017. Fifty-six patients were invited to participate in this phase. Fifteen interviews were undertaken. Patients were identified from endoscopy lists and radiology appointments. They were approached by either a research nurse or the student (LN) and invited to attend the hospital for an interview. Some participants from the original qualitative interviews were also included. During the initial interviews, participants were asked if they were happy to be contacted to return for a cognitive interview. The reason for this was to ensure that the questionnaire reflected the experience described in the qualitative phase, i.e. content validity. These previous participants were telephoned and, if still willing to participate, an interview was scheduled at a mutually convenient time.

Those who were potentially interested in participating were given a patient information leaflet (either face to face or by mail for those who had previously been interviewed) and were telephoned a few days afterwards. If they were willing to participate, a convenient time was arranged for the interview. Those who attended signed a consent form on the day of the interview. All interviews were conducted face-to-face, as it was considered important that the researcher (LN) could see how the patient was completing the questionnaire and reacting to the questions. Interviewees signed a consent form at the start of their interview.

3.2.6. Cognitive Pre-testing: Participant Selection

Purposive sampling was used to ensure a range of procedures (OGD, colonoscopy, CTC), ages (<54, 55-64, >65) and sex (male/female) amongst participants. Diversity in highest level of education completed was sought to ensure the wording of questions was acceptable and understandable by people with all levels of education.

Participant characteristics were examined as recruitment progressed, with unfulfilled purposive sampling strata targeted as the interviews progressed.

Individuals unable to give informed consent were excluded from the study. As in Phase 1, patients who had previous contact with the researcher (LN) in her clinical role were excluded. Individuals undergoing NHS BCSP procedures were excluded from the study.

3.2.7. Cognitive Pre-testing: Data Collection

The purpose of these interviews was to optimise the wording of questions, identify problems with the content or response options of questions and to help filter the number of questions where more than one question per theme or stage had been developed.

Beatty describes two broad approaches to cognitive interviewing, namely; 'think aloud' and 'verbal probing,' but appreciates that these terms are not standardised (Beatty *et al.*, 2007). 'Think aloud' cognitive interviewing consists of asking participants to talk through their thought processes as they answer questions (Conrad *et al.*, 1996). 'Verbal probing' requires the interviewer to ask questions as the participant responds in order to gain insight of understanding and response processing (Beatty *et al.*, 2007). A 'hybrid' approach is suggested by several authors, which allows participants to verbalise their response process but also enables the researcher to probe the participant on areas of interest or perceived difficulty (Willis, 2004; Blair *et al.*, 2010; Ryan *et al.*, 2012). The hybrid approach was adopted in this study.

Using the methodology described by Willis, several rounds of cognitive interviewing were undertaken, each consisting of three participants. There is no consensus agreement on the optimal number of participants for cognitive testing of questionnaires, however, undertaking 'rounds' with refinement of questions and subsequent retesting is recommended (Beatty *et al.*, 2007).

In the interview, participants were asked to complete the questionnaire for the last GI procedure they had undergone. They were asked to 'think aloud' as they completed the questionnaire. They were asked to describe their thoughts as they completed it and highlight any difficulties or suggestions for improvement. Where participants seemed to hesitate, this was probed by asking them to explain their thoughts or any difficulty with understanding or completion. After they had completed the questionnaire, participants were asked if any parts of their experience had been missed by the questionnaire. In addition to this, different visual styles of question format and layouts were tested, which had been developed with a graphic designer.

All cognitive interviews were tape-recorded, transcribed verbatim by the student and anonymised. Notes were taken at the time of the interview to identify areas for further

exploration in subsequent interviews. Rounds of cognitive interviews continued until all problems had been addressed and no new problems arose; five rounds were undertaken.

Participants were each allocated a unique personal identifying number to ensure anonymity. The interviews were anonymised after being transcribed verbatim by the student prior to analysis.

3.2.8. Cognitive Interviewing: Data Analysis

Analysis was undertaken following transcription, using a framework proposed by Conrad and Blair (1996). Problems were identified according to their response stage (problems that occur with understanding the question and required task; performing the task, i.e. producing a response; mapping the response to the given response categories) and further broken down to problem type (lexical, temporal, logical, computational or omission/inclusion) (table 3.1). This standardised approach was used to identify patterns of problems to identify underlying issues with specific questions, in order to inform how they might be improved.

Problem Class	Description	Example from this study
Lexical	Meaning of words not known or inability to use words in question or response context	Participants were asked to identify what procedure they had undergone. They did not understand the terms used to describe the procedures.
Temporal	Problem with the time period or time spent on an activity related to the question, including misunderstanding the descriptions of time used in the question	Participants were asked whether they had enough time to discuss the test before the test. They were not sure what time frame this referred to
Logical	Problem with question wording because of "connectives" such as "and" and "or." "False presuppostions" within a question, i.e. a question is asked in such a way that it assumes something about a respondent which is not true	Participants were asked if they were able to ask any questions before the test. Those with no questions did not know how to respond
Omission/ Inclusion	Problem where participants are unsure of the scope which is covered by a question	Participants were asked to indicate which test(s) and how many they had. Participants were not sure whether to include their most recent test
Computational	All other problems e.g. problems with long, complex questions, memory or use of mental arithmetic	Participants were asked to enter their age. The response option was three blank boxes which was confusing

Table 3.1: Description of problem classes, adapted from Conrad & Blair, 1996

Analysis was undertaken after each interview round and the questionnaire was modified before the next round. The revised questionnaire was tested in the next round.

3.2.9. Pilot Questionnaire

The finalised pilot questionnaire was produced using graphic design software, with the assistance of a graphic designer at the hospital trust (Appendix F).

3.3. Phase Three: Piloting the ENDOPREM™

3.3.1. Phase Three Overview

The final phase of the study involved piloting the questionnaire, through a survey of patients, in order to investigate its psychometric properties.

3.3.2. Respondent characteristics

Participant characteristics were captured as part of the questionnaire. This was to enable analysis of the properties of the questionnaire according to patient characteristics. These are shown in table 3.2:

Question Number	Question	Response options
A1	Please fill in today's date	DD: MM: YYYY
A2	How long ago was your most recent test?	Weeks: Days:
A3	Please fill in your age (in years)	Free text
A4	Are you? Male/Female	Tick box
A5	How many years of full-time education have you completed?	Free text
A6	To which of these ethnic groups would you say you belong?	White Mixed/ multiple ethnic groups Asian/ British Asian Black/ African/ Caribbean/ Black British
A7	Please tell us if someone is helping you complete this survey	- I am completing this survey by myself - Someone is helping me complete the survey
A8	Which test did you have on this occasion?	- Colonoscopy - Gastroscopy - Transnasal Gastroscopy - CT Colonoscopy/ pneumocolon - I'm not sure
A9	Have you had another camera test or CT scan in the past?	Yes/No (tickbox) If yes: - Colonoscopy- number - Gastroscopy- number - Transnasal Gastroscopy- number - CT Colonoscopy/ Pneumocolon- number - Flexible sigmoidoscopy- number
A10	How were you referred for your most recent test?	- I was referred directly by my GP - The test was organised by a hospital doctor - I have regular tests to monitor a medical condition - I have regular tests because of my family history - I was referred in another way (please tell us more in the box below- freetext)

Table 3.2: Participant characteristic questions and response options

3.3.3. Participant Recruitment

Individuals aged ≥ 18 years, undergoing OGD (including transnasal endoscopy) colonoscopy or CTC colonography were invited to participate. Those who were unable to consent for their procedure or who had difficulty conversing in English were

excluded from the study. Four sites across the North East of England participated; these were recruited following promotion of the study at a regional endoscopy research collaborative meeting (Northern Region Endoscopy Group; NREG) (Rajasekhar *et al.*, 2014). These sites were: South Tyneside District Hospital (STDH), County Durham and Darlington NHS Foundation Trust, North Tees and Hartlepool NHS Foundation Trust and Northumbria Healthcare NHS Foundation Trust. The results from each site are anonymised and represented by the letters A-D in chapter 6. Questionnaires were distributed from October 2017 to September 2018. Potential participants were identified from endoscopy or radiology lists in the department and were given a numbered questionnaire pack by a member of the research team before leaving the department. The pack contained a covering letter, information sheet (Appendix G), questionnaire (Appendix F)[3] and a freepost envelope to return the completed questionnaire to STDH. Each questionnaire was labelled with a unique study ID consisting of 3-4 letters as a site identifier, followed by three numbers. Both the research team and questionnaire pack documentation reiterated that participation was completely voluntary. It was made clear that the completed questionnaires would be analysed and presented anonymously. Returning a completed questionnaire was considered to be consent for participation. A reminder letter was sent by the research team if the questionnaire was not returned after two weeks. Completed questionnaires were stored securely in accordance with Trust information governance guidelines.

A recruitment log was maintained in each site to allow response rates to be computed and to compare characteristics of responders versus non-responders. Only very basic information was recorded, namely: questionnaire number, site, age, sex, procedure and local hospital number. To enable future analysis (beyond this thesis), clinical and procedural information was collected for the individuals who had returned completed questionnaires (date questionnaire given, return date, reminder date, procedure undertaken, primary indication, medication given, primary diagnosis, endoscopist grade and any complications) (Appendix H). On a rolling basis, research staff at STDH informed each site of the study IDs of the questionnaires which had

[3] A quality of life measure (EQ-5D) and an anxiety measure (DASS-21) were also included within the questionnaire booklet, however; these were intended to be used in analyses outwith the scope of this thesis, and are therefore not discussed further

been returned. The site completed the associated clinical details for these patients and returned the information to STDH for data entry.

3.3.4. Timing of Questionnaire

Patients were asked to complete the questionnaire and post it back to the research team. The reasons for this were: (i) if participants completed the questionnaire in the department, they may not have been given their results (or a plan to receive them), discharge or follow up plan and this would hinder their ability to complete the questionnaire; (ii) there was a question about how participants felt after they were discharged from hospital which could not be answered in the department; and (iii) as this was part of a research study, it was important that participants who had sedation did not complete the questionnaire until the next day, as sedation may impair capacity to consent.

3.3.5. Sample Size

The final sample size for the pilot study was determined by the number of questions included in the PREM. It was not the intention of this study to develop subscales, however, an exploratory factor analysis (EFA) was planned to explore whether there were any subscales within the questionnaire and to help inform further item reduction. Field recommends that 10 to 15 completed questionnaires per questionnaire item are required to perform a meaningful exploratory factor analysis (Field, 2018). The pilot PREM contained 59 questions; as six of these were specific to colonoscopy and CTC, and a further two were general satisfaction questions, a maximum of 51 would be included in the EFA. This meant that 510 to 765 completed questionnaires were required; the recruitment target was therefore set as 800.

3.3.6. Data entry, checking and cleaning

Question response options were coded for data entry and analysis: this involved assigning a numerical value (ranging from 1-5, left to right) to each response option. Consistent codes were used for N/A and missing options.

An information capture company, NData (http://ndata.biz), entered the clinical information sheets and the completed questionnaires into a Microsoft Excel file and SPSS database, respectively. Upon completion of data entry, 10% of the completed questionnaires (n=80) were checked for errors by the student. These were selected

using the Microsoft Excel random number function, were checked item-by-item against the database for errors. Although no data entry errors were found, consistent errors in coding of two questions were identified (E13 and E16). These questions consisted of a visual analogue scale (VAS) to measure pain and discomfort and were the only questions assessing experience which were not in Likert format. Participants had been asked to mark a cross on a 100mm line to indicate the level of pain or discomfort experienced during the procedure (figure 3.2).

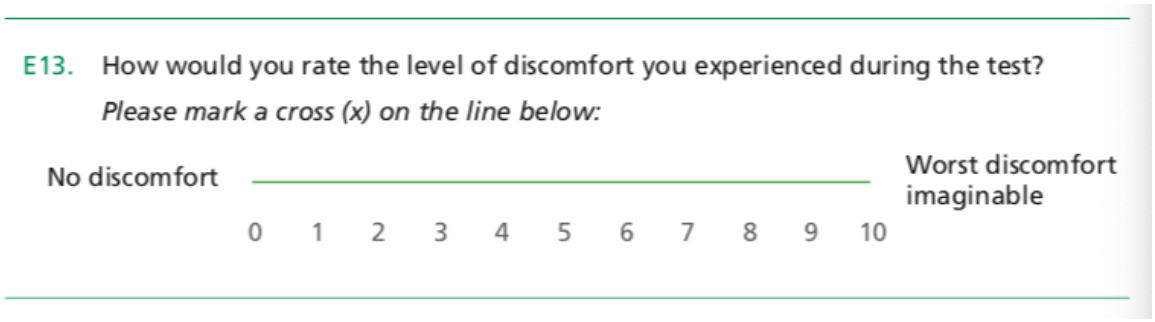

Figure 3.2: VAS discomfort question

The data entry company was asked to measure the distance along the line using a ruler and to input this as the response. Instead, the responses had been rounded, by the company, to the nearest 10mm. Responses to these questions were measured and re-entered into the database by the student. In addition, some participants did not follow the instructions for completion of the VAS. Some placed a cross either above or below the line; some circled a number or anchor; some both placed a cross on the line and circled a number; some indicated a range by circling several numbers or drawing arrows. Pragmatically it was decided that if a cross was placed in any position along, above or below the line then the distance from the beginning of the line to the point on the line which corresponded with the centre of the cross was documented as the response (in millimetres). For those who circled a number, this was multiplied by ten to give a response in millimetres. Where anchors were circled, zero millimetres was recorded for those who circled ‘no discomfort/pain’ and 100 millimetres recorded where ‘worst discomfort/pain imaginable’ was circled. Where a range was indicated the response was coded as missing.

The entire dataset was then cleaned by the student. First, checks were made that only plausible entries were recorded in the database by examining the descriptive statistics. For example, implausible questionnaire return dates were checked against

the original additional information sheets and with the research teams. The time since the procedure as reported by the participant was also checked (question A2): 12 instances which appeared implausible were double checked and corrected against the procedure date and date of completion as recorded by the participant. Three participants reported that they were aged over 90. These were double checked on the questionnaire hard copy and recruitment log. One of these participants had not entered their age and this was recoded as missing. All errors (in any fields) found in this way were corrected.

Data cleaning identified two blank questionnaires which were removed from the dataset. One further questionnaire had been completed in relation to an ineligible procedure (flexible sigmoidoscopy) and was also removed.

3.3.7. Data Analysis

Some variables were recoded and several new variables were created, including:

- a nominal variable to identify the site (hospital) from which the participant was recruited
- a continuous variable representing the number of days between procedure and questionnaire return
- a nominal variable for the procedure as recorded by the site (i.e. by coding OGD and TNE together)
- a categorical variable to order participant age into groups: ≤ 54 years, 55 -64 years, 65 – 74 years and ≥ 75 years.
- two categorical variables to describe how participants had answered the VAS questions on pain and discomfort (E13 and E16). The values were: cross on line, number circled, cross under line, number written, cross on line and number circled, circled anchor and range indicated.
- two additional variables were created each for question E13 and E16. The first included all responses regardless of how the question was answered and the second included only participants who answered the question correctly.

The coding direction was re-ordered where necessary to ensure that responses which corresponded with a positive experience had a higher score. For example, the coding for responses to question B1 (*I was happy with the way I was referred for the test)* are shown in brackets below:

- Responses:
  - Strongly agree (5)
  - Agree (4)
  - Neither agree or disagree (3)
  - Disagree (2)
  - Strongly disagree (1)

Statistical analysis focused on: patterns of response, respondents' characteristics, distributions of responses, levels and patterns of missingness, completion of pain and discomfort questions and exploratory factor analysis. Descriptive statistics were used to examine response patterns per question, including missing responses and floor and ceiling effects. Responses were observed to assess for individual floor and ceiling effects, defined as 40% of respondents choosing either the lowest or highest ordinal response option, respectively (Dean *et al.*, 2018).

Response patterns were examined for the entire sample and then compared, using chi-square tests, by sex, age, procedure (as recorded by the site) and site. The number of participants who erroneously completed Section C (i.e. they had not had a colonoscopy or CTC) was determined. Mean number of missing responses per patient were compared between groups using an independent *t*-test (when there were two groups) and one-way ANOVA (when there were more than two groups). If Levene's statistic indicated the assumption of homogeneity of variance between groups was violated, and this was confirmed by Welch's or Browne-Forsythe's tests, the Games-Howell's procedure was used as a post-hoc test (Brace *et al.*, 2016). All statistical tests were two sided and a p value of <0.05 was considered statistically significant.

The VAS scores for pain and discomfort (E13 and E16) were correlated using Spearman's rank correlation, as the data was not normally distributed. For each participant, the difference in their answers for question E13 and E16 was computed; an assessment of whether the mean difference was equal to 0 was made using a paired *t*-test.

The Likert response questions for pain and discomfort were cross-tabulated and the distributions of responses were compared, with Spearman's rank correlation used to assess correlation.

Factor analysis is a statistical technique which can be used to explore the underlying constructs, called factors, of a questionnaire (Ferguson *et al.*, 1993; Rattray *et al.*, 2007). The factors represent groups of variables which correlate highly with one another (Field, 2018). A correlation matrix was produced for all variables. The Kaiser-Meyer-Olkin (KMO) measure and Bartlett's test of sphericity were used to assess adequacy of sample size and relations between items to ensure that the criteria for a satisfactory factor analysis were met. Spearman's rank correlation was used to identify items which correlated poorly with others (r_s<0.3) or very highly with others (r_s>0.8) (Field, 2018) and these were examined to identify which items could be removed. In preparation for EFA, item-total correlations (ITC) were calculated for each question and those with ITC less than 0.3 were identified (Field, 2018); these were excluded from the EFA.

Exploratory factor analysis was then conducted using principal components analysis. Scree plots were produced and the points of inflection used to determine the potential number of factors that could be retained. Only factors with eigenvalues greater than 1 were retained in the analysis, according to Kaiser's criterion (Kaiser, 1960; Field, 2018). Factor rotation is applied to ensure that variables load on to only one factor (Field, 2018). An orthogonal rotation was initially applied to the component matrix; this assumes that the factors are independent. Examination of this suggested that the factors were not independent of each other and further analysis was performed using an oblique rotation (direct oblimin). Once an acceptable solution to the factor analysis was identified, the rotated factor loadings were assessed and themes were identified.

In order to determine the reliability of the final scale, Cronbach's α was calculated overall and for each factor. Cronbach's α of >0.6 was considered to demonstrate good internal consistency of the scales (Kline, 2000; Field, 2018).

Chapter Four: Describing Patient Experience of GI Procedures

4.1 Introduction

This phase of the study aimed to explore patient experience of OGD, colonoscopy and CT colonography, based on accounts of patients who have undergone these procedures. In addition, it aimed to identify themes that are important to patients in terms of their experience, in order to inform the content of the PREM.

4.2 Participant Characteristics

Participants were recruited between February 2016 and April 2017. One hundred and sixty-two patients were approached for an interview and 127 agreed to be telephoned to arrange an appointment. Twenty-eight did not answer the telephone call and seven agreed to an interview but failed to attend. A total of 35 patients attended for interview. Data saturation was reached following completion of 32 interviews. A further three interviews were undertaken to confirm themes and ensure heterogeneity of participants. Interviews ranged from 20 to 60 minutes in length.

The majority of participants were male (54.3%). The mean age was 61.9 years (range 38-86 years). The time interval from procedure to interview ranged from five to 44 days. All participants had recently undergone a GI procedure at the same hospital, however, a few (n=4) had previous experience of procedures in other hospitals. Additional participant characteristics are shown in table 4.1.

Variable		Number of participants (%)
Sex	Male	19 (54.3%)
	Female	16 (45.7%)
Age	≤54	12 (34.3%)
	55-64	6 (17.1%)
	65-74	12 (34.3%)
	≥75	5 (16.3%)
Procedure	OGD (including transnasal endoscopy)[4]	15 (42.8%)
	Colonoscopy	10 (28.6%)
	CTC	10 (28.6%)
Indication	Alarm symptoms	12 (34.3%)
	Routine symptoms	17 (48.6%)
	Surveillance procedures	6 (17.1%)

Table 4.1: Interview participant characteristics

4.3. Summary of patient experience

Six over-arching themes emerged from the initial inductive analysis: anxiety, expectations, information & communication, embarrassment & dignity, comfort and choice & control.

When invited to discuss their experience, a few participants focused on a single aspect of the experience which was most important to them; for example, the taste and volume of the bowel preparation, or the effect of good communication from staff. However, most participants described their experience in chronological order, that is, as stages of a process, starting with the referral process (henceforth, *Before attending for the test*), then visiting the hospital (*At the hospital, before the test)*, undergoing the procedure itself (*During the test)* and what happened afterwards (*After the test).* All of the six over-arching themes played out in more than one of the stages of the process; this is summarised in Table 4.2. Within each stage there were several subthemes. The results which follow have therefore been organised and presented in terms of the stages, and, within each stage, the subthemes. The following section will expand on themes identified at each time point. Footnotes are used to give explanations of clinical procedures and context.

[4] 12 participants had undergone traditional per-oral OGD and 3 participants had undergone transnasal endoscopy

Over-arching theme	Stage of Process	Subtheme	Example
Anxiety	Before attending for the test	Referral process	Long wait for test increased anxiety about it Shorter than expected wait increased anxiety about outcome Impact on cancelled appointments
		Anticipation of the test	Anxiety about what the test will entail Anxiety about what the test might find Previous bad experience made them more anxious about the test
		Preparing for test	Anxiety about preparation working
		Information about the test	Talking to others increased anxiety about the test
	At the hospital, before the test	Arriving at the hospital	Concern about getting to hospital with ongoing laxative effects of preparation
		Waiting in the hospital for the test	Anxiety while waiting in the department for the test
	During the test	In the procedure room	Procedure room is daunting
	After the test	Recovery	Anxious about time taken to recover in days following procedure
		Results and follow-up	Concern about how to get the results Anxiety about results
Expectations	Before attending for the test	Referral process	Expectations about appointment speed Expected to come for test but it was an outpatient appointment Speed of referral differed from expectations
		Information before the test	Information given helped patients to prepare for test as knew what to expect Some information did not explain test enough- differed from expectations on the day Talking to others impacted expectations
		Anticipation of the test	Previous experience meant they knew what to expect Previous bad experience- expected it to be just as bad

Continued from page 58

Over-arching theme	Stage of Process	Subtheme	Example
Expectations	Before attending	Preparing for the test	Effect of laxatives worse than expected Laxatives didn't work as quickly as expected
	At the hospital, before the test	Waiting in the department	Waiting time in the department for the test differed from expectations
	During the test	Medication	Effect of pre-medication compared with expectations- worked better/less/as expected
		The test	Didn't know what to expect Duration of test longer or shorter than expected How procedure was done: OGD patients- some expected it to be oral but was done transnasal
		Feeling of the test	Operator explained what was going to happen as they went along so knew what to expect
	After the test	Recovery	Took longer to recover than expected
		Results and follow-up	Results given in different way than expected Results given at different time than expected- eg not on day
Choice & Control	Before attending for the test	Referral process	Preference for appointment convenience versus specific endoscopist Able to rearrange appointment if didn't suit Not given choice of operator
		Information about the test	OGD: Choice of oral versus transnasal approach Some told of alternatives- choice
	During the test	Medication	Feel like nursing staff want them to choose throat spray rather than sedation (OGD) More information to help them choose medication would be helpful
		The test	Felt able to stop the procedure OGD: felt it was their responsibility to 'swallow' camera

Continued from page 59

Over-arching theme	Stage of Process	Subtheme	Example
Choice & control	During the test	Feeling of the test	When becoming painful operator could give choice of stopping
Communication & Information	Before attending for the test	Referral process	Written information about the test Clarity of information given Communication with person referring for the test Information about preparation for the test
		Information about the test	Given information about what the test would involve Would like more information for the person organising the test Told about risks of test Information didn't explain enough about test- differed from expectations Information good Information confusing about diet
	At the hospital, before the test	Waiting in the department	Not informed about delays in department
	During the test	Medication	More information about medication (eg sedation) needed
		The test	Operator explained each step Communication with other staff Staff communication put them at ease
		After the procedure	Information about how to get results Getting the results
	After the test	Results and follow-up	Would like more information about follow-up plan

Continued from page 60

Over-arching theme	Stage of Process	Subtheme	Example
Comfort	During the test	Feeling of the test	Discomfort of camera/tube insertion Feeling of mouthguard (OGD) Pain caused by biopsies Discomfort cause by air/gas insertion
	After the test	Recovery	Discomfort in days after test Throat pain after test
Dignity & embarrassment	At the hospital, before the test	Waiting in the department	Worried about someone walking in when getting changed Embarrassed waiting in gown Embarrassed waiting in busy waiting area Procedure room far from
	During the test	The test	Dignity shorts helped protect dignity Staff protected dignity Effect of operator gender on embarrassment
	After the test	Recovery	Toilet close to waiting area

Table 4.2: Overview of themes and sub-themes from qualitative interviews, illustrated with examples

4.4. Before attending for the test

Four themes were identified which related to this stage of the procedure, which included the time from being referred from the test to arriving at the hospital for the test.

4.4.1. Referral for the test

Some patients described being referred directly for their test by a GP, whereas others were seen by a consultant in the outpatient department first. Patient preference regarding this varied; a couple perceived being seen by a hospital doctor in the outpatient clinic prior to the procedure negatively as they felt that they simply repeated what had been said to the GP:

> *"So it was the nurse who actually explained it to us, that they do quite often get a lot of patients that think they're going for the camera there and then, but it's a consultation. I just found that little bit of the process a waste of time, cos I'd told the doctor [GP] exactly what I told the consultant."* OG3

Others felt that an outpatient appointment prior to the test was beneficial, as it enabled further discussion about the test:

> Patient (Pt): *"I would've liked to have come to have spoken to the consultant in an outpatient appointment really. I felt I was going in to it and not really knowing what was happening. Even though there'd been an explanation sheet, which I could understand, but I think it would have been, I felt it would have been better to have been to outpatients first and spoken to somebody about what was happening".*
>
> Interviewer (Int): *"What kind of things would you have liked to have gone through with the consultant?"*
>
> Pt: *"I think probably, maybe a few more reasons as to what this test might be showing up or, I suppose, I don't know, a discussion of my symptoms just I suppose to confirm that the GP was right in what he'd said or whether there was other options that were available or other things that it could've been or. I don't know really. There wasn't the opportunity to do any of it." OG11*

In some instances, the referral process differed from expectations. For example, a few patients arrived at the outpatient appointment prior to the procedure expecting that the procedure would be done on that day. Where this occurred, patients described the feeling of '*wasting the consultant's time'* and viewed the consultation as repeating things unnecessarily. Furthermore, where the outpatient appointment had been unexpected, it was perceived as an unnecessary delay to the procedure. A minority of patients had expected an outpatient appointment first but found that when they arrived the procedure would be done on that day. Patients said that knowing what to expect in this stage was important as it helped them to prepare for what would happen when they arrived at the hospital. Patients described being disappointed when the procedure wasn't done as expected.

> Int: *"How did you feel about that [not having the procedure on the day of the outpatient appointment]?"*
>
> Pt: "*Extremely disappointed and angry to be honest with you."*
>
> Interviewer: *"What was it about it that made you angry?"*
>
> Pt: "*It's just that you set yourself up for the test… all it does is tick a box that you've seen us, but nothing urgent has happened within those two weeks. Nothing medical or anything happened."* OG3

Waiting time between the referral for the procedure and the investigation being done was generally perceived as acceptable. Two patients felt that private healthcare was an alternative if the waiting time had been unacceptable. One patient had sought a private opinion because the waiting time was too long. Another had private cover which they would have used if the wait "*was lengthy I'd have jumped ship. But it wasn't lengthy, so I stayed with the NHS appointment."* Patients preferred to be seen quickly following the referral so they could *"get it over with."* A prolonged wait was perceived to increase anxiety about the test:

> *"I didn't have much time to think about it, which makes the procedure a lot better. I think the longer you've got to wait for it I think the more anxious people become. So obviously it was easier… this time than it has been in previous times because I didn't have that wait."* OG6

If the time to test differed significantly from expectations this also caused anxiety. For example, if the test was sooner than expected these patients inferred that this could mean a more serious outcome was anticipated:

> *"You realised, you know, you were rushed through the system, um and it had to be something serious the matter, but at the time I was thinking 'we'll sort the bloods out, everything will be fine.'"* CO10

> "*But he was going to do us anyway within the two-week pathway in any case. But when you get it that quick you think oh does he think it's something serious, because it was quick*." OG6

A few patients in all procedure groups described cancellation and subsequent appointment rearrangement by the hospital. When this occurred, patients were sent a cancellation letter and an alternative appointment, which was usually at a later date:

> *"I don't know if it was one or two months before my appointment, and they said unfortunately due to circumstances it had been altered and, I don't know if it was at least a month more I had to wait to have it done." CO3*

The effect of appointment cancellation on patients appeared to be related to the impact on the waiting time for procedure. While most patients had no problem with the cancellation, a few felt it prolonged the waiting process and increased their anxiety.

The convenience of the appointment for the procedure was also raised. Patients generally felt able to phone the department to rearrange their appointment if it didn't suit, however; some patients were only able to rearrange it for the same day in a different week. For some this was problematic due to their own work or home commitments. For those undergoing OGD or colonoscopy, this brought up the issue of choice regarding appointment time versus having a specific endoscopist do the test. Some patients prioritised having the same endoscopist who they had seen in the outpatient department, whereas others said they preferred convenience over continuity:

"I suppose in a way if there was another specialist that could have done it, rather than if there's only, I mean I don't know if there is but rather than just relying on Mr X to do it. So I suppose that would be a good thing from a patient's point of view, if there's another specialist that can do the same thing on another day." CO2

In terms of appointment time preference, most patients stated that they would prefer a morning appointment. The reasons for this included: a perception that it is easier to park at the hospital in the morning, fasting overnight is easier for a morning appointment, a perception that waiting time is likely to be shorter in the department (as there is little opportunity for the clinic to be running late) and less time to worry about the test on the day.

4.4.2. Information before the test: information about the test

All patients stated that they were given information about the test prior to the procedure, including; information about the test itself, the necessary pre-procedure preparation/diet and the risks of the test. Patients felt that being informed about the test reduced their anxiety prior to attending and on the day of the procedure. Most information was given in written form. Some patients were also given information by the person who referred them for the test. A few patients who had written information would have preferred a more detailed discussion with the person who referred them for the test, rather than in written form:

"So I think… the doctor sending you for the referral should tell you why you're going for it, and what it will entail, and then you're in the loop sort of style… Instead of sitting there thinking what the hell's the matter with us? You're worried about it. You start worrying and you're worried all the time, then you go down there so if you're worried when you go you'll tense up." OG2

"I think it's nice to speak to somebody personally… because a lot of people don't know what to expect and I think if you have someone talk to you beforehand, it [expectation of the test] would be fine." CT6

Opinions on the written information about the test were varied. Most patients seemed satisfied with the written information they had been given, stating that it enabled them to prepare for the test.[5]

> *"It was very, very good information. I'm glad I had a bit of paper to read on what was going to happen, what to expect when you come and what'll happen and they tell you all that's going to happen."* CT6

Some patients noted that more information about what would actually happen during the test, how the test might feel and how they may feel in the days after the test, would have been useful. Others felt that the information sheets were conflicting or confusing and some thought too much irrelevant information was included. In particular, some patients felt that the CTC information did not explain the test fully and the test differed significantly from their expectations as a result:

> Int: *"Do you think you had enough information before the test?"*
>
> Pt: *"No. Not for the CT no. I thought… I was just gonna go and stand in front of an x-ray machine, but once she said you're taking your clothes off right down to your socks, and putting these two dressing gowns on, I knew I was in for something totally different! (chuckles) I didn't expect the camera or anything at all for that fact."* CT3

A few patients said that they did not read the information they were given, most commonly those who had previous experience of the procedure:

> *"Because I've already done it, I felt I didn't need to read it. And whatever was written there I had gone through and I knew why I was having it done."* OG15

Another patient did not read the information as they felt it would put them off attending for the procedure and they '*didn't want to know.'*

> Pt: *"I had all the information on the tests saying what was going to happen yes. To be honest with you I didn't particularly read through it."*
>
> Int: *"Why not?"*

[5] Written information varies between hospitals: interviewees were from a single site

Pt: *"I was just I've got to go, I've got to go, I'm not going to read this to put myself off. Aye and somebody says if you read that you're going to put that down your throat. I would think I'm not going."* OG7

In addition to information from the hospital, some patients sought information elsewhere. Of those undergoing OGD, several spoke to friends or family members who had undergone the procedure. The majority of these patients '*wished they hadn't listened'* to other people as they tended to tell '*horror stories.'*

"You hear horror stories about people trying to rip the cord out but I'm sure they exaggerate. People like that exaggerate and I know that. I didn't, I try not to take notice but, you do let the nerves build up on the day." OG3

"It's not as bad as what people think. There's always people that makes it out to be worse than it actually is." OG1

One patient felt less nervous about the test after speaking to others as they realised it was '*just routine.'* A few patients turned to the internet for information and said this helped them know what to expect. Some patients described avoiding the internet as "*sometimes you can Google it and you've got two weeks to live!"* One patient looked at images of potential pathology and was reassured during the procedure when he did not see this on the monitor.

4.4.3. Information before the test: alternatives to the test

A few CTC and OGD patients were told of an alternative to the proposed test. For those who had CTC, some described choosing or being offered CTC instead of colonoscopy. For OGD, some patients were offered this via a transnasal route rather than the oral route. One patient described the reason for choosing CTC over colonoscopy because she "*want[ed] the easiest one possible… I'm a coward!"* One patient felt she was only offered CTC as an alternative to colonoscopy because she had expressed reluctance to undergo colonoscopy at the initial clinic appointment:

"Well she [the doctor] was just starting to describe what a colonoscopy was and… I sort of interrupted and said well I've already had one a few years ago and I think she picked up on the fact that I was quite reluctant to have another

one unless it was absolutely necessary and that was when she explained that there was an alternative if I would prefer that." CT8

Similarly, two patients who had transnasal endoscopy described being given the option between this and OGD at an appointment with a hospital consultant. The choice was based on previous experience:

"For me it [the OGD] was awful. So when they gave me the option of going through the nose, I thought well, the tube has to be smaller going through the nose than it does going straight down the throat… so I thought I've got to have it done... I'll try that [transnasal]." OG15

Of the two patients who opted for transnasal endoscopy, they chose this as it was perceived to be easier, with a thinner camera:

"I'd had a test previously, but 35 years previously, and that was the big tube down the throat. And that's, whilst it was uncomfortable, it certainly wasn't terrible. But I expected this to be easier. And I was proved right, it was fine both times." OG13

Others were happy to proceed with what the doctor recommended as "*doctor knows best*." One patient described being told that the "camera test" (i.e. colonoscopy) was always more accurate than CTC, but said that the referring doctor felt that CTC would be easier in her case:

"I wouldn't say I was given the option, but then again I didn't push for an option. I just took his word for it. He explained it to me. He said the camera is better. It's very accurate, but I think this would be less invasive for you. He said I can do it with you having a larger BMI, not a problem and I've never had a problem. But I think for you it might be easier. Because he knew I sometimes get problems with anaesthetic and things like that." CT6

Two OGD patients described being aware that there was choice to have the procedure done transnasally, but that this was either not made available to them or

they could not choose this on the day of the procedure[6]. One patient who had the test transnasally was referred by their GP and expected to have a standard OGD. When they phoned to make the appointment, the staff told them "*they're going to go down your nose and it's not as invasive."* The patient was satisfied with this.

4.4.4. Information before the test: risks

Several patients described being made aware of the risks of the procedures both verbally by the referrer and in the information leaflets they were given prior to the procedure. The general attitude to this was that the test '*had to be done'* which justified the risks:

> *"And obviously I know there's radiation involved. My friend's got a thing about radiation killing you and things like that; whereas me, I've never had anything done. I've had a couple of chest X-rays and I think over your time of life sometimes you've just got to do it, haven't you? …. So I was just a case of OK this needs to be done. That was all how I felt about it, so I was all right with it."* CT6

4.4.5 Preparation for the Test[7]

One patient did not read the information for the test and therefore did not fast appropriately, meaning he was turned away on the day of the test. This patient felt '*it was my fault'* and was impressed that the hospital rearranged the appointment for later in the same day.

Patients referred for colonoscopy and CTC stated that they found the diet beforehand very restrictive and the information about this was sometimes conflicting or confusing in terms of what could be eaten. Some commented that recipes or meal plans would be helpful in planning their pre-procedure diet. Patients were often

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[6] TNE is not available in all hospitals. At the site where the qualitative interviews were conducted this can only be undertaken by certain endoscopists.

[7] Pre-procedure preparation varies between tests. Patients undergoing OGD need to fast for a period of time, whereas those undergoing colonoscopy and CTC adhere to an altered diet followed by laxatives and a fasting period.

anxious that their bowel preparation wouldn't work and as a result some patients commenced the diet earlier than required:

> *"I probably started the dietary instructions maybe two days before their date because of…my same test five years previously [where preparation hadn't worked properly] I thought oh I'll give it an extra couple of days just in case."* CO9

The laxative drinks before the test were described as '*disgusting,' 'horrible'* and '*bitter."*[8] Those undergoing colonoscopy in particular 'struggled' with the volume of liquid:

> *"Oh, I didn't want to look at another piece of liquid again! It was just one tumbler after another and you were clock watching because you're thinking I should be drinking this, now I need to drink the water."*CO3

Both colonoscopy and CTC patients described the effects of the laxative preparation as '*severe.'* Some felt that neither the written nor verbal pre-procedure information prepared them for the extreme effects of the drinks:

> *"When it said you may have diarrhoea, that is just not enough to tell people, because I had four sets of leggings on. All over my toilet, all over my floor, I had to wash everything – I was in a right mess with it. So I think they need to prepare people a lot more for that."* CT6

Some patients found that the first dose of the laxative drink had no effect.

> *"And when it came to taking the mixture for to get things going, you had two 50ml glasses of stuff to take two days running, and the first day when I took it, nothing really happened. And I was getting a bit concerned because obviously your interest is as far as the clinical side is to have a real clear view of the bowel like to make sense of the thing."* CT10

This caused anxiety in relation to affecting the quality of the examination.

[8] Less volume is required for the preparation before CTC than for colonoscopy

4.4.6. Anticipation of the procedure

The most common topic when talking about before the test was anxiety. Patients were worried about the test itself, often because they didn't know what to expect or were worried about discomfort. In general, those with previous experience were less anxious:

> "*When I first started getting it [having regular colonoscopies], I was a bit apprehensive because it's all new but after 20 years it's just like water off a duck's back to be quite honest. It doesn't bother me whatsoever now."* CO4

A patient who described a previous bad experience felt this made her more anxious about the procedure:

> *"I was frantic, because I thought it would be no different. I thought it would be no different to what the first one was."* CT2

OGD patients were concerned about swallowing the tube and feeling sick or retching during the test. Colonoscopy and CTC patients were worried that the preparation would not have worked correctly. For a few patients this was because they felt embarrassed at the thought and others were worried that the bowel may not be clear enough to allow the procedure to be completed.

Other patients in the colonoscopy and CTC groups described feeling embarrassed in anticipation of the test. This related to the part of the body being examined:

> *"I think basically it all boils down to that I'm slightly embarrassed. You know, it's eh, private things getting poked about I suppose, you know?"* CO1

A few patients described feeling anxious about "*following through,"* during the test because of the preparation (i.e. opening their bowels).

Some patients in each group described feeling anxious about the results even before they had attended for the procedure. One participant who had a non-GI cancer in the past said that they were frightened about the possibility of finding cancer:

> Int: "*how did you feel when you were told you were going to have the scan?"*

Pt: "*A little bit, well frightened in case it had come back for the third time because, you know, you get people who get it once and twice, but three times I would've just given up then*." CT4

4.4.7. Arriving at the hospital

All patients arrived by car or public transport to the hospital, although some mentioned that patient transport was available had they needed it. Hospital parking was described as expensive and difficult to find a space. CTC and colonoscopy patients had concerns about getting to the hospital due to ongoing laxative effects.

> *"I think I got halfway down the road and I knew I had to go back for a change, which wasn't pleasant. I know I was a bit concerned about the time."* CO8

The staff in all areas were described as *'welcoming'* and *'friendly.'*[9] Patients said that staff guided them through each stage of the procedure whilst there:

> *"It's really taken out of your hands because when you go to the reception they're there, they take the forms off you. They tell you where to go. They come and get you and everything's, it's just taken out of your hands really; you've got no worries as such. You just sit there and wait for them coming. So I think they're pretty good*." OG10

4.4.8. Waiting in the department[10]

Some CTC and colonoscopy patients were unhappy with the hospital-provided gowns as they did not close or cover them adequately:

> *"Well, the CT scan, you're requested to go into a cubicle, get your kit off, put a gown on, which the gowns are hopeless – they're useless because half the strings are missing, so how do you fasten them?"* CT5

[9] Patients who attend for OGD and colonoscopy have routine observations such as blood pressure and heart rate checked by a nurse.
[10] Colonoscopy and CTC patients were encouraged to bring their own dressing gown to wear over the hospital gown, whereas OGD patients did not need to get changed.

Two colonoscopy patients said they felt that someone could have walked in to the changing room, but all other patients said that the changing areas were sufficiently private.[11]

Some patients were satisfied that the waiting areas were sufficiently private, but others who had to wait in gowns had concerns about privacy and dignity. Some patients described the waiting area as being on a public corridor. Others spoke about how one waiting area was mixed gender with family members and friends able to wait with patients. Some patients did not like this:

> Pt: *"There are husbands and wives and you're sitting waiting with just your dressing gown on and this silly little Wee Willy Winky night gown on."*
>
> Int: *"So what do you think about that?"*
>
> Pt: *"Well, I think I'm too old to be embarrassed, but the thing is I think other people can be embarrassed and so you have to be very careful for your dignity."* CT5

Waiting with others made a couple of patients feel more anxious and these patients expressed a wish for more private waiting areas. A few patients indicated that they would have preferred to be taken straight to the procedure after changing to prevent having to wait in communal areas when wearing a gown.

> *"What I found was a bit discomforting was… I'm very open, I'm very liberal minded, but it was the joint male-female waiting room. And people were, some people had like the gowns on. So that was a little bit off-putting."* CO9

When it was time to move from the waiting area to the procedure room, some patients described having to walk through a busy public corridor to get there. Most of those wearing gowns found this embarrassing and expressed a preference for the procedure room to be beside the waiting area:

> Pt: *"But the main thing I didn't like was once you got changed into your gown, your surgical gown, then you had to walk along the public corridors to the*

[11] CTC patients stated they got changed in a private cubicle, whereas colonoscopy patients were taken to a changing room which could be locked.

examination room. If anything you could change about that that would be better. I did find that a bit off-putting, a bit discomforting."

Int*: "What about that was discomforting? "*

Pt: *"Just everybody could see you. You're basically in a dressing gown walking down a corridor."*

Int: *"And what do you think could be done to, so what would your ideal situation for that be?"*

Pt*: "Ideal situation would be if you could go into a changing room, get changed there and then you walk directly into a procedure room."* CO9

Some patients described being unable to find a seat in the waiting room because it was too busy.

"Well, to be honest with you, the worst thing about the whole thing was the waiting room's never got any seats in it. And that's the honest truth. So I had to stand in the corridor both times." OG13

Patients having endoscopic procedures said that they were given a locker to store their belongings, however, CTC patients had to carry their belongings. For some, they were unsure what to do with their things:

"You get changed and you've got to carry your clothes around with you. There should be accommodation whereby…you're taken and you get a locker and you put your stuff in the locker, then you're escorted back to that locker and in that area; whereas, you haven't to carry – it's like the bag lady, you know, the bag woman on the streets. It's more archaic, as opposed to not being patient and area friendly." CT5

The waiting rooms were generally described as '*functional'* and '*pleasant'* with distractions including television and magazines. A few patients felt that the waiting areas could be less functional, for example, one patient suggested adding some plants.

Patients described anxiety whilst waiting for the test in the department, with one describing it as *'like waiting for the firing squad.'* This was exacerbated in some cases by a longer waiting time than had been expected:

> *"I did find I was getting more anxious in that waiting time…. yeah. A bit anxious. Just wanted it to be over as quickly as possible. And I may have been in there for about an hour and a half, two hours or something. Again, it's not a complaint, I wouldn't complain about that. I just found I was getting a bit agitated waiting to go in. I wanted to be in and out, you see."* CO1

While all CTC patients were satisfied with their waiting time (which did not exceed 20 minutes) some of those who had OGD or colonoscopy waited for over two hours. Patients said that they expected long waits in the department. Some patients said that being updated by staff about delays was helpful. One patient was unhappy that they had not received an apology for the delay in their procedure:

> *Interviewer: "What time was your appointment?"*
>
> *Pt: "It was about half past two and they called me down at half past four, quarter to five. And I hadn't had anything to eat since eight o'clock the following [previous] morning. And all you can have is water or clear liquids. And that wasn't very good. And I've never got an apology for that. Apparently, I mean they admitted there was an emergency, but surely they can do something?"* CO7

4.5. During the Test

4.5.1. Medication[12]

Some OGD and colonoscopy patients said they would have liked more written information about the effects of the medications and examples of situations where each option may be preferable. Patients said that they did not always know what to

[12] Patients undergoing CTC are sometimes given an injection to relax the bowel (Hyoscine butylbromide)- this is not a sedative and is not optional. Those undergoing OGD may have the option of no preparation, throat spray, sedation or both. Colonoscopy patients may choose sedation or use 'gas and air' (Entonox).

expect from sedation and a few asked acquaintances with experience before the day of the procedure.

Patients who opted not to have sedation said they had done so because it was more convenient. They thought that the recovery would be easier and quicker; they would not need someone to stay with them after the procedure and they could drive afterwards. However, a few of these patients acknowledged that the procedure itself would have been easier had they had sedation:

> *"It may have made it easier for the two minutes the camera was down but it wouldn't have made it easier recovery for the rest of that day, so to speak. And with regards to having the spray, like I say, I was picked up from here and I was back to work within half an hour."* OG3

Several patients said that having undergone OGD with throat spray, this was sufficient. Before having the procedure they expected that it would '*numb the throat.'* Some described the taste as sickly and the effects varied between patients; some spoke about not being able to feel endoscope insertion but others could still feel this (described in section 4.5.3.) One patient with previous experience of the test opted against throat spray as it caused a choking sensation:

> *"I didn't want the spray down my throat. I've had experience and it's the worst experience ever. You feel like you're choking to death."* OG6

Patients who chose sedation said they expected it to make the procedure easier but were unaware of what precisely to expect in terms of how they would feel. Patients hoped they could '*float away'* and that it would '*take the edge off'* or that they would not remember the procedure. One patient had hoped they would be '*knocked out'* but understood that this was not possible. Some patients saw sedation as the '*easy option'* but some patients would do anything to make the procedure easier. Others wished to '*be a man'* and manage without sedation.

Three OGD patients felt that staff would prefer them to have throat spray rather than sedation. This did not influence their choice. This impression was an inference rather than verbal instruction given by staff.

> *"But obviously I know they don't like to give you it [sedation] because obviously they've got to keep you in a bit longer and you've got to have somebody to look after you. I understand that, but if it makes my experience better I don't care personally."* OG6

One patient chose both throat spray and sedation for OGD. She felt that staff had seemed surprised by this and thought this dual option could be made clearer to all patients. Another patient who had opted for sedation was surprised to be given throat spray in addition. This patient would have preferred to have a discussion about this before proceeding:

> *"The nurse said to him [endoscopist], she's not having throat spray she's having sedation, and he just said well she's getting both. And I just thought well why? And by that time it was open your mouth and swallow… I still don't know why I had to have both."* OG11

The effects of sedation varied between patients and sometimes differed from their expectations, with some patients not remembering the procedure and others feeling they had not had enough sedation *('I don't think I was sedated at all… or very mildly'*). One patient who had previously had a colonoscopy with sedation said that the sedative did not seem to work as well on their most recent test.

4.5.2. In the procedure room

Patients described the procedure rooms as '*functional,'* with some feeling that the rooms could be made more relaxing with music or dimmed lights. A few patients found the medical equipment '*daunting*' and noted '*clutter*' outside the room.

4.5.3. Staff interactions

Patients spoke about the atmosphere in the procedure room and how staff attitudes and actions made them feel. Patients described how a *'jovial' or* '*teamworking*' atmosphere put them at ease.

> *"There was no I'm a doctor, you're a nurse, you're the patient- it was one family with him. He kept everybody going and everyone was relaxed. The nurses were relaxed, cos you were with a doctor who was relaxed. So nobody was nervous because no one was running around. It was a good atmosphere- that helps."* OG2

Examples of poor communication included failure of staff to introduce themselves or provide any explanations of the procedure or what would happen and staff discussing unrelated topics. This made patients feel like "*something else he'd [the endoscopist] got to get through in his working day."* An example of perceived poor communication clouded the entire impression of the experience for one patient:

> "*And again when coming back the nursing staff were, they were lovely, all of them. There wasn't one that I could say wasn't. But my lasting impression from having this gastroscopy will be the consultant which is unfortunate*." OG11

Patients stated that having the endoscopist (or radiographer) talk through what was happening during the procedure put them at ease.

> "*They know the situation. They know what they're going to tell you is pretty accurate. They can foresee it before it happens so it's taking away the unknown from people and I just felt that that's what they did*." CT6

Overall, nursing staff were described as '*fantastic,' 'friendly,' 'professional'* and patients spoke about how they played a large part in '*distracting'* them from the test. Several patients described how nursing staff '*took care'* of them by reassuring them, giving tips on how to cope, helping them to change position and distracting them with jokes or conversation.

One patient said that nurses were important for monitoring comfort and reporting back to the endoscopist:

> "*She [the nurse] could say excuse me, but can she have some more [sedation] because it's really hurting her*." CO7

Nurses were also perceived as helping to protect patients' dignity, for example, ensuring patients are '*all covered up.'* The majority of patients described the positive effects of staff, however, one patient who struggled to retain air during a CTC[13] described how staff made them feel like they had been '*bullied':*

> *"And one of the nurses was shouting at us because I couldn't hold the air in that they'd put in so she was shouting because the other nurse was saying it's all right. But by this time I just wanted to go home. I wanted to get out.*" P2

Opinions on who should do the test were varied and one patient described their overall preference as someone who was '*competent.'* One patient had expected a trainee but their procedure was done by a consultant; they were content with the prospect of having a trainee as they "*have to learn*." One female patient worried that a male staff member would be doing her CTC. In both lower GI procedures sex was raised in relation to embarrassment; no patients described having had a choice of the sex of the endoscopist:

> *"It would have been nice to have a female, yes, but I suppose it's the same as a man going and he gets a female doctor when it's his anatomy and he doesn't want to show it to a female, he's embarrassed. So it would have been nice if there had been a choice of a female specialist, so that would have definitely, I would have preferred that."* CO2

Some patients said that they would have preferred to have the procedure conducted by the same endoscopist who had referred them for the test; they felt that this endoscopist would already be acquainted with their case and had built a rapport with them. In contrast, other patients said that they would prefer to have the procedure at

[13] Inflation of 'air' (carbon dioxide) is required for CTC to inflate the bowel and enable the lumen to be visualised

a day and time that suited them rather than wait until the endoscopist whom they had already met was available.

4.5.4. The Test

The experience of the test varied between procedures and patients described both temporal and physical aspects. Patients' reports on the physical experience of the test differed across the three procedures (see 4.5.5 – 4.5.7). Some patients who had sedation could not remember anything about the procedure. Irrespective of procedure, patients were often unsure about how long the test would be likely to take and some, mainly in the colonoscopy group, spoke about how it seemed like it was "*going on forever*." Others, particularly in the CTC and OGD groups, said the test was "*over quickly."* These patients spoke about how inserting the camera was quick but that it took a longer time to remove it. Patients said that being told at the beginning how long the procedure would take made things more manageable for them:

> *"She [radiographer] said the whole [procedure] will take about just under twenty minutes which it did. So I knew I just had to suffer for twenty minutes and that was it all done."* CT3

Patients in all procedure groups described being embarrassed during the test. Some OGD patients described vomiting during the procedure and they spoke about how they were embarrassed about their lack of control over their reaction.

> *"The water that comes up and everything it's embarrassing for me. I think that's the worst of it all for me. But it's part and parcel of it isn't it? If that bit didn't happen it would be great."* OG10

In the CTC and colonoscopy groups, embarrassment was related to the nature of the procedure:

> *"Em, it's hard to put it into words, really. I think basically it all boils down to that I'm slightly embarrassed. You know, it's eh, private things getting poked about I suppose, you know? Women might go through a lot more than men do, but I was a bit embarrassed like, you know? Might sound silly."* CO1

A few patients said that the sex of staff affected their embarrassment.

> Pt: *"I'm saying that it's embarrassing but these nurses have got to do it day in and day out so to them it's nothing but to me it was, I felt embarrassed. I shouldn't have been but I'm just stupid."*
>
> Interviewer: *"What did you feel embarrassed about?"*
>
> Pt: *"About a young girl having to put her fingers into my bottom, that's the only thing; it's very embarrassing. I was thinking more embarrassed for her having to do it, but when you think about it it's her job and they do it all the time."* P4

Patients in the colonoscopy group described being given 'dignity' shorts to wear during the procedure, which they viewed positively:

> *"I just had a gown on. You know, that was the first time I had it done. But the second time, they gave me these knickers with the slit up and I thought that's a lot of better. That's a lot more dignified."* CO7

CTC patients were not given dignity shorts, but one patient who had undergone colonoscopy in the past thought that having dignity shorts for CTC would have reduced their embarrassment.

Patient reports on the physical experience of the test differed across the three procedures.

4.5.5. Sensory experience of the test: OGD

Prior to endoscope insertion, OGD patients stated that a mouthguard or "*dummy,"* was inserted into their mouth if they were having the test orally; this was generally perceived as unpleasant.

> *"And the clamp in the mouth, that's not very easy to deal with."* OG9

OGD patients felt that "*swallowing the camera"* was the hardest part of the procedure. Some patients felt that it was their responsibility to ensure they swallowed the camera, rather than that of the operator:

> *“The camera was going down and you’ve got to swallow it- you’re dead dry, you know, trying to get this thing down. Once it’s in, honestly, if you breathe properly and do what you’re told you don’t feel it.”* OG2

Although patients undergoing transnasal OGD did not describe needing to swallow the camera, insertion of the camera by either route was portrayed as unpleasant, with common descriptions of “*gagging,”* “*retching”* and “*choking.”* Transnasal patients described a *“strange”* feeling in the nose. OGD patients described the test as “*not pleasant,”* and “*uncomfortable.”*

> *“It just feels like you're swallowing a grape whole or something like that. Yeah, so like it's just like a grape or a cherry or something like that at first. But obviously it's not that size, it just feels like that.”* OG10

> *“it's just natural to try and get rid of whatever's stuck in your throat. And I know that you can't because it's there, but your body just automatically - and it's hard to try and stop it. So I'm trying to get it out, but trying to stop myself at the same time. And then the nurse is trying to keep your head straight and there's stuff coming out all over. But it's got to be done. It's got to be done. And I just kept thinking that. My eyes tight shut. It's got to be done. It's got to be done. And in a minute it'll be gone. And then it's finished.”* OG15 (transnasal)

Some patients said that the discomfort they experienced was due to air being inserted. A few patients who underwent biopsies described feeling pain as the biopsy was taken.

Some patients said that they knew the test could be stopped if needed, either by signalling to the staff or by the nursing staff picking up that they were not tolerating the procedure, and this made them feel reassured:

> *“She’s (the nurse) there all the time and she says if you feel discomfort, put your hand up and I’ll stop it. And it’s her that reassures you and relaxes you, so when you’re on the table, the talk she’s just given you know she’s there to keep an eye on you.”* OG2

Patients felt reassured by this.

4.5.6. Sensory experience of the test: Colonoscopy

Colonoscopy patients described how they had gel inserted rectally prior to colonoscope insertion, and that this was a "*cold shock"* and embarrassing to some. Some described discomfort as the colonoscope was inserted, while others felt nothing:

> *"It's just actually the penetration if that's the word I'm looking for. It's probably that but once it's inside it's great. He waxes it, what do you call it? He oils it, so it's, you know, he's very good and, as I say, you get a few twinges when it's going in, I can feel it, but of course they fill you full of air so you get a feel of pains but that's the air doing that to you."* CO4

The physical feeling during the test ranged from "*cramps"* and *"twinges"* to "*painful*." Patients who spoke about pain said that it tended to come and go throughout the procedure; they attributed the pain to air being pumped in and the camera going around bends. They described how nursing staff sometimes pressed on the stomach, which made pain worse.

Patients in this group described being able to stop the test, with two patients doing so. Having the endoscopist talk during the procedure and prepare them for discomfort helped some patients to cope with more painful parts, with one patient also describing how the endoscopist checked that they were happy to continue the procedure:

> *"He (the endoscopist) talked all the way through the procedure and he told us that it was going to be painful going round a bend. I found it uncomfortable and he says is that all right? I says yes. Can I proceed? Yes. So everything was all explained, he even explained parts of the bowel and everything."* CO5

Patients also spoke about how they found the procedure easier when staff pre-empted possible discomfort and increased their sedation.

> *"They give me some medication. It begins with 'B', I can't remember what they call it, but anyway. He put some in but he knew I was in a little bit of pain. But*

I didn't even have to ask him, he knew and he just topped it up again a little bit and after that it was fine." CO4

Conversely, one patient described the endoscopist continuing despite her obvious discomfort and wish to stop, leaving her feeling like a "*piece of meat on the bed."*

"He wasn't explaining he was going to have to go around a corner and it was going to hurt. He [was] just totally, get on with it, she's had one dose. Leave her to it; that should be enough. It wasn't enough." CO7

Only one patient described being given gas and air (Entonox, nitrous oxide) during the procedure; they did not feel this helped with pain control.

4.5.7. Sensory experience of the test: CTC

CTC patients spoke about having "*jelly"* inserted rectally before a tube was inserted. Patients described gas being in "*blown in"* and described "*severe cramps,"* "*discomfort"* or a feeling "*like a stitch."* Gas insertion also made some patients feel they needed the toilet. One patient attributed their discomfort to dye being inserted intravenously, but most patients attributed this to air being inserted:

"I felt bloated. Oh when the air, yes I felt it was very painful, but it were like bad wind, but because I get sort of twinges around the stomach area so I suppose it depends what's that matter with you as to how you're going to feel doesn't it." CT8

Some patients spoke about how they had to change position and this was difficult for some because the bed was small; some described how nurses helped them with this. Some found holding the same position for prolonged periods of time difficult.

4.6. After the Test

This stage of the process covered the time period from when the procedure was completed until after discharge.

4.6.1. Recovery

Following the test patients described returning to the waiting room or changing cubicle. Patients who had undergone CTC often described a feeling of needing to pass wind or use the toilet following the test. Some of these patients spoke about how the toilet that they could use after the test was immediately adjacent to a waiting room, which worsened their feelings of embarrassment:

> *"They said just go in there and I'm thinking well I'm sitting and I thought God I can't, there's seats out there. What if somebody come and sat out there? Could you break wind when there's people sitting out there and of course I'm sitting going, I panicked, get your clothes on there, go home."* CT2

As a result of this, some patients waited until they got home to go to the toilet. Other patients described relief that they were taken to a private toilet away from other patients. A few patients didn't feel the need to use the toilet or pass air until they left the department, whereas another few patients preferred to wait until they got home to use the toilet:

> *"She said just take as long as you like. I think it was just in case this wind was going to come away from us. But it didn't, it waited until I got all the way home! (laughs) And then I had to run upstairs to the toilet to get rid of it."* CT4

Patients generally felt that the nurses "*took care"* of them while they were recovering. Aside from those who had throat spray, who were unable to eat or drink for a period after the test, all patients spoke about being offered a cup of tea after the procedure. For some this was the best part of the experience because they were thirsty and because it indicated that the procedure was over:

> Pt: *"I'm impressed with the person that brings me a cup of tea afterwards because I'm so relieved, you know."*
>
> Int: *"What is it about that cup of tea?"*

Pt: *“I'm going to start crying again. It's just the relief it's over.”* CO7

Some patients said they felt able to stay in the department for as long as was required to recover. Others noted that the recovery area was busy and, in some instances, felt pressure to leave:

> *“Because I remember they knocked on the door and said are you finished? I went no, I'm not. And so therefore I think that time is enough, provided that it shouldn't be like a cattle market. It should be like if you say right, there's a benchmark for everything. If you say well OK then he's in there for half an hour, that's OK. So we can get the next patient in the time and just have a matrix, call it whatever you wish, and cross-check and just say OK, this one can go out now, instead of whoosh, whoosh, come on, out. At the end of the day, it's supposed to be patient care, isn't it?”* CT5

The physical after-effects of the test and sedation varied. While some patients said they felt back to normal almost immediately, others described feeling “*wobbly”* or “*fragile”;* and others spoke about ongoing cramps, wind, stomach discomfort or a sore throat. While most patients felt back to normal the following day, some described unexpected ongoing altered bowel habit and discomfort. This was unexpected and caused anxiety:

> *“I expected to have diarrhoea for at least a day like, but not for about three or four or five days like. I don’t know if this might just have aggravated what problem I may have, I don’t know.”* CT1

A few patients who had undergone OGD spoke about discomfort in the throat for a day following the procedure.

> *“It was like there was something lodged there and you got it free and it's a bit raw.”* OG15

A few patients who had throat spray also described a numb feeling in the throat for a few hours following the procedure.

4.6.2. Results and Follow-Up

Patients spoke about how they preferred to have the results of their test immediately. Most who had undergone OGD or colonoscopy said they were told results either by the endoscopist after the test or by the nursing staff before they left the department. These 'verbal' results were not always detailed and some patients spoke about receiving a letter at a later date with more thorough results or biopsy results.

Some CTC patients noted that the process by which they would receive results was not clear.[14]

> *"They did say that I would get a copy of them, but I haven't had that. So I'm a bit unsure whether I have to come back here for an appointment or whether I'd just be seeing my GP."* CT8

These patients were often anxious about how they would get the result and what it might show:

> Interviewer: *"How do you feel about that [waiting for the results]?"*
>
> Pt: *"Just a little bit worried: it could be something, it could be nothing. I think it's just understandable to feel a little bit apprehensive."* CT4
>
> Pt: *"I think obviously when you get tests like that and you're waiting, you are tending to be a little bit apprehensive naturally. So that's as far as it goes yeah."*
>
> Interviewer: *"Apprehensive about what?"*
>
> Pt: *"Well just wondering if everything's OK. And if it's not what it's [the result] going to be."* CT10

Some patients in each procedure group, who hadn't had results by the time of the interview felt that if something serious had been found then someone would have

[14] CTC patients never got their results on the day of the procedure. This is because following the procedure, the scan must be interpreted and reported by a radiologist.

contacted them. However, others felt they had to chase things in case they were "*lost in the system*."

Of those patients who had received their written results, some described these as confirming the verbal results, but a few wanted more information about their diagnosis and a follow up plan.

4.6.3. Willingness to attend for future tests

Most patients said they would have the test again if necessary, although a couple spoke about how they would prefer to change certain aspects (e.g. request another endoscopist, have sedation instead of throat spray).

4.7. Discussion

These interviews provided a detailed, descriptive account of aspects of the procedural pathway and revealed which aspects of the experience mattered to patients. This analysis did not set out to identify 'factors' that might influence experience since the primary purpose was to inform generation of topics and a question bank. Therefore, this is further research that could be undertaken.

4.7.1. Key findings

Six over-arching themes were identified; anxiety, expectations, choice & control, communication & information, comfort and dignity & embarrassment. These did not appear at every point in the procedure pathway; however, they were common across all procedures. This suggests it may be possible to develop a PREM that could be used for multiple procedures.

Some sub-themes fell into more than one over-arching theme, suggesting that some of the over-arching themes were closely related. For example, the time from referral to the procedure date (*subtheme: referral for the test)* fell into 'expectations' and 'anxiety.' Although a longer wait for the procedure appointment made patients feel more anxious, patients who received an appointment sooner than expected became anxious that this might reflect a potentially serious diagnosis. The subtheme *preparing for the test* fell into 'expectations,' 'information' and 'anxiety.' For example, when a CTC patient described that the laxative "*mixture"* didn't work as he had

expected this caused anxiety that the procedure wouldn't be able to go ahead. He noted that having appropriate information which managed his expectations could have prevented this anxiety. This has implications for questionnaire development, as basing questionnaire items purely on over-arching theme could result in questions being attributed to a single theme, where in fact they contribute to several.

4.7.2. Strengths and limitations of phase

This is the first time that patient perspectives across three different GI procedures have been explored using in-depth, qualitative methods. Qualitative interviews have been undertaken in GI procedures, however, these tend to focus on specific populations, such as Barrett's oesophagus surveillance or colorectal cancer screening (von Wagner *et al.*, 2009; Arney *et al.*, 2014), or specific aspects of the procedure to enable comparison between procedure types, such as comfort in colonoscopy and colon capsule endoscopy (von Wagner *et al.*, 2009; Thygesen *et al.*, 2019). Furthermore, where more than one procedure type has been explored the results are analysed and described separately, rather than identifying themes common to all, for example; one study comparing colonoscopy, barium enema and CTC in a screening population (von Wagner *et al.*, 2009).

The qualitative interviews provided in-depth, descriptive accounts of the patient experience of GI procedures. Semi-structured interviews were used as this allowed a detailed description of the individual patient experience, where participants could speak more freely about sensitive areas. Indeed, patients did speak about sensitive issues, such as the insertion of the tube or camera, detailed descriptions of the effects of bowel preparation and discussion about particular issues which caused them embarrassment.

Diversity was sought in several aspects, including; procedure, sex, age group, indication and outcome, in the anticipation that this would capture people who had a broad range of experiences. Effort was made to ensure as full a range of eventual diagnoses were included, including those who received a cancer diagnosis, although only one patient with cancer was recruited. This was likely due to a combination of factors, including difficulty in scheduling an interview time when a new cancer was being assessed and the majority of participants were approached prior to their test,

meaning that the diagnosis was not known at the time of recruitment. Participants who had undergone transnasal endoscopy were also recruited to ensure the full breadth of OGD experience was explored, however, only three such participants were included. Most participants described a generally positive experience; however, two participants described a negative overall experience. This was despite effort to include participants who might have been more likely to have a negative experience, such as those with incomplete procedures. It may be that patients generally do have positive experiences, but the possibility cannot be excluded that those who were approached, or agreed to participate, were somewhat selected.

A potentially significant limitation of this phase was that participants were recruited from a single site (STDH), and it is unknown as to whether additional issues may have been identified by including other sites. As noted above, participants in this phase were generally positive about their overall experience. It may be that this is a site-specific issue. The endoscopy unit from which participants were recruited is accredited with the Joint Advisory Group on GI endoscopy, meaning that it meets a number of standards across four domains: clinical quality, quality of the patient experience, workforce and training (Joint Advisory Group, 2016). 223 units (of approximately 454 in England) have full JAG accreditation, with a further 58 assessed but requiring improvement in 2018 (Joint Advisory Group on GI Endoscopy, 2019). Some endoscopists in the unit also undertake NHS BCSP procedures and are as such required to demonstrate high quality colonoscopy, which could have a positive impact on experience. However, at the time of the interviews only two of twelve independent endoscopists were bowel cancer screeners and patients were recruited from all endoscopist lists (excluding BCSP lists). In terms of general experience, the hospital performs ‘about the same’ as other hospitals in England in the annual NHS inpatient survey, although this only addresses inpatient experience (Care Quality Commission, 2008). Potential differences between sites include pre-procedure information sheets, which are generally site-specific. Referral pathways may differ, for example, some sites may accept all endoscopy referrals as ‘direct to test,’ whereas patients at other sites may be seen in outpatients first. At STDH there is a mixture of ‘direct to test’ and clinic referrals. Most endoscopy units give a written form of results when the patient leaves the department, although practice may vary. Furthermore, some units which operate ‘direct to test’ policies

may have pre-assessment for endoscopic procedures, which is where patients either attend an appointment with or are telephoned by a nurse to check they are fit for the procedure. This was not standard practice at STDH at the time of this study.

The effect of recruiting from a single site was somewhat addressed by recruiting patients with prior experience of GI procedures at other hospitals, however, it is noted that while comparisons could be made, the interviews focused on the most recent test.

All OGD and colonoscopy procedures in this study were undertaken by doctors, including gastroenterologists, surgeons and trainees. CTCs are undertaken by radiographers and nurses, usually without a doctor present. There are increasing numbers of nurse endoscopists both in the UK and internationally (Chapman *et al.*, 2009; Duncan *et al.*, 2017). It would have been helpful to include patients who had procedures done by nurse endoscopists in the qualitative phase, however, there were no such endoscopists in the unit from which participants were recruited. Research in this area has shown that nurse endoscopists and doctors perform colonoscopies to an equal standard and a majority of patients have no specific preference for who performs the procedure (van Putten *et al.*, 2012). No patients in this study brought up the grade or discipline of endoscopist as being important.

Participants were approached by health professionals (research doctor or research nurse) and this may have affected selection or willingness to participate, for example, patients may have viewed participation as improving or adding to their management (although it was made clear that decision to participate would not affect clinical care). Participants who were especially pleased (or displeased) with their experience may have been more willing to participate, and this could have influenced the results. Staff were encouraged to approach all eligible patients on a consecutive basis, but this did not always occur.

Using an inductive, data-driven analysis approach ensured that the themes were derived solely from the data. Review of the thematic analysis by the supervisory team and double-coding of a subset of interview transcripts strengthened the integrity of the analysis. The sub-themes that emerged from the qualitative interviews were presented chronologically as this was how most patients described their

experience. This order was then used as a template for the PREM in subsequent stages of the research.

4.7.3. Discussion of findings in context of literature

The findings of the qualitative interviews were reviewed within the context of the literature and current practice.

4.7.4. Information

The topic of 'information' arose several times across many sub-themes in the qualitative interviews. Participants described its effect on helping them to prepare for the test and knowing what to expect during the test. The British Society of Gastroenterology (BSG) guidelines emphasise the importance of written information prior to a procedure so that the patient is able to give informed consent (Beg *et al.*, 2017) In the current study, patients talked about the written information about the test and preparation, information given during the test verbally by staff and information after the test, for example, the results. Qualitative interviews comparing patient experiences of colonoscopy, barium enema and CTC corroborate that information provision is important to patients (von Wagner *et al.*, 2009).

4.7.5. Clarity and mode of information delivery

A few patients in this study found that the written information leaflets were 'confusing' or contained either too much or too little information. All interviews were conducted at the same hospital in this study and therefore the patient information leaflets were standardised for each procedure, meaning that it is unclear to what extent the findings can be generalised to other sites. However, it was clear that patients had differing opinions on these standardised information leaflets, suggesting that patients have different requirements. Studies from both the UK and Ireland have shown significant variation in the amount of information contained in patient information leaflets for both colonoscopy and gastroscopy in different hospitals, and that the reading level often exceeds recommended reading age standards of 11- 12 years (Parahoo *et al.*, 2003; Gargoum *et al.*, 2014; Mason *et al.*, 2018). Unclear or confusing information before colonoscopy is associated with increased anxiety (Luo, 2013; Shafer *et al.*, 2018). Approaches to improve pre-procedural information have

included written information interventions tailored to patient 'coping' style, web based interventions and videos explaining either the preparation or procedure (Morgan *et al.*, 1998; van Vliet *et al.*, 2004; Eberhardt *et al.*, 2006; Bytzer *et al.*, 2007), however, a combination of oral and written information appears to be preferable for pre-procedural information when compared with oral information alone (Pearson *et al.*, 2005; Felley *et al.*, 2008) but also for information about results following the procedure (Rubin *et al.*, 2007). The results of the qualitative interviews in this study suggest that patients want different types of information and even different modes of delivery. The ideal would be to find a way to offer patients information which can be personalised to their needs in terms of what the information covers and how it is delivered.

4.7.6. Information about sensory experience and effect on anxiety

Some patients would have liked more information about how the test would feel (the sensory component of the test), how long the test would take, what exactly would happen during the test and more information about what the sedation would do. A previous study exploring OGD patients experience of written information suggested that such information should be expanded to cover what would happen during the procedure and sensory components of the procedure (Thompson *et al.*, 2003). A further study showed that patients prefer to receive sensory information and in some cases this can reduce anxiety before the test (Liu *et al.*, 2018). The concept of sensory experience is not limited to GI procedures and has been described, for example, in women attending for colposcopy who describe different aspects to the sensation of the test (O'Connor *et al.*, 2016). This qualitative study also noted that a lack of sensory information affected women's expectations and was linked with a negative sensory experience during the procedure. Therefore, providing information about what the test will feel like may play a role in letting patients know what to expect during their procedure.

4.7.7. Alternative sources of information

A few patients in this study said that they had looked online for information about the test. In general, this behaviour has risen over recent years with increased internet accessibility. Studies suggest that improvements in publicly available patient

resources are required (Koch-Weser *et al.*, 2010; Amante *et al.*, 2015). A study comparing information seeking behaviour between referral pathways and indications found that overall, 31% of patients with internet access searched for information about their procedure online (Silvester *et al.*, 2016). In that study, patients with symptoms were more likely to seek information online than in screening patients.

In this study, the qualitative interviews did not explore what sources of online information were accessed. One American study examining patients accessing healthcare noted that patients find accessing online information online frustrating and access a variety of sources, not all of which are credible (LaValley *et al.*, 2017). Consistent with this, patients in the current study acknowledged that accessing online information was not always helpful and sometimes caused them to worry further about the outcome of the procedure. A study which administered a survey to haematology outpatients found that accessing internet information may increase anxiety in some patients (38%) but in others it can be reassuring (32%) and can improve coping (Laurent *et al.*, 2012). This was not explored in such detail in the current study and may be an area for further exploration in patients undergoing GI investigations. Regarding gastroenterology information online, a recent study assessing the quality of patient information leaflets on gastroenterology society websites (American College of Gastroenterology, American Gastroenterological Association, American Society of Gastrointestinal Endoscopy, British Society of Gastroenterology and National Institute of Diabetes and Digestive and Kidney Diseases) showed that no institute provided information at a suitable level for patients, in terms of reading level (Hansberry *et al.*, 2017). In terms of endoscopy specific information on the internet, one study found that only three websites out of 45 identified sites provided information of a satisfactory quality about OGD (Priyanka *et al.*, 2018). Ensuring patients have access to adequate information is important, particularly given that the number of ‘open access’ referrals in the UK is rising, meaning that patients have their test without being seen by an endoscopist first in the outpatient department (Siau *et al.*, 2017). Further areas of research may explore what patients see as trusted sources of online information and focusing on providing good quality information within these sources.

4.7.8. Communication

Communication was very strongly linked with information in this study, and they were therefore incorporated into one over-arching theme. Patients described poor communication as having a negative effect on their experience, for example, staff failing to introduce themselves, not talking through the procedure or talking amongst themselves about unrelated topics. Furthermore, patients described staff attitudes as important. Staff could make the atmosphere in the room more relaxing and patients also gave examples of when staff negatively affected their experience. Several previous studies highlight the importance to patients of good staff communication, manner of staff and explanations by staff in OGD, colonoscopy and CTC (del Río *et al.*, 2007; von Wagner *et al.*, 2009; Sint Nicolaas *et al.*, 2012; McEntire *et al.*, 2013; Qureshi *et al.*, 2013).

4.7.9. Role of nursing staff

The perceived role of nursing staff was commonly discussed by participants and was represented in four out of the six over-arching themes. In addition to giving information before the test, patients described nurses as having a role in protecting their dignity, distracting them during the procedure, helping them to cope with discomfort and monitoring them and feeding back to the endoscopist if they were finding the test too uncomfortable. Most of the literature describes the role of nurses as largely being about communicating and giving information to patients, and monitoring patients (Voynarovska *et al.*, 2008). Nursing staff's role in helping patients to manage pain using non-pharmacological methods has been described in colonoscopy (Ylinen *et al.*, 2007). Outwith GI procedures, a UK study of patient experiences of prostate cancer care found that those who saw a specialist nurse had more positive experiences (Tarrant *et al.*, 2008). Patients in that study felt that nurses had more time to explain results in a simplified way, were able to give more information and support and also had a role as the patient's advocate. Although the latter was not described in the current study, patients did describe how nurses could intervene when they felt the patient was too uncomfortable, for example, and ask for more analgesia. This is an area that could be addressed in the PREM.

4.7.10. Anxiety

Patients described anxiety about various stages of the procedures, for example, anxiety about what the test would involve, what the result of the test would be, how they would access their results and whether the bowel preparation would work properly (CTC and colonoscopy).

In colonoscopy, one study examined specific aspects contributing to anxiety by asking patients to complete a survey in which they rated their levels of anxiety immediately prior to the colonoscopy appointment (Shafer *et al.*, 2018). Patients were anxious about the bowel preparation, the procedure itself and the results. Since this was a quantitative study, the potential causes of anxiety were listed for patients to endorse and rate, rather than exploring patients' anxieties in detail. The current study provided more detail about what aspects of the procedure caused anxiety and demonstrated that causes of anxiety were actually similar across all procedures (aside from concerns about the effects of bowel preparation, which were limited to those undergoing CTC and colonoscopy) and were evidenced across all phases. This means that questions within the PREM could examine anxiety in more detail, as described by patients.

Within CTC, there is a relative paucity of literature exploring patient anxiety. One study asked patients undergoing CTC and colonoscopy as part of a randomised controlled trial to complete a diary, which included questions about anxiety. This found no significant difference in anxiety levels between procedures (van Dam *et al.*, 2013). The current study did not explore levels of anxiety but instead described several dimensions of anxiety which were common across all procedures.

The role of information in reducing patient anxiety before the test has already been discussed, for example, information about the sensory experience of OGD has been shown to reduce pre-procedural anxiety (Liu *et al.*, 2018).

4.7.11. Effect of previous experience on anxiety

In the current study, participants described two distinct reactions to previous experience and its effect on anxiety. A patient who underwent regular surveillance colonoscopies felt that the procedure was '*routine*' and did not feel anxious, whereas

another patient who felt they had a previous bad experience of CTC described feeling *'frantic'* before the procedure.

Previous studies are inconsistent. One study that administered questionnaires to patients before and after colonoscopy found that previous colonoscopy experience had no effect on either pain during the current colonoscopy or anxiety prior to the procedure (Ylinen *et al.*, 2009). Another study comparing the effects of video information on pre-procedure anxiety in patients undergoing colonoscopy administered Spielberger state trait anxiety inventory (STAI) questionnaires to patients a week prior to and immediately before the procedure (Luck *et al.*, 1999). This found that patients who had not had a previous colonoscopy had significantly higher baseline anxiety scores than those with previous experience. A further qualitative study involving interviews with patients who were about to or who had recently undergone colonoscopy found that those with previous experience of the test described less anxiety as they knew what to expect from the procedure (Rollbusch *et al.*, 2014). The current study identified this in patients who attended for the test regularly, but patients who had a perceived 'bad' experience previously were more anxious about the procedure.

4.7.12. Reducing anxiety during the procedure

A few patients in the current study mentioned that they would have liked to have music in the procedure room, or that they liked that music was playing. This has been well explored in patients undergoing colonoscopy, with studies finding that listening to music can reduce anxiety, reduce patient discomfort and reduce the amount of sedation required (Chlan *et al.*, 2000; Lee *et al.*, 2002; Binek *et al.*, 2003; Ko *et al.*, 2017).

4.7.13. Anxiety about the test results

Some patients in this study expressed anxiety about what the results may be after the test and how they might receive them, if they hadn't already. A study randomised patients undergoing OGD or colonoscopy with sedation to receive standard verbal results or standard verbal results in addition to a copy of the endoscopy report (Spodik *et al.*, 2008). The rationale for undertaking this study was that patients who received sedation may not remember being told the results. The study found that

patients who received written results reported significantly less anxiety (measured using the Beck Anxiety Inventory) than those who did not. This level of detail was not assessed within the current study's qualitative interviews, but it is standard practice in the endoscopy unit where recruitment took place to give a written report after OGD and colonoscopy. For patients undergoing CTC, an immediate written report is not possible as the images need to be interpreted by a radiologist, which is time consuming.

4.7.14. Embarrassment

Patients in the current study described embarrassment at various stages of the procedure. For colonoscopy and CTC, embarrassment was reported when patients had to wait in public areas wearing gowns, during the procedure due to the private part of anatomy involved and after the procedure if they had to use toilets which were within earshot of the waiting area. Some patients felt the sex of the operator affected their embarrassment.

Some work has been undertaken to compare embarrassment, associated with different procedures (e.g. CTC compared with colonoscopy) however, this work focused on overall embarrassment (Gareen *et al.*, 2015). In the context of colorectal cancer screening, feelings of vulnerability and embarrassment in female patients were identified in a systematic review of the literature as a barrier to uptake (McLachlan *et al.*, 2012). A further two questionnaire studies found that women were more likely than male patients to have a preference for an endoscopist of the same gender (Fidler *et al.*, 2000; Shah *et al.*, 2011). In the current study, men expressed embarrassment with regards female operators undertaking intimate procedures, suggesting this issue is not just limited to female patients. This appears to be a novel finding. In order to explore this further in a PREM, questions about embarrassment and patient preference for endoscopist/ operator gender should be included.

The literature focuses on embarrassment mainly with regards lower GI procedures, however, the current study demonstrated that patients undergoing OGD also experienced embarrassment by their physical reaction to the endoscope being inserted.

4.7.15. Choice and control

In this study, patients described having control over their choice when considering what test to undergo (e.g. colonoscopy or CTC) and what medication to have (e.g. sedation or throat spray for OGD). Control was also described in terms of being able to stop the test and the feeling that they were responsible for swallowing the endoscope (OGD). Although patient preferences have been investigated in patients undergoing GI procedures (for example, when comparing the acceptability between per-oral and transnasal endoscopy, Alexandridis et al., 2014), patient perspectives of choice and control have not been explored in a detailed fashion. Involving patients in decisions about their clinical care and enabling patients to make choices relating to their management is a priority of the NHS in England (NHS England, 2017). The qualitative interviews highlight areas where patients describe the importance of choice related to GI procedures.

4.8. Summary

This phase of the study identified aspects of the experience that are important to patients and provided a structure for questionnaire item generation. Several themes emerged that are present in the literature; however, this phase provided more detail regarding aspects of these, such as anxiety and embarrassment. No themes were identified in the current literature which did not emerge from the qualitative interviews.

Chapter Five: Developing the ENDOPREM™

5.1. Aims of phase

This second phase aimed to develop a pilot PREM. It involved two stages: a question bank was generated and initially refined by discussions within the study team, with areas of interest explored with a focused literature review; this was then further refined and finalised through cognitive testing with patients.

5.2 Generating the Question Bank

5.2.1. Determining question topics

In order to generate a question bank, it was first necessary to determine what topics should be addressed in the questionnaire. The themes identified within the qualitative interviews were organised into chronological order according to stages of the patient 'journey,' as described during the patient interviews. Questions were derived according to the stage of the procedure. Review confirmed that the over-arching themes were covered by questions within each procedure stage, further ensuring content validity. Focused literature review found no additional aspects of patient experience.

The first iteration of the question topics is shown in table 5.1. The wider study team agreed on these areas broadly, however, question phrasing and some topics for inclusion/exclusion were debated in the review and revision rounds. Some explanatory questions were added as they were factors that might influence experience, for example: *my appointment was cancelled or changed by the hospital (Yes/ No/ Not sure or can't remember)* and *the person doing the test was male/female*. In the early iterations, discussion centred mainly on phrasing of questions to ensure they encapsulated the patient experience as described by the qualitative interviews, rather than asking questions about service delivery. An example of this relates to the waiting room. An early draft of the question asked about patient satisfaction of the waiting area. The question was intended to ask whether patients felt comfortable whilst waiting. However, it could be interpreted as a question about the facilities rather than experience, and as such, didn't fall within any

of the over-arching themes. It was therefore rephrased to ask about the extent to which patients felt comfortable whilst waiting.[15]

[15] Comfort was one of the over-arching themes which emerged from the qualitative interviews

Procedure Stage	Item	Overarching theme(s)	Suggested Question/ Topic
Participant Characteristics	-	-	Age Education level Ethnicity Number of previous GI procedures How participant referred for test
Before attending for the test	Referral process	- Expectations	Experience of referral mode- e.g. referred directly or appointment with doctor in outpatients first
	Information before the test	- Information & Communication	Was there enough opportunity to discuss the test before the day of the test? Were you able to discuss the test prior to the day of the procedure?
	Waiting time for appointment	- Expectations - Anxiety	How satisfied were you with the waiting time for the procedure appointment?
	Appointment choice	- Choice &Control	Were you able to organise an appointment that was convenient for you?
	Appointment convenience	- Choice & Control	Were you able to change the appointment if it didn't suit?
	Alternatives	- Information & Communication	Were you told of any alternatives to the test?
	Information about the test	- Information & Communication - Expectations	Did you receive enough written information before the test about: 1. What would actually happen on the day 2. What the procedure would involve 3. How you may feel after the test Did you feel the information prepared you for the test?
	Clarity of information before the test	- Information & Communication	Was the information before the test easy to read? Did you understand it?
	Other sources of information	- Information & Communication	Did you talk to others about the test? How did this affect anxiety?

		- Expectations - Anxiety	
	Anticipation of the test	- Anxiety - Expectations	Prior to the test, were you worried about what it might entail? Prior to the test, were you worried about the results?
Preparing for the test	Information about diet	- Information & Communication	Was the information regarding the diet clear? Did you need any further information?
	Taste of bowel preparation	- Comfort	The bowel preparation tasted acceptable/ was manageable
	Volume of bowel preparation	- Comfort - Expectations	Was the volume of bowel preparation more than you expected?
	Effects of bowel preparation	- Expectations	Did the laxative drinks work as well as you expected?
	Trouble-shooting	- Information & communication	If you had problems with the drinks did you know where to find help/ advice?
Arriving at the hospital	Parking		If you drove, how easy was it to get parked at the hospital?
Waiting in the hospital	Getting changed at the hospital	- Embarrassment & dignity	Was the dressing area private enough?
	Waiting in the department	- Embarrassment & dignity	Was the waiting area private enough?
	Waiting areas	- Comfort	How satisfied with the waiting area were you?
	Waiting time in the department	- Expectations - Anxiety	Did you wait in the department for longer than you expected?
During the test	Choice of pre-medication	- Choice & Control - Information & Communication - Expectations	Were you pressured into taking a particular pre-medication option?
	Effect of the pre-medication	- Expectations - Comfort	How satisfied were you with the effect of the pre-medication

	The procedure room	- Comfort	How satisfied were you with the environment where the procedure took place?
	Procedure room atmosphere	- Comfort - Information & Communication	How satisfied were you with the atmosphere?
	Staff attitudes	- Information & communication	How satisfied were you with: 1. Attitude of nursing staff 2. Attitude of the Endoscopist 3. Communication skills of the nursing staff 4. Communication skills of the endoscopist
	Discussion before the test	- Information & Communication	Were you given adequate time to discuss the test before it started?
	Staff reassuring	- Information & Communication - Anxiety	Did staff put you at ease?
	Maintaining dignity	- Embarrassment & dignity	Did you find the procedure embarrassing? Did staff protect your dignity during the test?
	Ability to stop the test	- Choice & Control - Comfort	Did you feel able to stop the test if it became too uncomfortable?
	Endoscopist gender	- Choice & Control -Embarrassment & dignity	Were you given the option of Endoscopist gender? Options to include no but it didn't matter to me, yes and this mattered to me etc[16]
	Discussion with Endoscopist	- Information & Communication	Were you happy with the explanation/ discussion with the Endoscopist during the test?
	Feeling of the test	- Comfort	How unpleasant/ uncomfortable was the procedure?
After the test	Comfort after	- Comfort	Following the test how uncomfortable were you?

[16] This question was reviewed and refined. It was decided to add a question regarding gender to enable its association with embarrassment to be assessed

	the test		1. Immediately after 2. Before leaving the department 3. In the days following the test
	After-effects of test	- Expectations	In the days following the test, did you continue to have diarrhoea?
	Results	- Expectations	Were you satisfied with how you were given results? If you were not given results at the time of the test, did you know when you would get them? How satisfied were you with the waiting time for results? Were you given enough information after the test about 1. Results and explanation 2. Follow up plan
	-	-	Refreshments after the test

Table 5.1: Initial question bank

Ten rounds of review and revision within the study team were conducted. This involved circulating questionnaire drafts via email and inviting group members to comment, and several teleconference discussions. Those discussions and decisions taken are summarised in the sections below.

5.2.2. Before the Test

The qualitative interviews found that referral for the test or initial outpatient appointment by primary care, and patient expectations around this, was an important aspect of patient experience (e.g. patients believing they had been referred for an OGD but instead being seen in clinic first for a discussion with the procedure being undertaken in a subsequent appointment). The study team agreed that consultations and decisions made in primary care were beyond the remit of this PREM, but that inclusion of a question assessing satisfaction with the referral process could be useful in assessing experience; therefore a question addressing this was added (*I was happy with the way I was referred for the test- Likert response options).*

5.2.3. Preparing for the Test

This section centred on questions about bowel preparation for colonoscopy and CTC patients. First drafts of questions asked about the taste of the preparation, but review by the team concluded this did not capture all of the over-arching themes associated with the bowel preparation. Further questions were developed relating to the taste and volume of the preparation compared to patient expectations and anxiety associated with whether the preparation worked properly.

5.2.4. At the Hospital, before the Test

Some questions in this section asked about experience of waiting in the department. The first iteration of questions asked about cleanliness and adequacy of the waiting areas. As discussed above, this addressed the facilities rather than patient experience. Questions considered to better address the themes in this phase were developed. These focused on the waiting time in the department compared with expectations and comfort and privacy whilst waiting in the department.

5.2.5. During the Test

The items which generated the most discussion within the team in this section were related to pain and discomfort. Debate centred on defining pain and discomfort, whether these terms were interchangeable and the presence of pain across different stages of the procedure. Three approaches were undertaken to review this. Firstly, the qualitative interviews were revisited, specifically looking at times when pain or discomfort were mentioned. This clarified that patients described three aspects to pain/discomfort: intensity, duration and number of times pain/discomfort was experienced. Secondly, a focused literature review was conducted to identify descriptions of pain and discomfort and potential differences between the two and how they are measured (Appendix I). This showed that the majority of studies used the terminology 'discomfort' rather than 'pain.' Pain and discomfort were measured in a variety of ways, including numbered response scales (NRS), verbal response scales (VRS) and visual analogue scales (VAS). Thirdly, pain and discomfort were explored further in the cognitive interviews (section 5.3.6).

For the purposes of the PREM, the study team decided that different approaches to pain and discomfort measurement should be explored within the cognitive interviews, including VAS, VRS and NRS. The concepts of pain and discomfort were also explored in more detail.

5.2.6. After the Test

Discussion in this section centred mostly on the results of the procedure. Although the question domains here were clear from the qualitative analysis (namely anxiety about what the results would show, uncertainty about how they would get their results and uncertainty about next steps in terms of management), discussion centred on how to best assess these areas, given variation in practice about how and when results are received. There was concern within the team that reporting of aspects of patient experience could be affected by whether someone had received their results. A question to determine whether and how results had been received was therefore added with multiple response options. Where questions asked about results, an extra option was added allowing participants to declare that they hadn't yet received their results.

One question which wasn't covered by any of the over-arching themes was included in this section: *I was pleased with the refreshments offered.* In the qualitative interviews, this was seen as a 'marker' of the end of most procedures and patients described its importance as a signal at the end of the test.

5.3. Cognitive Testing

Five rounds of cognitive testing were undertaken, with three participants in each round. Four participants had taken part in the qualitative interviews and 11 had not been interviewed before. Table 5.2 shows participants' characteristics.

Variable		**Number of participants (%)**
Gender	Male	6 (30.0%)
	Female	9 (60.0%)
Age	≤54	5 (33.3%)
	55-64	5 (33.3%)
	65-74	3 (20.0%)
	≥75	2 (13.3%)
Procedure	OGD (including transnasal endoscopy)	7 (46.7%)
	Colonoscopy	7 (46.7%)
	CTC	1 (6.7%)
Education Level	High School	9 (60.0%)
	College	4 (26.7%)
	Higher education	2 (13.3%)

Table 5.2: Cognitive Interviewee Characteristics

Issues identified in these interviews are described according to procedural stage in the following subsections.

5.3.1. Patient Information

In the questionnaire drafts used in the first three rounds, three boxes were provided for participants to enter their age in single digits. The rationale for this was that patients could have been 100 years old or over. 5 out of 9 participants found this format confusing and hesitated over which boxes to use. This issue was in the *formatting* response stage and was a *computational* problem. Subsequently, this was

changed to a large box for participants to write their age; this caused no problems in subsequent rounds.

In terms of the procedures participants had had, three participants who had undergone colonoscopy were confused by the descriptions of colonoscopy and CTC (*lexical problem, understanding response stage*). The wording of the descriptions of both colonoscopy and CTC were refined and found to be acceptable in further cognitive rounds.

Participants were asked to record how many procedures they had undergone previously. Understanding of this question was variable in terms of whether the current test should be included (*omission/inclusion problem).* The question was reworded to clarify that this included the current test. A summary of the questions amended in this section, the response stage and type of problem they represented is shown in table 5.3.

Question Tested	**Response Stage**	**Problem Type**	**Final Question**
Please fill in your age (in years): Response options three boxes	Formatting	Computational	Response option changed to one large box
Which test did you have on this occasion? Colonoscopy :*(Camera or tube inserted through the back passage)* CT Colonoscopy/ pneumocolon: *(Scan where air is passed into the bowel through a small tube)*	Understanding	Lexical	Response options changed: Colonoscopy: *Camera or tube inserted through the back passage* CT Colonoscopy/ pneumocolon: *CT scan where a short tube is inserted into the back passage- done in the x-ray department*
Please indicate which test and how many you have had	Understanding	Omission/ inclusion	Including your most recent test, please indicate which tests and how many you have had

Table 5.3: Patient characteristic question development

5.3.2. Cognitive Interviews: Before coming for the test

"I was able to choose a time that was convenient for me to have the test"

This question posed a problem in the *performance response* stage as participants noted that they didn't actually choose the appointment slot. Participants pointed out that they didn't have choice over the time, but this didn't necessarily adversely affect them (*logical problem).* The wording of the question was changed to "I felt able to change the appointment if it didn't suit me," and was considered acceptable in further cognitive rounds.

"I was given enough information before the test about what it would involve"

This question was designed to assess whether patients had enough information prior to the day of the test. In the first round, 2 out of 3 participants answered this question based on the information given in the department on the day of the test (*understanding response phase, temporal issue).* The question was reworded and headings indicating the stage of the test were inserted in all sections of the questionnaire. No issues were identified in subsequent questionnaire rounds with this question.

"I had enough time to discuss the test"

This question was intended to ask participants if they had adequate opportunity to discuss the test with the referring clinician prior to the day of the test. In the first and second round of interviews, one participant was not sure who they could have discussed the test with (*computational problem)* and two participants answered the question for the wrong time stage of the test (*temporal problem).* Section headers stating 'Before the test' were placed at the top of each new page. The question was also restructured to state that it was referring to having time to discuss the test with the referring clinician. No further issues with this question were identified in subsequent rounds.

"I felt anxious about the results of the test"

One participant in the first round of cognitive interviews and another in the fourth round answered this question in relation to how they felt after the test, whilst awaiting the results (*understanding, temporal problem)*. To address this, sections of the

questionnaire were labelled according to the stage of the procedure they related to. Where a section stretched across pages the section header was repeated at the top of the page.

The issues arising in this section, the response type and problem stage, are summarised in table 5.4.

Question	Response Stage	Problem Type	Final Question
I was able to choose a time that was convenient for me to have the test	Performance	Logical	I felt able to change the appointment if it didn't suit me
I was given enough information before the test about what it would involve	Understanding	Temporal	Before coming for the test, I was given enough information about what the test would involve
I had enough time to discuss the test	Understanding	Temporal Computational	I had enough time to discuss the test with the person who referred me
I felt anxious about the results of the test	Understanding	Temporal	Before coming for the test I felt anxious about the results of the test

Table 5.4: Before the test question development

5.3.3. Cognitive Interviews: Preparing for the test

No problems with specific questions were identified for this section of the questionnaire, which applied only to those undergoing CTC and colonoscopy. One interviewee (in round 1) of the seven who had undergone OGD started to complete this section. On further questioning, they had understood that it wasn't relevant to them but stated that they wanted to be helpful and so had answered the questions based on a relative's experience. A large text box stating that the section should only be answered by those undergoing colonoscopy and CTC was inserted. No further similar issues were identified.

5.3.4. Cognitive Interviews: At the hospital, before the test

"I felt able to ask any questions I had before the test"

In the first round of interviews, one participant understood the question and said they felt able to ask questions, but felt embarrassed about asking questions. They therefore found difficulty formatting their response. A further participant in the second round felt able to ask questions but didn't have any (*logical, formatting problem).* The question was intended to ask whether participants felt that staff could be asked questions and address any concerns they had. This centred on communication but also on information. The question was reworded and a further question added to assess whether all questions had been answered. No further issues were identified in subsequent testing.

"I had enough privacy when getting ready for/ waiting for the test"

These two questions- one which referred to privacy when getting ready for the test and the other whilst waiting- were initially in the same section. Patients undergoing OGD (round three) pointed out that they did not need to get changed for the test and therefore the question relating to privacy when getting ready was moved to the section about preparing for the test in the department. One participant undergoing OGD (round three) didn't feel that they needed privacy whilst waiting for the test and was not sure how to answer. This was a *performance* problem and related to an *logical* issue.

The issues arising in this section are summarised in table 5.5.

Question	**Response Stage**	**Problem Type**	**Final Question(s)**
I felt able to ask any questions I had before the test	Formatting	Logical	I felt able to ask the staff any questions before the test I had no unanswered questions before the test
I had enough privacy when getting ready for/ waiting for the test	Performance	Logical	Question moved to colonoscopy/ CTC specific section

Table 5.5: At the hospital, before the test question development

5.3.5. Cognitive Interviews: During the test

"I was able to choose what medication (e.g. throat spray, sedative), if any, to take without feeling pressurised by staff"

An interviewee in the first round who underwent CTC could not answer this question as they were not offered any medication *(performance stage, logical issue).* A further OGD participant had the same issue as they did not realise there was a choice (round three). After discussion within the research team, the response options were not altered; had an option of 'no choice was provided' been added, the team felt this could cause further confusion for those undergoing OGD/colonoscopy/CTC who did have a choice but didn't feel free to choose. The question was simplified and reworded, with no problems in subsequent rounds.

"It was important that I was able to choose the gender of the person doing the test"

Participants in the first and second cognitive interview rounds demonstrated *logical performance* problems with this response as they were not given a choice in the sex of the person doing the test. Revisiting the qualitative interview data indicated that not all participants expressed a preference for operator sex, but that some found that operator sex affected whether they felt embarrassed. A separate question with Likert response options to the 'Before coming to the hospital for your test' section was added, which asked (*I hoped the person doing the test would be the same sex as me)* and a question asking the sex of the person doing the test was added. No further problems were identified in subsequent rounds.

"The atmosphere in the test room put me at ease"

This question had been intended to assess communication between staff and staff behaviour in the procedure room. In the first and second cognitive interview rounds 4 out of 6 participants were confused and did not understand the wording of the question (*lexical issue*). One participant suggested this meant the equipment, and another explained:

> Researcher: *"What do you think that question means- the atmosphere in the test room put me at ease?"*

Pt: *"When I was in there… the nurse was talking to us, the doctor was talking to us all the time. You know I just felt like I was just having a chat with them. It doesn't really bother us at all."*

Researcher: *"Does that question seem different to E7 and E8, the person doing the test and the other staff in the test room, are they asking the same thing or…?"*

Pt: *"they constantly asked us if you ok? Yes, fine. And they were calling us by name. It was just general chat and familiar with you. They were friendly and I didn't feel threatened in any way, there wasn't any embarrassment or anything like that even though I knew what was going to happen. It's not pleasant or something that's done every day really but I felt really at ease with them." (COG4)*

This question was removed as there were already two other questions asking about staff behaviour and communication in the procedure room.

A summary of the above issues is shown in table 5.6.

Question	**Response Stage**	**Problem Type**	**Final Question**
I was able to choose what medication (eg throat spray, sedative), if any, to take without feeling pressurised by staff	Performance	Logical	I felt free to choose what medication to take (e.g. throat spray, sedative, no medication)
It was important that I was able to choose the gender of the person doing the test	Formatting	Logical	The person doing the test was: male/female Additional question added: I hoped the person doing the test would be the same sex as me
The atmosphere in the test room put me at ease	Understanding	Lexical	Question removed

Table 5.6: During the test question development

5.3.6. Cognitive Interviews: Pain and Discomfort

The decision was taken to include pain and discomfort questions in this phase to investigate whether people complete these in the same way or differently. In the first cognitive interview round, 10 questions about pain and discomfort were included: two VAS each for pain and discomfort regarding the overall and worst pain/discomfort experienced; one VRS relating to the number of pain/discomfort episodes and two VRS relating to the length of time the pain/discomfort was experienced both overall and at its worst (Appendix I). The anchors used in the VAS were 'no discomfort' to 'worst discomfort imaginable' and 'no pain' to 'worst pain imaginable.' No problems with understanding the anchors arose within the cognitive interviews. The first iteration of the VAS more closely related an NRS, as shown in Figure 5.1.

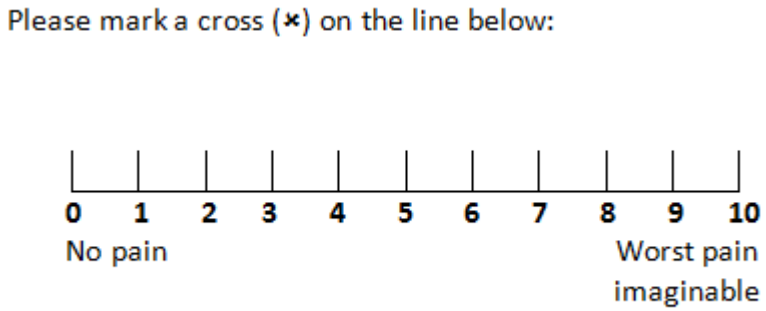

Figure 5.1: First iteration VAS

Participants found this format difficult to complete and were not sure where to put the cross. The final iteration is shown in Figure 5.2. All participants completed this correctly within the third to fifth cognitive interview rounds.

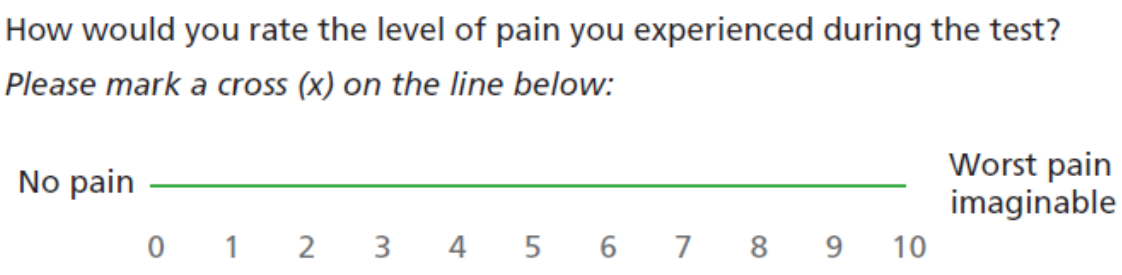

Figure 5.2: Final VAS

Participants in earlier rounds felt that there were too many questions and that the questions repeated themselves. One participant felt like they were being '*caught out.'*

Pain and discomfort were explored further in the cognitive interviews and it was clear that the meaning of these terms varied between participants. Some equated the two, whereas others described pain as more severe than discomfort:

> *"Now me, I never got any pain. There was discomfort but I wouldn't have classed it as pain. Potentially some people might get pain."* (COG5)

> *"Well if I'm not comfortable I'll say I just don't feel right but that's as far as it goes. Oh I feel awful today, it's an everyday phrase that people use. And to me it's just that, you're not 100% yourself, you're out of kilter. That's all it means to me. But pain is an entirely different thing. Pain to me is something which is unbearable; you just can't wait for it to go away. It drives you crazy and drives you insane when you've got real pain."* (COG12)

It also became clear that participants could not differentiate between the overall length of pain/discomfort experienced and the time that the worst pain/discomfort lasted. These questions were therefore changed and instead participants were asked how long the pain/discomfort lasted during the test. Instead of asking about overall compared to worst pain/discomfort, participants were instead asked to rate the level of pain/discomfort experienced during the test using a VAS.

No problems with the pain/discomfort questions were identified in the final round of cognitive interviews.

5.3.7. Cognitive Interviews: After the Test

"I was pleased with the refreshments offered"

Participants who had throat spray were unable to eat and drink following the test. An OGD participant in the first round therefore encountered a *logical* problem with the response *formatting* for this question. A further response option was added to account for those not offered refreshments. No further issues with this question were raised in subsequent rounds of testing.

"I felt uncomfortable before/after I left the hospital/ clinic"

One participant in the first round, two in the second round and one in the fourth round had difficulty answering this question as they were unsure about the time period that was being referred to (*understanding, temporal problem)*. The questions were reworded to include an example of the time period referred to. No further problems with the questions were identified following this.

"When I left the hospital, I was unsure of how I would get the results of my test"

Two participants in the second round noted that there were sometimes two parts to the results for endoscopy patients: the findings of the test (which they may have been told on the day of the procedure) and the results of any biopsies taken, which usually followed later. Some participants were not sure which result the question related to. An additional question asking how participants received their results was inserted, asking participants to tick one of seven response options to indicate whether they did not have any results, had some of their results and had all of their results. A further response option was added to the question above (*When I left the hospital, I was unsure of how I would get the results of my test)* for those who already had results. No further issues were identified in later cognitive interview rounds.

The issues raised in this round of cognitive interviews are summarised in table 5.7.

Question	**Response Stage**	**Problem Type**	**Final Question**
I was pleased with the refreshments offered	Performing	Logical	Additional response option entered
I felt uncomfortable before/after I left the hospital/ clinic	Understanding	Temporal	I had discomfort before I left the hospital/clinic I had discomfort after I left the hospital/ clinic (*e.g. when I got home*)
When I left the hospital, I was unsure of how I would get the results of my test	Formatting	Computational	Additional response option entered

Table 5.7: After the test question development

5.3.8. Cognitive Interviews: Overall Experience

Three questions on the overall experience were tested in the first three cognitive interview rounds;

1. Overall I was happy with my experience of the test
2. Overall the experience was better than I expected
3. I would recommend this test to a friend or relative if they required it

The wording of the first question was changed from happy to satisfied, after feedback from participants. The final question regarding recommending the test was removed as participants noted that they wouldn't advise relatives against procedures recommended by clinicians. No further issues were identified in subsequent rounds of testing.

5.4. Discussion

5.4.1. Key findings

This phase of the study generated an initial question bank which was refined through multiple rounds of revision and review within the study team, followed by cognitive pretesting. The most common issues arising in the cognitive interviews were *logical* problems, which were refined in subsequent interview rounds. The pilot PREM is shown in Appendix F.

5.4.2. Strengths of phase

The strengths of this phase lay in the multiple rounds of revision and review within the wider study team, supplemented with cognitive interviews with patients who had undergone GI procedures. Circulation of the qualitative analysis to the study team alongside the questionnaire iterations helped ensure all aspects of the patient experience were covered and facilitated expert consensus on question wording and response options. This also helped to refine and remove questions which did not assess patient experience according to the over-arching themes but instead covered service delivery issues (for example, satisfaction with the waiting area). Where there were areas of disagreement or uncertainty, such as the measurement of pain and discomfort, the qualitative interviews were revisited, and focused literature reviews undertaken.

The aim of cognitive pre-testing is to ensure that intended recipients correctly understand and respond to questionnaire items (Willis, 2004). Analysis was undertaken using a framework proposed by Conrad and Blair (1996), enabling problems to be identified according to their response stage and further broken down to problem type. This standardised approach was useful in identifying patterns of problems but also facilitated improvement of problem questions by easily identifying the underlying issues. There is no agreed optimal number of participants for cognitive testing of questionnaires, however, undertaking 'rounds' of cognitive interviewing with refinement of questions and subsequent retesting is recommended (Beatty *et al.*, 2007); the current study involved five rounds, by which point all issues were resolved.

A further strength of this work was the inclusion of previous qualitative interview participants (n=4) in the early rounds of cognitive pre-testing. This provided content validity as the participants agreed that the questionnaire represented their experience, with no suggested additions. These four participants were supplemented by new participants who had no prior contact with the researcher or knowledge of the study. This helped to provide confidence that patients that were 'new' to the topic/ study could understand and complete the questionnaire. Moreover, they did not suggest any additions to the content.

5.4.3. Limitations of phase

A limitation of this phase is that only one CTC patient was included in the cognitive pre-testing. This was partly because recruitment from this group was more difficult due to the relatively low numbers of these procedures at the research site and also that CTC is often used for patients deemed too frail for colonoscopy, meaning that re-attendance was not always easy. An alternative to this could have been telephone interviews; however, it was felt that this would be difficult as the researcher would not be able to see participant's reactions or identify hesitation to enable probing.

A further limitation was that participants were only included from one hospital site, meaning that some aspects of experience could be specific to that site. This is a particular risk because the qualitative interviews used to generate the items were undertaken at the same site.

Another limitation is that health professionals approached people to ask them if they were potentially willing to take part (researcher, research nurses). It is therefore

possible that this emphasised recruitment of health literate or more highly educated participants who might be expected to be better able to complete a questionnaire, however, this was difficult to mitigate. Purposive sampling was used to ensure a range of education levels were included, to try and limit this effect. Nine participants had not undertaken any further or higher education.

The researcher leading questionnaire development and undertaking the cognitive interviews (LN, student) was a gastroenterology research fellow with a dual role as an endoscopist. This could potentially have influenced interpretation of the cognitive interviews and questionnaire development. The effect of this was somewhat mitigated through supervision by non-GI supervisors, and multiple rounds of review and revision within the team who were mainly non-gastroenterologists or clinicians (Appendix E).

5.4.4. Pain and discomfort

The main area of discussion in both the initial review and revision rounds and the subsequent cognitive testing was pain and discomfort. Literature review, described in Appendix I, revealed heterogeneity between methods to assess pain and discomfort in endoscopy and CTC studies, with VAS and VRS being the most commonly used. A literature review examining response scale selection in pain measures has recently been published and concludes that 11-point NRS demonstrates slight superiority in terms of reliability, validity and responsiveness compared to other measures (Safikhani *et al.*, 2018). However, the authors are clear that pain/discomfort measurement tools should be tailored to the context in which they are being used. The difficulty with designing the pain/discomfort measure in this study lay in the diversity of patient descriptions across and even within procedural groups in the qualitative interview phase and in the cognitive testing.

The first draft of questions presented in cognitive testing contained several detailed questions about pain/discomfort at various stages of the test, but participants found this confusing and repetitive (Appendix J). The questions were therefore refined and focused to cover three broad categories; intensity, duration and frequency, which had emerged from the qualitative interviews. This description aligns with that used in a nurse- reported measure of comfort in colonoscopy (Rostom *et al.*, 2013) and also a patient-reported measure in the Norwegian colorectal screening population (Hoff *et al.*, 2006). In some cases, qualitative interview participants attributed their

pain/discomfort to certain stages or circumstances of the test, for example, air/gas insufflation, biopsies, bend negotiation in colonoscopy and camera/tube insertion (see sections 4.5.5-7). Including every eventuality described in the qualitative interviews would have resulted in a lengthy, and potentially confusing, questionnaire, the detail of which may have been difficult for participants to discriminate.

A further problem with these questions was the meaning of pain and discomfort. The qualitative work elicited that some patients perceived pain as a more severe form of discomfort, whereas others equated the two. This was clear in the cognitive interviews also, as some participants answered the same for pain and discomfort, whereas others scored discomfort higher than pain. A literature review revealed that exploration of this is lacking with regards GI procedures, however irritable bowel syndrome (IBS) qualitative work has noted that most patients describe pain and discomfort as two different entities (Spiegel *et al.*, 2010). Further study described that discomfort can be non-painful in this setting (Sach *et al.*, 2002). Bearing this in mind, the study team agreed that asking the same questions for pain and discomfort in the pilot PREM was the most pragmatic approach and would enable further investigation and analysis in phase 3 (chapter 6).

5.4.5. Summary

In summary, this stage of question development including multiple rounds of expert revision and review, followed by cognitive pre-testing, resulted in a pilot PREM (ENDOPREM™) comprising 59 questions encompassing patient experience, in addition to a section addressing participant characteristics (Appendix F). The questions were divided into seven sections, namely; Section A- Completing this survey, Section B- Before coming to hospital for your test, Section C- Preparing for your test, Section D- At the hospital, before the test, Section E- During the test, Section F- After the test and Section G- Overall experience.

Chapter Six: Piloting the ENDOPREM™

6.1. Introduction

This phase of the study investigated the psychometric properties of the pilot ENDOPREM™ (Appendix F). The statistical analysis focuses on the following areas:

- Patterns of response
- Respondents' characteristics
- Distributions of responses
- Levels and patterns of missingness
- Completion of pain and discomfort questions
- Exploratory factor analysis and internal consistency

6.2. Patterns of Response

6.2.1. Response rate

Questionnaires were distributed from October 2017 to September 2018. Participants were asked to return their questionnaire using a pre-paid envelope using the freepost address of the host organisation. Due to an issue with the freepost license from March 2018 to mid-May 2018, recruitment had to be paused and therefore the total recruitment time was 9.5 months. 1651 questionnaires were distributed and 802 were returned. Two of these questionnaires were blank and another had been distributed in error (patient had undergone a procedure not covered by the study). Thus, the overall response was 799 out of 1650 eligible participants, a rate of 48.4%.

6.2.2. Comparison of respondents vs non-respondents

Of the 851 patients given questionnaires who didn't respond (including the two blank questionnaires), 350 (41.2%) were male. Non-respondent's ages ranged from 18-89 with mean of 58.6 (SD 15.7). Table 6.1 compares respondents and non-respondents by sex, age, procedure type and recruitment site. There was no significant effect of sex on response (χ^2_1=0.91, p = 0.342), however age (χ^2_1= 94.45, p <0.001), procedure (χ^2_1= 18.31, p <0.001) and site (χ^2_1= 8.04, p = 0.045) were all significantly associated with response.

Variable		Respondents n (%)	Non-Respondents n (%)	p value
Sex	Male	346 (49.7%)	350 (50.3%)	p = 0.342
	Female	444 (47.3%)	494 (52.7%)	
Age	≤54	142 (30.4%)	325 (69.6%)	p < 0.001
	55-64	191 (48.7%)	201 (51.3%)	
	65-74	271 (60.4%)	178 (39.6%)	
	≥75	181 (56.4%)	140 (43.6%)	
Procedure	OGD	328 (45.6%)	392 (54.4%)	p < 0.001
	Colonoscopy	346 (54.3%)	291 (45.7%)	
	CTC	115 (55.0%)	94 (45.0%)	
	OGD and Colonoscopy	10 (29.4%)	24 (70.6%)	
Site	A	98 (43.9%)	125 (56.1%)	p = 0.045
	B	193 (53.8%)	166 (46.2%)	
	C	220 (50.1%)	219 (49.9%)	
	D	288 (45.7%)	342 (54.3%)	

Table 6.1: Characteristics of respondents vs non-respondents

6.3. Response distributions

6.3.1. Content of questionnaire and questions included in analyses

73 questions were included in the questionnaire booklet (Appendix F). The ten questions in Section A (socio-demographics and previous endoscopy experience) were included to enable comparison between groups in further analyses beyond this thesis. A summary of the responses to these questions is shown in table 6.2 (excluding A1 which asked for the date of questionnaire completion).

Question	Response
A2. Time since test (days)	Range: 0-196 Mean: 6.8 SD: 12.5 Missing: 17.6%
A3. Age (years)	Range: 18-95 Mean: 65.3 SD: 12.6 Missing: 1.6%
A4. Gender	Male: 43.3% Female: 55.6% Missing: 1.1%
A5. Years of full-time education	Range: 0-25 Mean: 12.1 SD: 3.3 Missing: 0.1%
A6. Ethnicity	White: 98.4% Asian/ British Asian: 0.3% Black/ African/ Caribbean/ Black British: 0.1% Other: 0.1% Missing: 1.1%
A7. Is someone helping you complete the survey	No: 93.0% Yes: 5.3% Missing: 1.8%
A8. Which test did you have	OGD: 37.2% TNE: 0.8% Colonoscopy: 42.3% CTC: 12.9% OGD and colonoscopy: 5.1% Colonoscopy and CTC: 0.5% Not sure: 0.3% Missing: 1.0%
A9. Have you had another endoscopy test in the past?	Yes: 72.8% No: 23.4% Missing: 3.8%
A10. How were you referred for your most recent test?	GP: 45.3% Hospital doctor: 38.8% Regular monitoring tests: 6.8% Regular tests because of family history: 2.3% Other: 0.9% Missing: 6.0%

Table 6.2: Responses to Section A

A free text box was provided for completion by participants who stated that they were referred in a way not listed in A10. Of the seven participants who selected 'other,' one did not complete the free text box, three stated they had been referred by 'endoscopy' and one was referred by a nurse. Two participants reported that they were referred through the Bowel Cancer Screening Programme. When this was

queried with the site it transpired that both patients had had OGDs, therefore this referral mode was not possible.

Three questions were included as potential 'explanatory' questions for future analyses beyond this thesis:

- B4: *My appointment was cancelled or changed by the hospital* (Yes/ No/ Not sure or can't remember)
- E4: *The person doing the test (inserting the tube or camera) was*: Male/ Female
- F7: *How did you receive the results of your test?* (various options offered)

A free text question was included at the end of the questionnaire for participants to complete if they wished to provide any further information, however; this was not analysed in this thesis.

Section B contained 15 questions which covered various aspects of the experience before arriving at the hospital for the test.

Section C included six questions which were only relevant to participants who had undergone colonoscopy or CTC and are therefore described separately. Questions E13 and E16 were visual analogue scales (VAS) where respondents were asked to rate their discomfort and pain respectively. Questions E14 (*how long did the discomfort last during the test)*, E15 (*how many times did you experience discomfort during the test)*, E17 (*how long did the pain last during the test)* and E18 (*how many times did you experience pain during the test)* followed the VAS questions and, in order for the response options to make sense, used different Likert scales from the remainder of the questionnaire. As such, the questions designed to assess discomfort and pain are analysed separately in section 6.6. The final list of questions, and their abbreviations is shown in Table 6.3.

Question Number	Question	Abbreviated Question[17]
B1	I was happy with the way I was referred for the test	Referral Happy
B2	The time from first being referred to having the test done was satisfactory	Referral Wait
B3	I felt able to change the appointment if it didn't suit me	Apt Change
B5	Before coming for the test, I was given enough information about what the test would involve	Info
B6	The information I received before the test was easy to understand	Info easy
B7	After reading the information, I did not have any questions about the test	Info questions
B8	The instructions on what I needed to do before the test were easy to follow	Instructions
B9	I had enough time to discuss the test with the person who referred me	Discuss referrer
B10	I felt anxious about what the test would involve	Anxious involve
B11	I was made anxious by talking to other people who had previously had the test	Other people
B12	I felt anxious about the results of the test	Anxious results
B13	I expected the test to be uncomfortable	Expect Uncomf
B14	I expected the test to be painful	Expect Pain
B15	I was worried that inserting the tube/camera would be uncomfortable	Expect insert
B16	I hoped the person doing the test would be the same sex as me	Same sex
C1	The bowel preparation had an unpleasant taste	Prep taste
C2	The bowel preparation tasted better than I expected	Taste better
C3	The volume (amount) of the bowel preparation was more than I expected	Prep volume
C4	The amount of bowel preparation I had to drink was manageable	Prep manage
C5	I was worried that the bowel preparation would not clear my bowel properly	Prep work
C6	I had enough privacy when getting ready for the test	Change privacy
D1	I waited longer in the department than I expected	Dept wait
D2	I was comfortable while sitting in the waiting area	Comf wait
D3	I felt able to ask the staff any questions before the test	Ask staff
D4	I had no unanswered questions before the test	No questions
D5	I had enough privacy when waiting for the test	Privacy wait
E1	During the test my dignity was maintained at all times	Dignity

[17] This is how questions are referred to in subsequent tables in this chapter

E2	I felt free to choose what medication to take	Choose meds
E3	The medication worked as well as I expected	Meds work
E5	I felt confident that the person doing the test what they were doing	Confident
E6	The person doing the test did their best to put me at ease	Ease endoscopist
E7	The other staff in the test room did their best to put me at ease	Ease other
E8	I was satisfied with the explanation given to me about the test	Explanation
E9	The person doing the test addressed any concerns I had	Concerns add
E10	I felt I could stop the test if it became too uncomfortable	Could stop
E11	I felt embarrassed during the test	Embarrassed during
E12	The test took longer than I expected	Test duration
E14	How long did the discomfort last during the test?	Discomfort last
E15	How many times did you experience discomfort during the test?	Discomfort number
E17	How long did the pain last during the test?	Pain last
E18	How many times did you experience pain during the test?	Pain number
E19	Overall, the test was more uncomfortable than I expected	Overall comf
E20	Overall, the test was more painful than I expected	Overall pain
E21	I felt embarrassed by the discomfort I experienced	Discomf emb
E22	I felt embarrassed by the pain I experienced	Pain emb
F1	I was satisfied by the explanation given to me by the person doing the test	Explan after
F2	I was pleased with the refreshments offered	Refreshments
F3	I had discomfort before I left the hospital/clinic	Discomf hosp
F4	I had discomfort after I left the hospital/clinic	Discomf home
F5	It took longer than I expected to recover from the test	Recovery
F6	I was worried about the test results	Results worry
F8	When I left the hospital, I was unsure of how I would get my test results	Unsure results
F9	I was happy with the way I received the results of my test	Happy results
F10	I received the results of my test sooner than I expected	Results sooner
F11	I know what the next steps are going to be	Next steps
G1	Overall I was satisfied with my experience of the test	Satisfied
G2	Overall the experience was better than I expected	Better expected

Table 6.3: Items with abbreviated form

6.3.2. Respondents' characteristics

Respondents' ages ranged from 18-95, with a mean age of 65.3 (SD 12.6). 43.3% of respondents were male and the majority (99.5%) were of white British ethnicity. According to procedure, documented by research staff, 41.1% of respondents underwent OGD (including 0.8% who underwent transnasal endoscopy), 43.3% underwent colonoscopy, 1.3% underwent both OGD and colonoscopy on the same day (referred to as 'OGD & colonoscopy' henceforth) and 14.4% underwent CTC.

There was sometimes a discrepancy between the procedure documented in the site-completed additional information sheet and that reported by the patient. All discrepancies were firstly queried with sites to confirm the actual procedure. Of the 328 participants who underwent OGD, 298 (90.8%) self-reported as having an OGD, 4 (1.2%) as having a colonoscopy and 23 (7.0%) reported having OGD & colonoscopy. Of the 346 participants who underwent colonoscopy, 326 (94.2%) agreed with this, 1 (0.3%) reported CTC, 3 (0.9%) reported OGD and 13 (3.8%) reported having both procedures. 115 participants underwent CTC, of whom 102 (88.7%) reported CTC, 5 (4.3%) reported colonoscopy and 4 (3.5%) reported both colonoscopy and CTC.

Table 6.4 shows respondents' characteristics according to procedure. Mean age was similar across all procedures with the exception of CTC, who were older, on average. The percentage of male participants was similar across all groups except OGD & colonoscopy, however; there were comparatively fewer overall participants in this group.

Procedure	**Number of respondents (%)**	**Percentage male**	**Mean age**	**SD**
OGD	328 (41.1%)	40.6%	64.3	12.7
Colonoscopy	346 (43.3%)	48.3%	64.0	12.6
OGD and Colonoscopy	10 (1.3%)	20.0%	64.2	9.5
CTC	115 (14.4%)	39.5%	72.2	10.4
Overall	799 (100%)	43.3%	65.3	12.6

Table 6.4: Respondents' characteristics according to procedure

The demographic characteristics of participants by recruitment site are shown in Table 6.5. This shows variation in the numbers of respondents across sites, ranging

from 98 to 288. Aside from site A (52.1%) the percentage of male respondents was similar across sites (39.4- 44.6%). The mean age was similar across sites (63.8 - 66.2).

Site	**Number of respondents (%)**	**Percentage male**	**Mean age**	**SD**
A	98	52.1%	63.8	13.40
B	193	43.5%	66.1	11.65
C	220	39.4%	64.3	12.25
D	288	44.6%	66.2	13.14
Overall	799	43.3%	65.3	12.60

Table 6.5: Respondent demographics according to site

6.3.3. Response distributions

Table 6.6 shows the response distribution for the questions listed in table 6.3 (with the exception of section C, which is reported in section 6.3.9); 'conditional' indicates that the question had a 'not applicable' response option (e.g. in question E3 participants were given the option of ticking 'I did not have any medication' instead of completing the Likert scale).

Q	N	Missing %	Strongly Agree %	Agree %	Neither Agree or Disagree %	Disagree %	Strongly disagree %	Conditional %
B1	797	0.3	**68.8**	27.0	2.5	1.5	0.3	
B2	791	1.0	**63.8**	30.7	3.2	1.6	0.6	
B3	771	3.5	**57.7**	34.2	6.1	1.7	0.3	
B5	796	0.4	**70.8**	26.9	0.8	0.9	0.3	
B6	795	0.5	**69.1**	27.8	1.6	0.9	0.3	
B7	794	0.6	**63.3**	28.3	3.3	3.8	0.8	
B8	798	0.1	**66.3**	31.1	1.1	1.1	0.4	
B9	788	1.4	**50.9**	32.2	11.0	4.9	0.9	
B10	788	1.4	16.0	34.4	19.3	19.0	11.3	
B11	781	2.3	6.5	13.3	18.2	33.4	28.6	
B12	789	1.3	21.9	44.6	18.5	9.8	5.2	
B13	794	0.6	28.6	55.8	8.7	4.9	2.0	
B14	793	0.8	13.4	29.9	28.2	23.1	5.4	
B15	793	0.8	21.6	43.8	16.4	14.5	3.8	
B16	791	1.0	7.5	7.1	41.3	20.7	23.4	
D1	759	5.0	8.0	10.7	17.0	36.4	27.9	
D2	760	4.9	36.8	50.8	5.4	4.2	2.8	
D3	758	5.1	**50.0**	45.0	3.2	1.2	0.7	
D4	759	5.0	**52.0**	40.6	3.6	2.5	1.3	
D5	760	4.9	**49.7**	43.6	3.6	1.8	1.3	

E1	792	0.9	**70.8**	27.5	1.0	0.4	0.3	
E2	769	3.8	**65.8**	26.5	5.3	1.8	0.5	
E3	774	3.1	**42.2**	31.1	5.3	5.6	1.8	14.0
E5	791	1.0	**75.6**	22.6	0.9	0.6	0.3	
E6	791	1.0	**74.3**	22.3	2.1	0.9	0.4	
E7	792	0.9	**77.8**	20.1	1.6	0.3	0.3	
E8	794	0.6	**70.4**	28.0	0.9	0.6	0.1	
E9	792	0.9	**64.0**	29.3	5.6	0.9	0.3	
E10	793	0.8	**53.6**	32.7	9.5	3.2	1.1	
E11	791	1.0	4.3	8.0	16.1	37.0	34.6	
E12	793	0.8	3.8	9.7	23.7	36.7	26.1	
E19	789	1.3	7.4	16.5	20.3	35.9	20.0	
E20	789	1.3	4.9	12.4	17.4	39.8	25.5	
E21	789	1.3	2.5	7.0	15.5	42.2	32.8	
E22	789	1.3	2.0	5.2	15.2	41.7	35.9	
F1	784	1.9	**61.5**	33.3	2.7	1.9	0.6	
F2	783	2.0	**45.7**	29.9	5.0	1.1	0.3	18.0
F3	778	2.6	5.3	14.5	11.4	37.0	31.7	
F4	783	2.0	5.2	21.2	10.3	33.0	30.3	
F5	782	2.1	4.7	7.9	13.9	40.9	32.5	
F6	778	2.6	10.2	33.0	24.2	19.4	13.2	
F8	731	8.5	3.7	9.4	7.8	30.1	19.4	29.5
F9	760	4.9	32.1	30.4	3.7	1.8	1.2	30.8
F10	743	7.0	22.2	23.8	14.5	3.0	1.6	34.9
F11	730	8.6	35.9	39.6	9.7	9.2	5.6	
G1	791	1.0	**55.6**	37.4	4.2	2.3	0.5	
G2	784	1.9	**45.8**	32.4	14.5	5.9	1.4	

Table 6.6: Response patterns by question

6.3.4. 'Floor' and 'ceiling' effects

24 items within the questionnaire showed evidence of a 'ceiling' effect:[18]

- B1, B2, B3, B5, B6, B7, B8, B9
- D3, D4, D5
- E1, E2, E3, E5, E6, E7, E8, E9, E10
- F1, F2
- G1, G2

The remainder of questions showed a more even distribution of responses. Response patterns were similar according to sex, age, procedure and age (not shown); some subtle differences are described in the following sections.

[18] This was defined as more than 40% of respondents choosing the highest response option

6.3.5. Response patterns by sex

Response patterns by sex were similar to the overall response pattern. The 'ceiling' effect in question E3 (*medication worked as well as I expected*) was more marked for men (43.7%) than for women (37.6%).

6.3.6. Response patterns by age

Response patterns by age were similar to the overall response patterns. The 'ceiling' effect regarding question E3 was less marked in the 65-74 (39.9%) and 75+ (34.8%) age groups than in those ≤ 54 years (43.0%) and those aged 55-64 (47.1%). This may reflect larger proportions of respondents who did not have medication in the upper two age groups (14.9% and 20.0%, respectively) compared with the lower two age groups (7.1% and 12.8%, respectively).

6.3.7. Response patterns by procedure

Response patterns by procedure were similar to the overall data and 'ceiling' effects were observed in the same questions as the overall data. Of interest, there was a 'ceiling' effect in F2 for patients who had undergone OGD (*I was pleased with the refreshments offered)*. The 'ceiling' effect in question E3 (*medication worked as well as I expected*) was 35.0% in participants undergoing colonoscopy and 13.9% of participants undergoing CTC. In both groups, the majority of respondents agreed or strongly agreed (colonoscopy: 63.3%; CTC: 47.8%- 33.9% in this group had no medication) with the statement.

6.3.8. Response patterns by site

Ceiling effects were observed in the same questions as the overall data, with the exception that centre D showed a 'ceiling' effect of only 39.8% for question G2 (*Overall the experience was better than I expected)*. In addition, centres B and C showed a mild 'ceiling' effect in question D2 (41.3% and 42.8%, respectively) (*I was comfortable while sitting in the waiting area)*. No 'floor' effects were observed.

6.3.9. Section C response patterns: overall

Only respondents who underwent colonoscopy or CTC were asked to complete section C, as this focused on questions related to the preparation (oral contrast or laxatives) required prior to the test. The number of correct respondents for whom this

section was relevant was, therefore, 471 (colonoscopy, 346; OGD & colonoscopy, 10; CTC, 115). Table 6.7 shows, by procedure, the number and percentage of participants who responded to each question in section C. Fifty-nine participants (18.0%) who underwent OGD responded to these questions. These responses are removed from further analysis of this section.

	OGD N (%)	**Colonoscopy N (%)**	**OGD and Colonoscopy N (%)**	**CTC N (%)**
C1	59 (18.0)	338 (97.7%)	8 (80.0%)	111 (96.5%)
C2	56 (17.1%)	337 (97.4%)	8 (80.0%)	112 (97.4%)
C3	57 (17.4%)	340 (98.3%)	8 (80.0%)	111 (96.5%)
C4	58 (17.7%)	340 (98.3%)	8 (80.0%)	111 (96.5%)
C5	58 (17.7%)	338 (97.7%)	8 (80.0%)	111 (96.5%)
C6	57 (17.4%)	340 (98.3%)	8 (80.0%)	112 (97.4%)

Table 6.7: Section C number of responses according to procedure

The overall response patterns for section C, for those who underwent colonoscopy, CTC or OGD & colonoscopy are shown in table 6.8. There were no floor effects. Question C6 (*I had enough privacy when getting ready for the test)* demonstrated a ceiling effect of 65.5%.

Question	**N**	**Missing %**	**Strongly Agree %**	**Agree %**	**Neither agree or disagree %**	**Disagree %**	**Strongly Disagree %**
C1	457	3.0	30.1	26.5	21.2	15.5	3.6
C2	457	3.0	9.3	34.4	18.0	21.9	13.4
C3	459	2.5	21.7	26.5	28.7	16.6	4.0
C4	459	2.5	14.4	54.6	12.1	10.8	5.5
C5	457	3.0	10.2	32.7	21.4	25.5	7.2
C6	460	2.3	**64.3**	29.9	1.7	1.1	0.6

Table 6.8: Section C responses (excluding OGD)

When broken down by procedure (colonoscopy and CTC as only 10 respondents in OGD & colonoscopy group), response patterns were similar to those seen for all procedures combined (tables 6.9 and 6.10). Although the ‘ceiling’ effect of question C6 was less marked in the CTC group, this was still above 50% in both groups. No further ‘floor’ or ‘ceiling’ effects were identified.

Question	N	Missing %	Strongly Agree %	Agree %	Neither agree or disagree %	Disagree %	Strongly Disagree %
C1	338	2.3	31.7	27.2	21.6	15.4	4.1
C2	337	2.6	9.5	34.7	19.0	22.8	13.9
C3	340	1.7	25.6	28.5	28.5	13.8	3.5
C4	340	1.7	11.5	54.7	14.1	13.8	5.9
C5	338	2.3	9.2	30.8	24.0	29.3	6.8
C6	340	1.7	**68.2**	30.3	1.2	0.3	0.0

Table 6.9: Colonoscopy group responses to section C

Question	N	Missing %	Strongly Agree %	Agree %	Neither agree or disagree %	Disagree %	Strongly Disagree %
C1	111	3.5	28.8	26.1	23.4	18.9	2.7
C2	112	2.6	9.8	38.4	17.0	21.4	13.4
C3	111	3.5	12.6	23.4	30.6	27.0	6.3
C4	111	3.5	25.2	61.3	6.3	2.7	4.5
C5	111	3.5	14.4	42.3	17.1	16.2	9.9
C6	112	2.6	**57.1**	33.0	3.6	3.6	2.7

Table 6.10: CTC group responses to section C

6.3.10. Section C response patterns: by sex, age group and site

The response patterns by age-group, sex and site were similar to those seen overall and no new ceiling or floor effects were observed (not shown). The ‘ceiling’ effect observed in question C6 was 67.5% in females and 62.8% in males. The ‘ceiling’ effect of C6 was much higher in those aged 55-64 (74.8%) compared to the remaining groups (range 60.5-62.8%).

6.4. Missing Responses

Patterns of missing values were described firstly according to the questionnaire items themselves and secondly on a respondent basis.

6.4.1. Missing entries per question

Descriptive analyses of missing items for pain and discomfort questions (E13, E14, E15, E16, E17 and E18) are described in section 6.5. The overall rate of missing responses for each of the remaining questions was low, as shown in table 6.6 (section 6.3.3.) and table 6.8 (section 6.3.9), meaning that completion rates on a per

question basis were high. Missingness was over 5% for only three questions (F8, F10, F11); F11 had the highest rate of non-completion (8.6%).

6.4.2. Number of questions missed per participant

Excluding section C, 274 (34.3%) respondents failed to complete one or more questions. The mean number of items missed in all participants was 1.2 (range 0-28, SD 2.79); the maximum was 28. The distribution of number of questions missed per participant (where at least one question was missed, mean 3.4) is shown in figure 6.1.

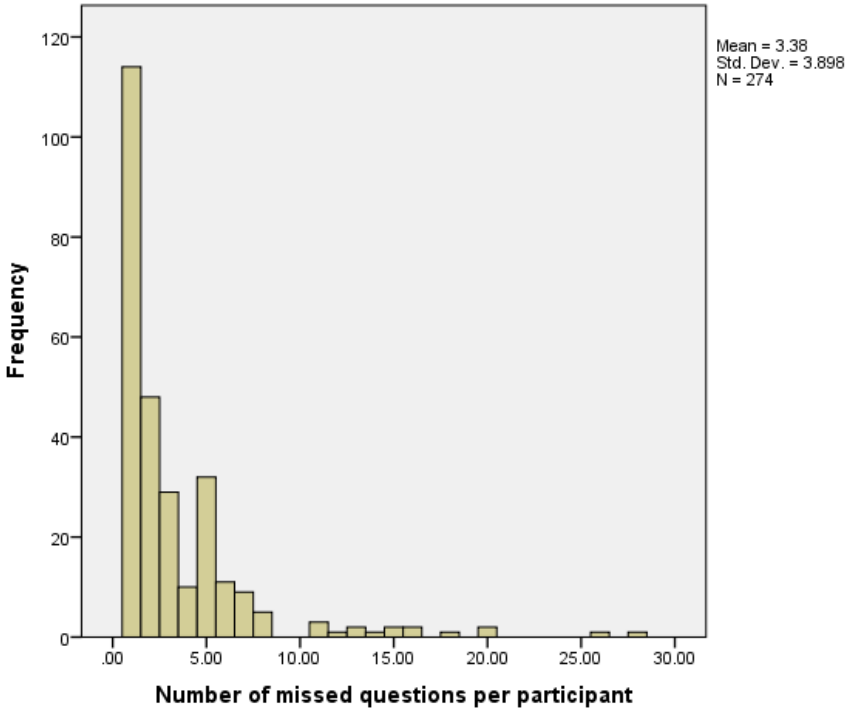

Figure 6.1: Distribution of number of questions missed per participant

6.4.3. Missing responses according to sex

The mean number of missing responses was less in male than female respondents (1.0 vs 1.23) but this difference was not significant (*t*=-1.318, df=788, p=0.188).

6.4.4. Missing entries according to age

The mean number of missing responses increased by age and was considerably higher (2.4) for the oldest group than the others (0.5, 0.7, 0.9) (Table 6.11). The mean number of missing responses for those aged 75 and older was 2.4.

Group	N	Mean	Std Deviation	95% CI for Mean		Minimum	Maximum
				Lower	Upper		
≤ 54	142	0.5	1.3	0.3	0.7	0	7
55-64	191	0.7	1.6	0.5	1.0	0	8
65-74	271	0.9	2.6	0.6	1.3	0	26
≥ 75	181	2.4	4.2	1.8	3.0	0	28
Total	785	1.2	2.8	1.0	1.4	0	28

Table 6.11: Missing entries according to age group

The one-way ANOVA indicated a significant effect of age on the mean number of missing responses ($F(3,781)=17.98$, $p<0.001$). The Games-Howell post-hoc test indicated the mean number of missing responses in the 75+ group was significantly different from each of the other groups.

6.4.5. Missing responses according to procedure

There was no statistically significant association between procedure and mean number of missing responses ($F(2,786)=2.931$, $p=0.054$).

6.4.6. Missing responses according to site

There was no difference in mean number of missing questions by site ($F(3,795)= 0.768$, $p=0.512$).

6.5. Missing responses: Section C

The mean number of missing responses among the 471 who should have completed section C was 0.2 (range 0-6, SD 0.9). 451 (95.8%) participants answered all questions; six participants missed one questions, five missed 2-5 questions and nine did not answer any questions in this section.

There was no significant difference in mean number of missing responses in section C by sex (males: 0.14, [SD= 0.9]; females:0.16 [SD 0.8]; $t=-0.226$, df=463, $p=0.821$). Mean number of missing questions varied significantly by age-group (ANOVA $F(3,458)=3.411$, $p=0.017$), with post-hoc testing indicating that the mean number of missing responses in the 75+ group was significantly different from the 65-74 group (table 6.12).

Group	N	Mean	Std Deviation	95% CI for Mean		Minimum	Maximum
				Lower	Upper		
≤ 54	78	0.15	0.96	-0.06	0.37	0	6
55-64	111	0.17	0.98	-0.01	0.36	0	6
65-74	158	0.01	0.08	-0.01	0.02	0	1
≥ 75	115	0.35	1.23	0.12	0.57	0	6
Total	462	0.16	0.88	0.08	0.24	0	6

Table 6.12: Section C Mean number of missing responses overall and according to age

There was no significant difference in the mean number of missing responses in section C for those who underwent colonoscopy (0.12, SD 0.8) and CTC (0.2, SD 0.9; *t*=-0.756, df= 459, p=0.450).

One-way in-between ANOVA showed a statistically significant difference in mean number of missing responses to section C between sites ($F(3,467)= 3.389$, p=0.018). Post-hoc tests indicated that the mean number of missing responses per participant in site B (0.0) was statistically significantly less than those in site C (0.4; p=0.013). Differences between the means in other centres did not reach statistical significance.

6.6. Pain and Discomfort

The analysis of the questions on pain and discomfort was focused on determining the relationship between responses to the pain and discomfort questions, with a view to reducing the number of items within the questionnaire.

6.6.1 Visual Analogue Scale: Method of Response

9 (1.1%) participants failed to complete the VAS for discomfort (E13) and 16 (2.0%) failed to complete the VAS for pain (E16). 780 respondents completed both the pain and discomfort VAS.

Of those who completed E13 and/or E16, 55.2% and 60.3% correctly followed the instructions. Table 6.13 shows the response modes for each VAS question.

	Question E13 (discomfort)	Question E16 (pain)
Correct method used[19]	441 (55.8%)	482 (61.6%)
Number circled	260 (32.9%)	237 (30.3%)
Cross under/above line	41 (5.2%)	44 (5.6%)
Number written	8 (1.0%)	7 (0.9%)
Cross on line and number circled	37 (4.7%)	8 (1.0%)
Anchor circled	1 (0.1%)	4 (0.5%)
Range indicated	2 (0.3%)	1 (0.1%)

Table 6.13 Response modes to VAS questions

6.6.2. Visual Analogue Scale: All Responses

The mean discomfort score was 41.3 (SD 25.9) and the mean pain score was 27.0 (SD 26.3). Figures 6.2 and 6.3 show the distribution of discomfort and pain scores, respectively. A higher percentage of respondents reported a score of zero for pain than did for discomfort (12.0% vs 4.7%). Responses tended to crowd around 'whole' numbers in each question, rather than being normally distributed.

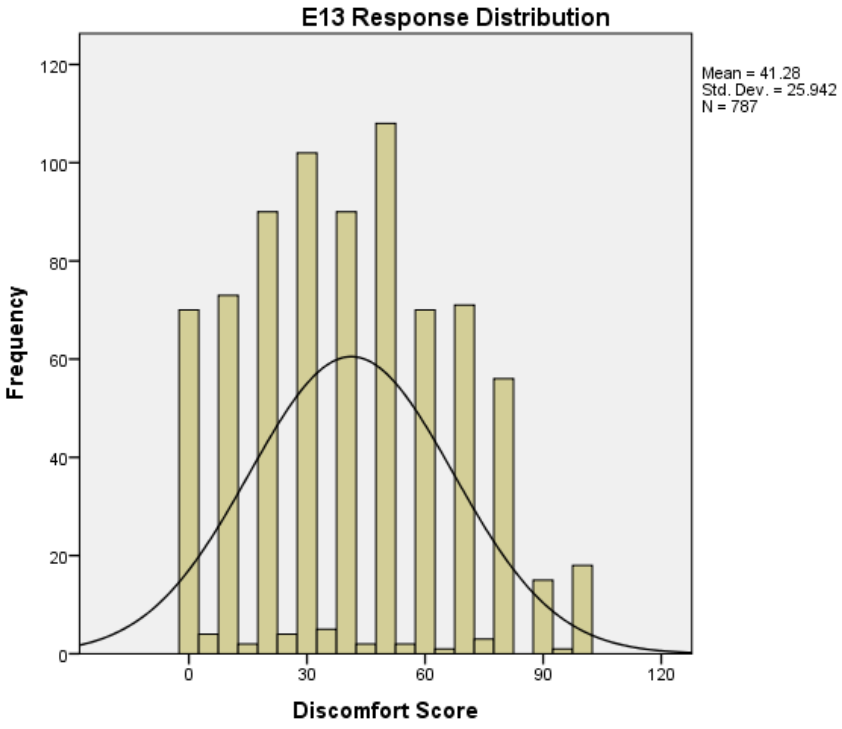

Figure 6.2: E13 (discomfort) Response Distribution

[19] The correct method was to mark a cross on the line provided

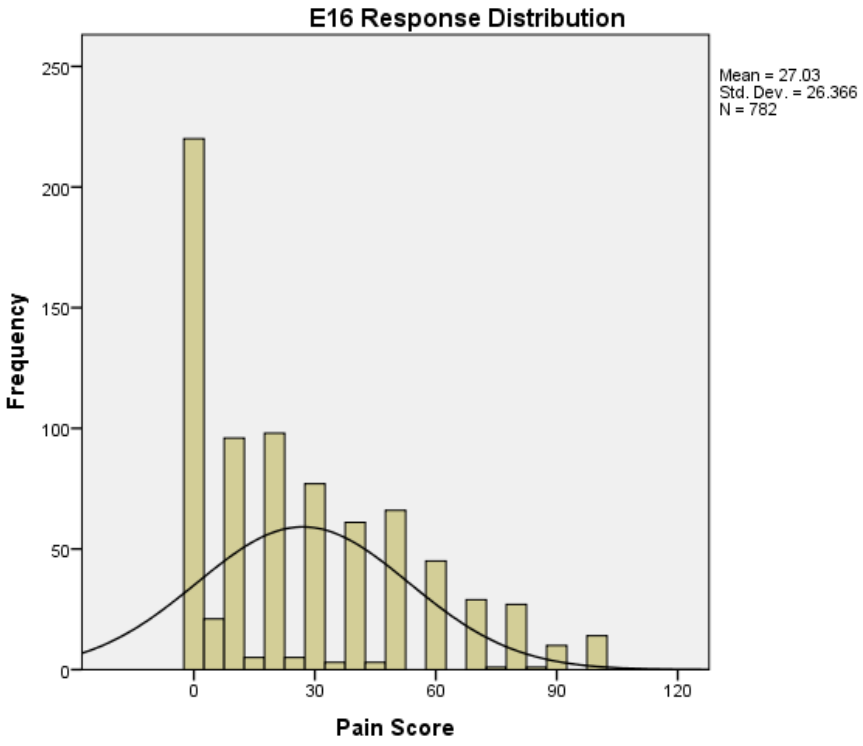

Figure 6.3: E16 (pain) Response Distribution

Figure 6.4 shows the scattergram produced when questions E13 (discomfort) and E16 (pain) are cross-tabulated. Spearman's rank correlation test showed a statistically significant positive correlation between responses to E13 and E16 (r_s= 0.667, N=777, p<0.001). However, the scattergram line does not cross zero and shows that one set of scores (pain) appears to be systematically lower than the other (discomfort).

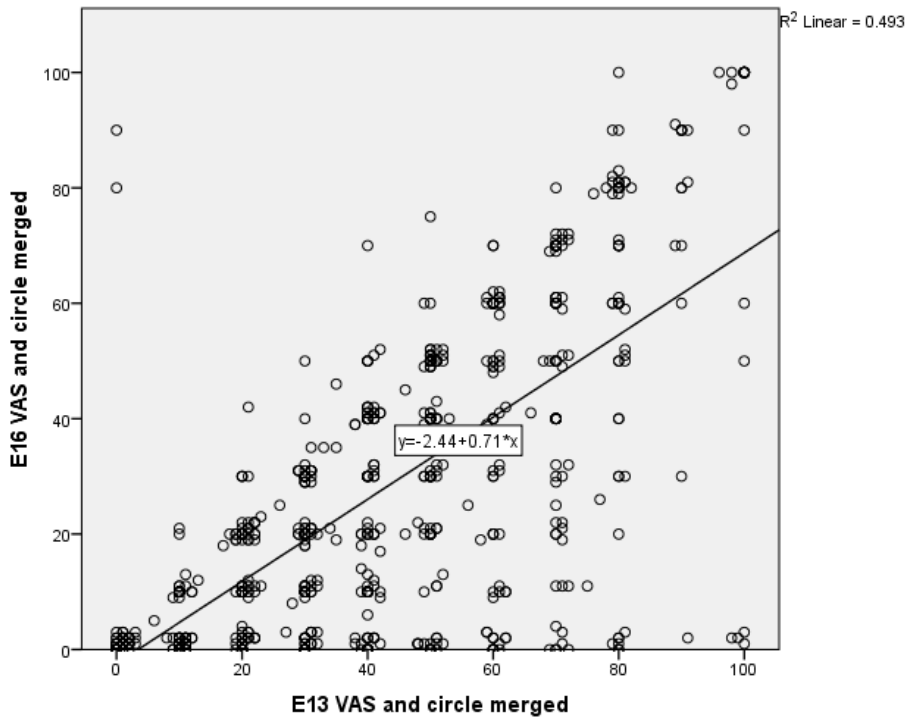

Figure 6.4: Correlation between E13 and E16.

In a paired analysis (n=777), the mean difference in self-reported discomfort and pain was 14.3 (SD 20.14). The distribution of differences is shown in figure 5.5. 12.1% of participants had a difference of less than zero (i.e. pain score was higher than discomfort score), 23.3% had a difference of zero and 64.6% had a difference over zero.

The main difference in (paired) scores was significantly different from zero and the size of the effect was moderate. A paired *t*-test showed that the difference between the pain and discomfort scores was significant (t=19.8, df = 777, p <0.001).

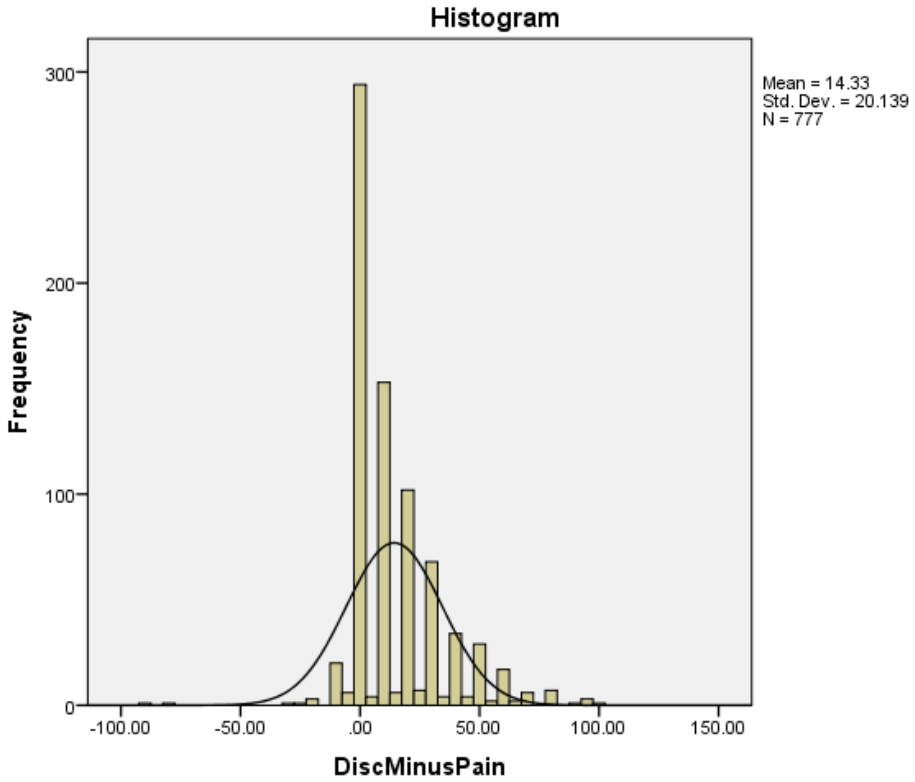

Figure 6.5: Difference in discomfort and pain scores.

There was no significant effect of gender (*t*= 0.786, df=767, *p*=0.432), age (*F* (4,772) = 1.19, p=0.310) or site (*F* (3,773) = 1.22, p=0.301) on the mean difference in scores (Table 5.14).

There was a significant difference in mean scores according to procedure type (*F* (3,773) = 36.2, *p*<0.001). OGD scores were significantly different from those for other procedures (p≤0.05). There was no significant difference between colonoscopy and CTC (p=0.638), colonoscopy and OGD & colonoscopy (p=1.000) or CTC and 'OGD & Colonoscopy' (p=0.955).

Group	Variable	Mean difference in score	Standard deviation	p value
Sex	Male	13.7	20.0	0.432
	Female	14.9	20.1	
Age Group	≤54	16.5	21.2	0.310
	55-64	15.9	20.5	
	65-74	13.1	19.8	
	≥75	12.8	19.1	
Procedure	OGD	21.9	22.6	<0.001
	Colonoscopy	8.4	15.4	
	OGD and Colonoscopy	8.4	12.9	
	CTC	10.7	18.3	
Site	A	12.4	23.4	0.301
	B	12.7	18.6	
	C	14.7	19.7	
	D	15.8	20.2	

Table 6.14: Effect of sex, age, procedure and site on pain and discomfort

6.6.3. Visual Analogue Scale: Score according to response mode

The analyses described in section 5.5.2 were repeated to compare those who used different response modes. Participants (n=2) who indicated a range were excluded from this analysis. The findings were consistent with those for the entire sample (Table 6.15).

Response Mode[20]	Question E13 (discomfort)	Question E16 (pain)	Mean score E13	Mean score E16	Correlation co-efficient (r_s)	Mean difference in scores
Cross	519 (65.9%)	533 (61.6%)	39.5 (SD 24.6)	24.9 (SD 24.4)	0.645 (p<0.001)	14.6 (SD 19.8)
Number	269 (34.2%)	248 (31.7%)	44.0 (SD 27.9)	30.9 (SD 29.3)	0.719 (p<0.001)	13.83 (SD 20.8)

Table 6.15: Comparison of mean scores according to VAS response mode

[20] 'Cross' response mode included: those who placed a cross on, above or under the line, or who both placed a cross on the line and circled a number.

'Number' response mode included: those who circled or wrote a number or who circled an anchor.

6.6.4. Duration of Discomfort and Pain

Questions E14 and E17 asked respondents to rate how long the discomfort or pain lasted during the test, respectively, according to the following responses:

- I didn't have pain/ discomfort
- A short time
- A moderate time
- A long time

The distribution of responses to each question is shown in table 6.16. No floor or ceiling effects were demonstrated and the percentage of missing responses was low. A similar proportion of participants chose 'a long time' for both pain and discomfort, however, a higher proportion of participants indicated that they had no pain (34.5%) than had no discomfort (10.9%).

Question	**N**	**Missing n (%)**	**No discomfort/ pain n (%)**	**Short time n (%)**	**Moderate time n (%)**	**Long time n (%)**
E14 (Discomfort)	791	8 (1.0%)	86 (10.9%)	487 (61.6%)	181 (22.9%)	37 (4.7%)
E17 (Pain)	783	16 (2.0%)	270 (34.5%)	378 (47.3%)	111 (14.2%)	24 (3.0%)

Table 6.16: Response distributions to E14 and E17

Comparison of the questions (Table 6.17) indicated reasonable consistency in responses (Spearman's rank correlation: r_s=0.552, N=779, p<0.001).

		Pain				
		No pain	**Short time**	**Moderate time**	**Long time**	**Total**
Discomfort n (%)	No discomfort	**20 (54.2%)**	5 (13.5%)	5 (13.5%)	7 (18.9%)	37 (100%)
	Short time	2 (1.1%)	**91 (51.7%)**	52 (29.5%)	31 (17.6%)	176 100.0%
	Moderate time	2 (0.4%)	14 (2.9%)	**317 (66.0%)**	147 (30.6%)	480 (100.0%)
	Long time	0 (0.0%)	0 (0.0%)	3 (3.5%)	**83 (96.5%)**	86 (100.0%)
	Total	24 (3.1%)	110 (14.1%)	377 (48.4%)	268 (34.4%)	779 (100%)

Table 6.17: Crosstabulation of duration of pain and discomfort (E14 and E17)

6.6.5. Frequency of Discomfort and Pain

Questions E15 and E18 asked respondents to rate the number of times they experienced discomfort or pain, respectively, during the test:

- None
- 1 or 2 times
- 3 or 4 times
- More than 4
- Constantly

The distribution of responses is shown in table 6.18. No floor or ceiling effects were demonstrated. The percentage of patients who indicated they had constant pain (3.5%) was lower than those with constant discomfort (8.1%). Fewer participants indicated that they had no discomfort (11.8%) than no pain (35.6%).

Question	**N**	**Missing n (%)**	**No discomfort /pain, n (%)**	**1 or 2 times, n (%)**	**3 or 4 times, n (%)**	**More than 4, n (%)**	**Constant, n (%)**
E15 (Discomfort)	788	11 (1.4%)	93 (11.8%)	371 (47.1%)	196 (24.9%)	64 (8.1%)	64 (8.1%)
E18 (Pain)	781	18 (2.3%)	278 (35.6%)	288 (36.9%)	129 (16.5%)	59 (7.4%)	27 (3.5%)

Table 6.18: Response distributions to E15 and E18

Comparison of the questions (Table 6.19) indicated reasonable consistency in responses (Spearman's rank correlation: r_s=0.617, N=775, p<0.001). Only 41.3% of participants who had zero episodes of discomfort indicated they had zero episodes of pain, with 33.3% selecting 'constant' pain.

		Number of pain episodes					
Number of discomfort episodes, n (%)		**Zero**	**1 or 2**	**3 or 4**	**More than 4**	**Constantly**	**Total**
	Zero	**26 (41.3%)**	4 (6.3%)	4 (6.3%)	8 (12.7%)	21 (33.3%)	63 (100.0%)
	1 or 2	0 (0.0%)	**47 (73.4%)**	7 (10.9%)	4 (6.3%)	6 (9.4%)	64 (100.0%)
	3 or 4	0 (0.0%)	6 (3.2%)	**110 (58.2%)**	48 (25.4%)	25 (13.2%)	189 (100.0%)
	More than 4	1 (0.3%)	1 (0.3%)	6 (1.6%)	**225 (61.3%)**	134 (36.5%)	367 (100.0%)
	Constantly	0 (0.0%)	0 (0.0%)	1 (1.1%)	2 (2.2%)	**89 (96.7%)**	92 (100.0%)
	Total	27 (3.5%)	58 (7.5%)	128 (16.5%)	287 (37.0%)	275 (35.5%)	775 (100.0%)

Table 6.19: Correlation of number of episodes of pain and discomfort

6.6.6. Comparison between the duration and frequency of discomfort

Responses to E14 (*how long did the discomfort last during the test)* and E15 (*how many times did you experience discomfort during the test)* were cross-tabulated (table 6.20). and were correlated (r_s 0.744, p<0.0001). The majority of participants who chose the lowest score for discomfort duration (zero) also chose this response for the number of episodes of discomfort (zero; 97.6%). Participants who chose the highest score for discomfort duration (long time) chose one of the two highest response options for number of discomfort episodes (more than 4 and constantly; 97.3%). Participants choosing the lowest scores for one question never chose the highest scores for the other and vice versa.

Number of discomfort episodes							
Duration of discomfort, n (%)		Zero	1 or 2	3 or 4	More than 4	Constantly	Total
	Zero	83 (97.6%)	2 (2.4%)	0 (0%)	0 (0%)	0 (0%)	85 (100.0%)
	Short time	9 (1.9%)	341 (70.2%)	113 (23.3%)	11 (2.3%)	12 (2.5%)	486 (100.0%)
	Moderate time	1 (0.6%)	28 (15.6%)	81 (45.3%)	44 (24.6%)	25 (14.0%)	179 (100.0%)
	Long time	0 (0%)	0 (0%)	1 (2.7%)	9 (24.3%)	27 (73.0%)	37 (100.0%)
	Total	93 (11.8%)	371 (47.1%)	195 (24.8%)	64 (8.1%)	64 (8.1%)	787 (100.0%)

Table 6.20: Correspondence between the duration and number of episodes of discomfort

6.6.7. Comparison between the length and number of episodes of pain

Responses to E17 (*how long did the pain last during the test)* and E18 (*how many times did you experience pain during the test)* were very highly correlated (r_s =0.909, p<0.001) (Table 5.21).

Number of pain episodes							
Duration of pain, n (%)		Zero	1 or 2	3 or 4	More than 4	Constantly	Total
	Zero	266 (99.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	268 (100.0%)
	Short time	10 (2.7%)	273 (72.4%)	81 (21.5%)	12 (3.2%)	1 (0.3%)	377 (100.0%)
	Moderate time	0 (0.0%)	13 (12.0%)	46 (42.6%)	38 (35.2%)	11 (10.2%)	108 (100.0%)
	Long time	0 (0.0%)	0 (0.0%)	1 (4.2%)	8 (33.3%)	15 (62.5%)	24 (100.0%)
	Total	276 (35.5%)	288 (37.1%)	128 (16.5%)	58 (7.5%)	27 (3.5%)	777 (100.0%)

Table 6.21: Correlation between the duration and number of episodes of pain

6.6.8. Discomfort and pain compared to expectations

Responses to questions E19 and E20 (*Overall, the test was more uncomfortable/ painful than I expected)* were cross-tabulated (table 6.22). Responses were significantly positively correlated (r_s=0.769, N=789, p=<0.001).

		Pain worse than expected					
Discomfort worse than expected, n (%)		**Strongly Agree**	**Agree**	**Neither agree or disagree**	**Disagree**	**Strongly disagree**	**Total**
	Strongly Agree	**31 (53.4%)**	5 (8.6%)	2 (3.4%)	8 (13.8%)	12 (20.7%)	58 (100%)
	Agree	5 (3.8%)	**74 (56.9%)**	23 (17.7%)	23 (17.7%)	5 (3.8%)	130 (100%)
	Neither agree or disagree	0 (0%)	17 (10.6%)	**106 (66.3%)**	32 (20.0%)	5 (3.1%)	160 (100%)
	Disagree	2 (0.7%)	2 (0.7%)	6 (2.1%)	**246 (86.9%)**	27 (9.5%)	283 (100%)
	Strongly disagree	1 (0.6%)	0 (0%)	0 (0%)	5 (3.2%)	**152 (96.2%)**	158 (100%)
	Total	39 (4.9%)	98 (12.4%)	137 (17.4%)	314 (39.8%)	201 (25.5%)	789 (100%)

Table 6.22: Comparison of E19 and E20

6.7. Correlations

In this section the pain and discomfort VAS questions were excluded, partly due to the reverse scoring nature of the responses and also because the type of question varied significantly. Furthermore, the previous section identified that these questions were correlated with one another. The final PREM may include only discomfort or only pain and it was not appropriate to include questions that may be omitted in a factor analysis, therefore, the pain questions were excluded. Questions from Section C were excluded as they were only answered by participants undergoing lower GI examinations and therefore would only produce factors, if relevant, for a subset of patients. Questions included within the questionnaire as ‘explanatory’ questions were excluded from the factor analysis. The overall satisfaction questions in section G were also removed.

6.7.1. Inter-item correlations

When responses to pairs of questions were correlated, two pairs of questions emerged as strongly correlated (r_s >0.8):

- B5 and B6 (*Before coming for the test, I was given enough information about what the test would involve* and *the information I received before the test was easy to understand)*
- F3 and F4 (*I had discomfort before I left the hospital/ clinic* and *I had discomfort after I left the hospital/ clinic)*

Although all questions had some degree of correlation with at least one other question, one question correlated relatively weakly (r_s <0.35) with only one other question and a further three questions correlated weakly with only two other questions:

- B16 (*I hoped the person doing the test would be the same sex as me)*
- D1 (*I waited longer in the department than I expected)*
- F2 *(I was pleased with the refreshments offered)*
- F8 (*When I left the hospital, I was unsure of how I would get the results of my test*)

Inter-item correlations are shown in Appendix K.

6.7.2. Item total correlations

Corrected item total correlations were calculated for the same questions included in section 6.7.1[21]. The ITCs are shown in table 6.23. Eight items showed poor corrected item-total correlation, i.e. ITC <0.3:

- B11, *I was made anxious by talking to other people who had previously had the test* (ITC 0.292)
- B13, *I expected the test to be uncomfortable* (ITC 0.196)
- B16, *I hoped the person doing the test would be the same sex as me* (ITC 0.281)

[21] Questions included: B1, B2, B3, B5, B6, B7, B8, B9, B10, B11, B12, B13, B14, B15, B16, D1, D2, D3, D4, D5, E1, E2, E3, E5, E6, E7, E8, E9, E10, E11, E12, E14, E15, E19, E21, F1, F2, F3, F4, F5, F6, F8, F9, F10, F11

- D1, *I waited longer in the department than I expected* (ITC 0.225)
- F2, *I was pleased with the refreshments offered* (ITC 0.175)
- F8, *When I left the hospital, I was unsure of how I would get my test results* (ITC 0.165)
- F9, *I was happy with the way I received the results of my test* (ITC 0.081)
- F10, *I received the results of my test sooner than I expected* (ITC -0.006)

Item	**Item Number**	**Scale mean if item deleted**	**Scale variance if item deleted**	**Corrected item-total correlation**
Referral Happy	B1	176.79	320.54	0.441
Referral wait	B2	176.86	321.01	0.376
Apt change	B3	176.97	321.03	0.354
Info	B5	176.74	319.70	0.525
Info Easy	B6	176.76	319.35	0.525
Info Questions	B7	176.91	317.67	0.446
Instructions	B8	176.80	318.44	0.531
Discuss Referrer	B9	177.17	315.39	0.439
Anxious Involve	B10	178.62	311.34	0.402
Other People	B11	177.72	317.23	0.292
Anxious Results	B12	179.08	317.68	0.305
Expect Uncomf	B13	179.45	323.93	0.196
Expect Pain	B14	178.58	317.40	0.309
Expect Insert	B15	179.07	317.32	0.323
Same Sex	B16	177.91	318.12	0.281
Dept Wait	D1	177.74	319.68	0.225
Comf Wait	D2	177.27	316.56	0.424
Ask staff	D3	176.97	317.64	0.530
No questions	D4	176.99	317.39	0.480
Privacy wait	D5	177.05	316.74	0.484
Dignity	E1	176.74	319.69	0.547
Choose meds	E2	176.83	319.56	0.430
Meds Work	E3	176.68	310.07	0.333
Confident	E5	176.69	320.68	0.504
Ease endoscopist	E6	176.74	318.50	0.533
Ease other	E7	176.67	320.21	0.544
Explanation	E8	176.72	319.83	0.571
Concerns add	E9	176.84	317.39	0.549
Could stop	E10	177.07	315.07	0.492
Embarrassed During	E11	177.52	313.08	0.426
Test Duration	E12	177.69	314.40	0.405
Discomf last	E14	179.64	321.48	0.366

Discomfort number	E15	178.98	316.49	0.355
Overall Comf	E19	177.94	310.44	0.460
Discomf Emb	E21	177.44	313.98	0.457
Explan after	F1	176.88	317.44	0.504
Refreshments	F2	176.31	319.06	0.175
Discomf hosp	F3	177.66	312.51	0.404
Discomf home	F4	177.81	310.73	0.419
Recovery	F5	177.53	313.74	0.416
Results worry	F6	178.46	315.43	0.333
Unsure Results	F8	176.34	313.71	0.165
Happy Results	F9	176.06	322.42	0.081
Results sooner	F10	176.20	326.93	-0.006
Next steps	F11	177.52	314.84	0.357

Table 6.23: Item total correlations

6.8. Exploratory Factor Analysis

6.8.1. Questions included in factor analysis

The questions with few or weak inter-item correlations (B16, D1, F2, F8) and those with ITC <0.3 (B11, B13, B16, D1, F2, F8, F9, F10) were not included in the factor analysis. Of the questions asked for both pain and discomfort, only the discomfort questions were retained.

The questions included in the factor analysis are listed below:

B1, B2, B3, B5, B6, B7, B8, B9, B10, B12, B14, B15

D2, D3, D4, D5

E1, E2, E3, E5, E6, E7, E8, E9, E10, E11, E12, E14, E15, E19, E21

F1, F3, F4, F5, F6, F11

A second correlation matrix for these 37 remaining questions was produced (not shown). The determinant for this correlation matrix was 1.550E-9.

6.8.2. Sampling adequacy

The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.904 (‘*meritorious’* according to Kaiser et al, 1974, or ‘*superb*’ according to Hutcheson &

Sofroniou, 1999), suggesting sample size was adequate for factor analysis. On inspection of the anti-image correlation matrix, all KMO statistics were above 0.5, again indicating acceptable sampling (not shown). Bartlett's test of sphericity (χ^2 (666) = 12005.5, $p<0.001$) indicated that relations between items were sufficiently large for principal component analysis.

6.8.3. Principal components analysis

The Scree plot (figure 6.6) shows one obvious point of inflection, suggesting that three factors could be retained. The three-factor solution explained only 44.8% of the variation.

Principal components analysis (PCA) revealed seven potential factors with eigenvalues over 1. The average communality after extraction was 0.615, which suggests that all factors could be retained. The seven-factor solution was settled upon as this explained 61.5% of the variance.

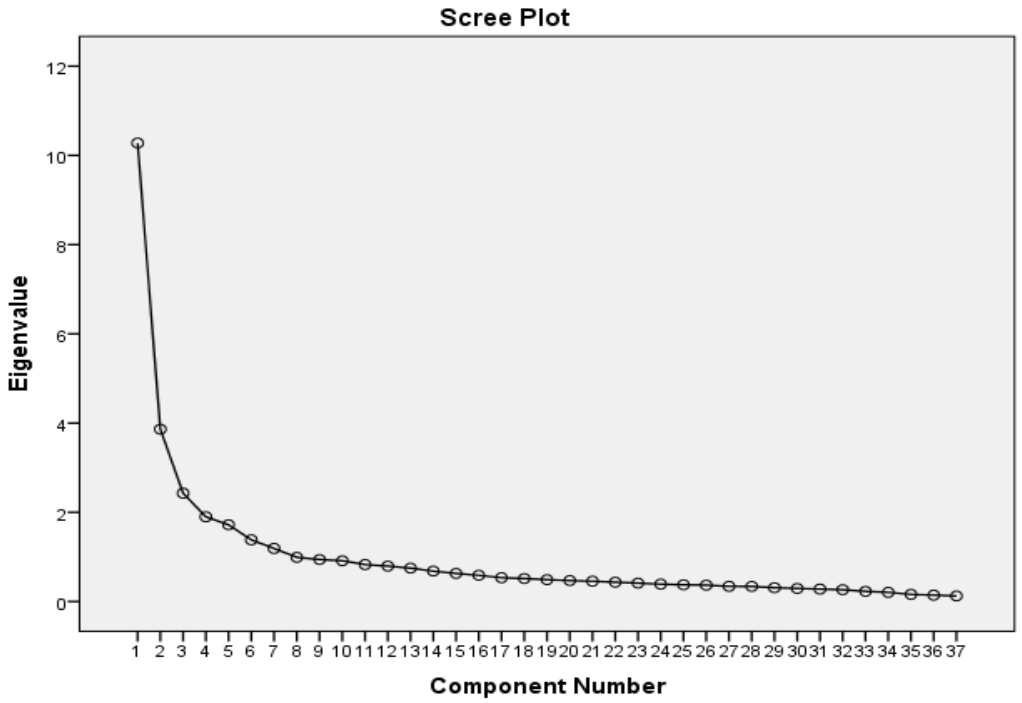

Figure 6.6: Scree plot for principal components analysis

The pattern matrix for the seven factors is shown in table 6.24[22]

[22] Values under 0.4 have been suppressed

Item	Abbreviation	Component						
		1	2	3	4	5	6	7
E6	Ease endoscopist	.893						
E5	confident	.881						
E9	Concerns add	.813						
E8	Explanation	.800						
E7	Ease other	.790						
F1	Explan after	.657						
E1	Dignity	.568						
E10	could stop	.547						
E2	Choose meds	.410						
E3	Meds Work							
E15	Discomfort number		.877					
E14	Discomf last		.839					
E19	Overall Comf		.706					
E12	Test Duration							
B12	Anxious Results			.815				
B10	Anxious Involve			.776				
B15	Expect Insert			.746				
B14	Expect Pain			.650				
F6	Results worry			.617				
B7	Info Questions				.828			
B6	Info Easy				.818			
B5	Info				.758			
B8	Instructions				.748			
B9	Discuss Referrer				.740			
B1	Referral Happy				.661			
B2	Referral wait				.601			
B3	Apt change							
D5	Privacy wait					.800		
D3	Ask staff					.775		
D2	Comf Wait					.774		
D4	No questions					.765		
F11	Next steps							
F4	Discomf home						.939	
F3	Discomf hosp						.884	
F5	Recovery						.803	
E11	Embarrassed During							-.688
E21	Discomf Emb							-.558

Table 6.24: Pattern matrix for seven components

Table 6.25 shows the list of items within each component and a suggested name.

Component	Overall theme	Included items
1	The test itself	E1. *During the test my dignity was maintained at all times* E2. *I felt free to choose what medication to take* E5. *I felt confident that the person doing the test knew what they were doing* E6. *The person doing the test did their best to put me at ease* E7. *The other staff in the test room did their best to put me at ease* E8. *I was satisfied with the explanation given to me about the test* E9. *The person doing the test addressed any concerns I had* E10. *I felt I could stop the test if it became too uncomfortable* F1. *I was satisfied by the explanation given to me by the person doing the test*
2	Discomfort during the test	E14. *How long did the discomfort last during the test?* E15. *How many times did you experience discomfort during the test?* E19. *Overall, the test was more uncomfortable than I expected*
3	Anxiety and expectations about the test and results	B10.*I felt anxious about what the test would involve* B12. *I felt anxious about the results of the test* B14. *I expected the test to be painful* B15. *I was worried that inserting the tube/ camera would be uncomfortable* F6. *I was worried about the test results*
4	Before coming for the test	B1. *I was happy with the way I was referred for the test* B2. *The time from first being referred to having the test done was satisfactory* B5. *Before coming for the test, I was given enough information about what the test would involved* B6. *The information I received before the test was easy to understand* B7. *After reading the information, I did not have any questions about the test* B8. *The instructions on what I needed to do before the test were easy to follow* B9. *I had enough time to discuss the test with the person who referred me*
5	At the hospital, before the test	D2. *I was comfortable while sitting in the waiting area* D3. *I felt able to ask the staff any questions before the test* D4. *I had no unanswered questions before the test* D5. *I had enough privacy when waiting for the test*
6	Recovering	F3. *I had discomfort before I left the hospital/ clinic*

	from the test	F4. *I had discomfort after I left the hospital/ clinic* F5. *It took longer than I expected to recover from the test*
7	Embarrassment during the test	E11. *I felt embarrassed during the test* E21. *I felt embarrassed by the discomfort I experienced*

Table 6.25: List of principal components and descriptions

Inspection of the component matrix (table 6.26*)* indicated that component 1 (*the test itself)* correlated with component 4 (*before coming for the test)* and component 5 (*at the hospital, before the test).* All other relationships between components were relatively small.

Component Correlation Matrix							
Component	**1**	**2**	**3**	**4**	**5**	**6**	**7**
The test itself	1.000	.165	.046	.509	.448	.257	-.093
Discomfort during the test	.165	1.000	.216	.071	.057	.312	-.090
Anxiety and expectations about the test and results	.046	.216	1.000	.095	.112	.172	-.121
Before coming for the test	.509	.071	.095	1.000	.378	.174	-.007
At the hospital, before the test	.448	.057	.112	.378	1.000	.242	-.115
Recovering from the test	.257	.312	.172	.174	.242	1.000	-.109
Embarrassment during the test	-.093	-.090	-.121	-.007	-.115	-.109	1.000

Table 6.26: Component correlation matrix

6.9. Reliability of Scale

The Cronbach's α score for all seven components was >0.6 with six over 0.7. This suggests good internal consistency (Table 6.27). The overall reliability was 0.897.

Component	**α**
The test itself	0.904
Discomfort during the test	0.791
Anxiety and expectations about the test and results	0.773
Before coming for the test	0.879
At the hospital, before the test	0.811
Recovering from the test	0.866
Embarrassment during the test	0.622
Overall	**0.897**

Table 6.27: Internal consistency of scales

6.10. Reliability of Section C

Cronbach's alpha was 0.592 when all six questions in section C were included in a reliability analysis. Corrected item-total correlations suggested that two questions correlated poorly with the overall total: C5 (*I was worried that the bowel preparation would not clear my bowel properly,* ITC 0.021*)* and C6 (*I had enough privacy when getting ready for the test,* ITC -0.011). When these two items were removed, the overall reliability of the scale improved to 0.693, indicating reasonable reliability.

6.11. Discussion

6.11.1. Key Findings

The response rate was 48.5%, with a mean respondent age of 58.6. The response rate did not vary by sex; however, it was lower in those aged ≤54 years (30.4%) and in patients undergoing 'OGD& colonoscopy' (29.4%); however, only 34 individuals who had both OGD and colonoscopy were approached to take part in the study.

There was a discrepancy between the patient reported procedure and the procedure confirmed by the research team in 53 cases (6.6%).

Section C, which should have been completed by those undergoing colonoscopy and CTC only, was completed by 96.1% of participants to whom it applied and 18.0% of those to whom it did not.

Completion rates of individual questions were high, with only three questions showing missingness of over 5%, and none over 10%. Excluding section C, one third of participants (34.3%) failed to complete one or more questions, and the oldest age group (>75 years) were significantly more likely to miss questions. 3.9% of participants to whom Section C applied missed questions within this section, with patients in the oldest age group significantly more likely to miss questions.

For the two VAS questions, the responses were formatted correctly by only 55.2% (E13, discomfort) and 60.3% (E16, pain) of respondents. Analysis showed these scores were correlated but responses for pain were systematically lower than for discomfort.

Two pairs of questions correlated strongly (r_s >0.8) and four questions poorly correlated with any others (r_s <0.3). Eight questions (including the four with poor inter-item correlations) had poor corrected item-total correlation (ITC <0.3). Some questions with poor correlation also had higher missingness, i.e. D1 (*I waited longer in the department than I expected)*; F8 (*When I left the hospital, I was unsure of how I would get the results of my test)*; F9 (*I was happy with the way I received the results of my test)*; F10 (*I received the results of my test sooner than I expected)*.

Principal components analysis identified seven components (The test itself; Discomfort during the test; Anxiety and expectations about the test and results; Before coming for the test; At the hospital, before the test; Recovering from the test; Embarrassment during the test), all of which had Cronbach's alpha of >0.6.

6.11.2. Strengths and limitations of this phase

This phase of the project was undertaken across four different sites in order to increase diversity of patients and experiences. A good range of participants were included. There was notable variation in the numbers of participants recruited per procedure type; only ten patients who had OGD & colonoscopy responded to the questionnaire (of 34 invited) and 115 CTC participants (of 209 invited). Far fewer

CTCs are done at each of the sites than OGD and colonoscopies and this was reflected in the number of participants recruited in this group.

In terms of limitations, there was little diversity in ethnicity amongst respondents, with 98.4% self-reporting as White British. This is in keeping with ethnicity data for the region, which indicates that the North East has the highest percentage of White British residents (93.6%) within England and Wales (Office for National Statistics, 2011). This may also indicate that non-White British groups are less likely to respond to the questionnaire and translation of the questionnaire could be considered. The small percentage of non-White British ethnicity means that the performance and properties of the questionnaire are not known in this group.

A recruitment log was kept in order to monitor characteristics of respondents and non-respondents. However, patients who were approached but who declined to participate in the study were not reliably recorded by the research teams, in part because they had not been asked to consent to their details being logged. It was not possible to be certain that every eligible patient was systematically invited to take part. There are significant differences between respondents and non-respondents in terms of age and the procedure undertaken, which is indicative of non-response bias; this may have implications if the data was used subsequently to measure experience. Non-response bias has been studied elsewhere, with lower age groups and females less likely to respond (Etter *et al.*, 1997). In this study, only the former was observed.

6.11.3. Timing of questionnaire

Participants were asked to post the completed questionnaire back to the research team, rather than complete it on the day of the test. This was in part due to the fact that participants who had sedation may have impaired capacity to consent to research as a result. 8.3% (n=66) of respondents indicated that they completed the questionnaire on the day of the procedure. A priori two options were identified for timing questionnaire distribution by the study team: giving patients the questionnaire pack on the day of their test or posting it at a later date. It was considered possible that having the results may influence how participants would respond to the PREM. This has been shown in a study investigating PROMs in the setting of men undergoing prostate biopsies (Sharp *et al.*, 2018). Biopsy-related distress was higher in those with a biopsy indicating cancer or those awaiting results than those with a normal result. An advantage of posting the questionnaire to participants was that

distribution could be delayed for a period to allow them to receive the results of their test, if they hadn't already received them. However, participants in the qualitative interviews described varying methods and timescales of receiving their test results so this would not have ensured that all participants had their results. Giving the questionnaire pack on the day of the test allowed the procedure to be relatively fresh in participants' minds. The outcome of the method used was that participants varied in terms of whether they had had their results; some had all results (31.5%), some had partial results (37.8%) and some had no results (23.7%). Further analysis (beyond this thesis) would be valuable to explore whether experience varies in these groups. In retrospect, an alternative approach would be to administer the questionnaire at two points and ask participants to indicate whether they had their results at each time point. This would have enabled test-retest reliability and responsiveness and whether responses are impacted by receipt (or not) of results, and what those results show, to be assessed.

6.11.4. Ceiling effects

Twenty-five items within the whole questionnaire showed a ceiling effect. No floor effects were found. This may suggest that participants viewed their experience positively in these domains. However, it could also indicate that those with positive experiences are more likely to respond.

In terms of performance of the questionnaire, a high number of ceiling effects may mean that the questionnaire is not able to discriminate between levels of positive experiences. Similarly, a high number of floor effects (had that been observed) would suggest the same for the 'low' end of the scale (Dean *et al.*, 2018). Traditionally, floor and ceiling effects are described in relation to questionnaire scales (rather than in relation to individual questions) and defined, in that context, as over 15% of participants endorsing the highest ('ceiling') or lowest ('floor') response option (Terwee *et al.*, 2007; Wamper *et al.*, 2010). Within the field of patient-reported measures, a proportion of less than 40% of respondents choosing the highest or lowest ordinal response score to an individual item may be taken to indicate the absence of a significant ceiling or floor effect (Dean *et al.*, 2018). In this study, the ceiling effects were broadly similar across gender, age, procedure and site, with the exception of question E3 (*the medication worked as well as I expected),* which had

no ceiling effect in women. Furthermore, there was no ceiling effect for this question in the older two age groups.

Previous studies have indicated that positive wording can affect how questions are answered (McColl *et al.*, 2001; Locker *et al.*, 2007; Jaensson *et al.*, 2017). This was the rationale for using a mixture of positive and negative wording in this questionnaire. It was interesting, therefore, that ceiling effects were only present in questions that were worded in a positive way, e.g. *during the test my dignity was maintained at all times.*

A possible solution to the issue of ceiling effects would be to increase the number of Likert response options to seven. Alternatively, the wording of some of the questions with ceiling effects could be changed to being negatively framed.

6.11.5. Missingness

On an individual question basis, missing responses were low (all < 10%), suggesting that the questions were acceptable to participants. The rate of item non-response was higher among participants >75 years old. In a study of patient reported outcome measures (PROMs) in patients with prostate cancer, older age was also associated with increased missingness (Drummond *et al.*, 2015). Previous work has suggested that this observation could, in part, be due to reluctance in older patient age groups to report poorer experience and they therefore may instead leave responses blank (Voutilainen *et al.*, 2014).

6.11.6. Pain and discomfort

Three questions were asked about both pain and discomfort, with the objective of refining and reducing the number of items in the questionnaire and, specifically, determining in future versions whether to ask about pain *or* discomfort. Comparisons between each of the questions indicated that the paired answers were well correlated, but discomfort tended to be scored more highly than pain. This could be because either pain is seen as a more severe form of discomfort or they are measuring different things. This quantitative assessment does not give insight into the difference between pain and discomfort as perceived by patients. Therefore, it is not possible to discriminate whether these questions are different descriptors of a similar entity or whether they describe separate entities altogether, although the

qualitative work suggested that individuals had one of these viewpoints. Tian et al describe comfort as “not only a state of peace and serenity but also relief, ease or transcendence from the discomfort,” and that pain is a contributor to discomfort (Tian *et al.*, 2019). Using this definition and noting that discomfort appears to be rated higher than pain in this population, retaining questions which focus on discomfort rather than pain might be a pragmatic approach. Alternatively, in terms of experience, it may be that some discomfort during the procedure is acceptable from a patient experience, but pain is not, and removing these questions may not fully address this aspect of experience. This could be explored in future research.

The VAS questions for discomfort and pain (E13 and E16, respectively) were answered by a majority of respondents (98.9% and 98.0%, respectively), however, only 55.8% and 61.6% of respondents, respectively, answered these in accordance with the instructions. This problem was not identified in cognitive pretesting. In addition, there was a problem with data entry- both VAS on every questionnaire had to be measured (by LN) and the data re-entered. This was a laborious process and raised questions about the practicality of using a VAS in the questionnaire going forward. A solution to these problems could be to alter the VAS to make it clearer, remove the numbers from the ‘line’ or to change the scale to a numerical rating scale. Another approach could be to categorise responses into four or five groups, however, given the variable response modes even this could prove cumbersome in a practical setting. The final option would be to remove the VAS questions from the questionnaire and retain the other Likert response questions.

6.11.7. Exploratory factor analysis

There was not an intention from the outset to create a questionnaire with subscales. Principal components analysis suggested seven factors which accounted for 61.5% of the variation in the data. Evaluation of the scree plot indicated that three factors could be retained, however, the three-factor solution only explained 44.8% of the variation. Seven factors had eigenvalues >1 and explained 61.5% of the variation. Four of the factors appeared to be related to stages of the procedure (experience before coming for the test; at the hospital, before the test; the test itself; recovering from the test), whereas the remainder seemed to cover some aspects of the over-arching themes identified in the qualitative interviews (discomfort during the test; anxiety and expectations about the test and results; embarrassment during the test).

Cronbach's alpha was over 0.7 in all components aside from embarrassment, which was comparatively low at 0.622. Kline (2000) and Field (2018) suggest that $\alpha > 0.7$ indicates good reliability. Whilst the embarrassment component had a relatively low reliability, this could in part be explained by the fact that the scale only comprised two questions (which had a correlation of 0.454).

6.12. Summary

In summary, psychometric testing of the PREM identified low rates of missingness and 25 questions with a ceiling effect. Pain and discomfort were correlated, but pain was given a lower score than discomfort. Seven factors were identified which explain 61.5% of data variation. Suggestions for final refinement are made in Chapter 7.

Chapter Seven: Discussion

7.1. Summary of work

The preceding chapters have described the rationale for and the methodological approach to developing the Newcastle ENDOPREM™. Phase one described the patient experience of GI procedures and six over-arching themes were identified stretching across six procedure stages. Phase two involved item generation and refinement followed by cognitive pre-testing with patients who had recently undergone GI procedures. This phase resulted in a pilot PREM. The psychometric properties of the questionnaire were investigated in phase three.

The key findings, strengths, limitations and discussion of each phase in the context of the literature are described in the discussion at the end of each chapter. This final discussion aims to discuss the ENDOPREM™ in the context of patient experience of GI procedures, make suggestions about further refinements and future research and to discuss the potential future uses of the ENDOPREM™.

7.1.1. Domains of patient centred care

The over-arching themes which emerged from the phase one qualitative interviews were: anxiety, expectations, choice & control, information & communication, dignity & embarrassment and comfort. The Picker Institute has defined eight principles of patient centred care; respect for patients' preferences; coordination and integration of care; information, communication and education; physical comfort, emotional support and alleviation of fear and anxiety; involvement of family and friends; continuity and transition; access to care (Picker Institute Europe, 2019). There is some overlap between the themes identified in the current study and the Picker dimensions. Information & communication in the current study is broadly related to information, communication and education. Physical comfort is addressed by both the current study and the Picker domains. The themes of anxiety and expectations which emerged from the current study are covered partly by 'emotional support and alleviation of fear and anxiety' in the Picker domains, however, emotional support did not emerge during the qualitative interviews. This could be that emotional support is not required for these procedures, whereas it may be important to patients undergoing treatment for cancer, for example. The domains of continuity and transition and access to care did not emerge as over-arching themes from the current

study. However, some participants did express a preference for continuity of endoscopist rather than convenience of appointment, for example. This was included in the 'choice & control' theme. The differences between the themes identified in the current study and the domains of patient centred care may partially be explained by the fact that the ENDOPREM™ focuses on the experience of a specific (usually one-off) procedure after the patient has been referred, meaning that items such as continuity of care and involvement of family and friends may be less relevant.

7.2. Refining the questionnaire

7.2.1. Item reduction

Question B16 (*I hoped the person doing the test would be the same sex as me*) correlated weakly with other questions. It had been designed to identify patients' preference for endoscopist gender and to enable comparison with embarrassment in further analyses (out with the remit of this thesis). In retrospect, the question did not require the Likert responses 'strongly agree' to 'strongly disagree' as it was an explanatory question, rather than a question about experience. Furthermore, the wording of the question was complex, in that it asked participants about their 'hopes' for the person doing the test. For future versions of the ENDOPREM™ this question could be removed and replaced with a simpler question, for example: *I would prefer the person doing the test to be the same sex as me* (response options: yes/ no/ I don't mind).

Question F2 (*I was pleased with the refreshments offered)* did not fit in to any of the over-arching themes identified in the qualitative interviews but had been included as several participants described the importance of a 'cup of tea' and its' significance in representing the end of the procedure. The question did not correlate strongly with any others and 75.6% either agreed or strongly agreed with the statement (bearing in mind that 18.0% stated they were not offered a refreshment as they had throat spray). This question should be removed from future versions of the questionnaire.

Question D1 (*I waited longer in the department than I expected)* correlated poorly with other items. The question was worded in terms of expectations because participants in the qualitative interviews described waiting longer than expected as having an impact on anxiety. In the pilot questionnaire, participants could have

waited for several hours in the department but if this is what they expected then they would disagree with the statement. This means that negative experiences could be missed. Given the poor correlation with other items, this question could be removed from future questionnaire versions. An alternative would be to reword the question to something more direct, for example: *I waited too long in the department before the test.*

Question F8 (*When I left the hospital, I was unsure of how I would get my test results)* was another item that correlated poorly with any others. This was one of four questions addressing the results of the test and followed an 'explanatory' question which asked participants to identify how they received their results. The question was reasonably complex; however, no problems were identified with it in cognitive pre-testing of the questionnaire. Given the poor correlation with others, and relatively high missingness, this item could be removed from the questionnaire.

Responses to questions F3 (*I had discomfort **before** I left the hospital/ clinic)* and F4 (*I had discomfort **after** I left the hospital/ clinic, eg when I got home)* had a similar distribution of responses and correlated highly with one another. This could be because patients who had discomfort at home were more likely to have had this in the hospital/clinic, or it may be that participants are unable to discriminate between the two. The questions could be refined into one question, for example, *I had discomfort after the test.*

Several items were included for both pain and discomfort, as described in chapters 4 and 5. The VAS questions were answered using an incorrect response format by 44.8% (E13, discomfort) and 39.7% (E16, pain) of respondents. The question could be restructured by removing the numbers from below the line, therefore removing the ability to circle a response. Alternatively, a numerical rating scale could be used. Due to the high number of questions assessing both pain and discomfort, removing the VAS and instead keeping the other two questions would be an alternative option.

Aside from the two VAS questions, a further six questions address pain and discomfort: E14 and E17 (*How long did the discomfort/pain last during the test?)*; E15 and E18 (*How many times did you experience discomfort/pain during the test?)*; E19 and E20 (*Overall, the test was more uncomfortable/ painful than I expected).* Both sets of questions were included to identify whether participants answered differently

for discomfort and pain, with the goal of removing one set of questions. When the pain and discomfort responses were cross-tabulated for each of these questions, the responses were well correlated, and pain tended to be scored less highly than discomfort. This could indicate that pain is a more severe form of discomfort, but also the two could represent different concepts. More missing responses were observed for pain than discomfort. If the discomfort questions are removed, patients who experience non-painful discomfort may not be identified. Another option would be to remove the questions about pain. It could be argued however, that some non-painful discomfort may be acceptable, but pain is not. Therefore, both sets of questions, excluding the VAS, have been retained for the next iteration of the ENDOPREM™. Further analysis could be undertaken to better understand what is associated with pain and discomfort and this could shed further light on these concepts.

7.2.2. Item rewording or restructuring

Ceiling effects were present in 25 questions, all of which were positively worded. It may be that this patient population genuinely had 'positive' experience of these items. Although some questions in the pilot PREM were negatively worded, the majority were positive. One solution would be to restructure some of these questions to be negatively worded.

Questions F8 – F10 all addressed how or whether participants had received their results (*When I left the hospital, I was unsure of how I would get my test results; I was happy with the way I received the results of my test; I received the results of my test sooner than I expected)* and were situated in a 'cluster' within Section F of the questionnaire. Additional responses were included to allow participants to indicate if they already had their results (F8) or did not yet have their results (F9, F10). A similar percentage of respondents used the additional response option in each question (29.5%, 30.8% and 34.9%, respectively); in addition, 23.7% of participants had reported in a previous question that they did not yet have their results. This suggests an issue with the consistency of the additional response option and suggests that one of the additional response options (F8) has been misread. The questions should be reworded to ensure the same response options are offered for each question.

Question F7 was used as an 'explanatory' question to identify whether patients had received all, some or none of their results. Several response options were provided, including; *I do not have my results, I was told some results but have to wait for a*

biopsy/tissue sample, I was told all of the results before I left the hospital, the results were posted to me, I received a written copy of all of the results before I left the hospital, I received a written copy of some of the results before I left the hospital but have to wait for a biopsy/tissue sample, I received my results in a different way (free text). Participants were asked to indicate all responses that applied to them. No problems with this question were identified in the cognitive pre-testing. The response options are long and as participants can choose more than one option, this could make identifying who actually had their results and who didn't difficult. Simplifying the question in future versions would overcome this, for example: *Have you received the results of your test?* Response options: I have received all of the results; I have received some of the results; I have not received any results.

Questions B5 (*Before coming for the test, I was given enough information about what the test would involve)* and B6 (*The information I received before the test was easy to understand)* were strongly correlated (r_s >0.8). This may indicate that participants perceived these questions to be addressing the same issue. For future versions of the final questionnaire, B6 could be removed. The rationale for this is that if participants agree that they have been given enough information, this implies that they understood it.

7.3. Using the questionnaire in practice

7.3.1. Potential uses

There are two broad potential uses for the ENDOPREM™; to assess patient experience in routine practice or as a research tool. For the former, ENDOPREM™ could be used as a tool to assess patient experience of OGD, colonoscopy and CTC. This could be used either within a single site to monitor care over time or in multiple sites to compare care across sites. This could identify areas where patient experience is negative and enable aspects to be targeted to improve the overall patient experience. The Global Rating Scale (GRS) in the UK is not prescriptive about how patient experience should be measured (Joint Advisory Group on Gastrointestinal Endoscopy, 2016a). Potentially, the ENDOPREM™ could be introduced as part of the Joint Advisory Group on Gastrointestinal Endoscopy (JAG) accreditation process to standardise reporting of experience between units. This would also be useful to benchmark quality of care.

The ENDOPREM™ could also be used as a research tool, for example, to compare patient experience between procedures. Its use could also be extended to assessing patient experience where new interventions or processes are introduced to GI procedures, for example, in studies assessing interventions to improve pathology detection, the ENDOPREM™ could be used to identify if such interventions impact patient experience. A specific example of this is the ADENOMA study, which investigated adenoma detection rate in patients undergoing colonoscopy with a device attached to the colonoscope compared to those undergoing standard colonoscopy (Ngu *et al.*, 2018). A secondary outcome of the study was to demonstrate non-inferiority in terms of comfort and patient experience. This was measured using a nurse-reported comfort score and patient reported comfort specific to endoscope insertion. Potentially, ENDOPREM™ could be used to assess the impact of such interventions on patient experience.

The ENDOPREM™ was developed to measure patient experience of endoscopy procedures (OGD and colonoscopy) and the most common alternative, CTC. Transnasal endoscopy is an increasingly popular approach to OGD and therefore participants who had undergone this procedure were included within the OGD recruitment to all stages of the study. For example, video-capsule endoscopy (VCE) has been developed as a means of imaging the small bowel. This involves swallowing a pill-shaped capsule containing a camera, which takes pictures through the GI tract and transmits this to an external data recorder (McAlindon *et al.*, 2016). VCE is also being used to assess the colon and stomach, meaning that this may become more commonplace (Parker *et al.*, 2015). Future use of the ENDOPREM™ could be to compare patient experience of capsule endoscopy with optical endoscopy, however, this would require validation of the ENDOPREM™ in a capsule population.

7.3.2. Self-report of procedure undertaken

7.1% of participants reported that they had undergone a different procedure from the actual procedure recorded by the research team. Participants may have had another test in the recent past which could partially explain this. This raises the issue as to whether patient self-reporting is reliable enough for future use. The procedure descriptions used in the pilot questionnaire did not raise any issues in the cognitive pretesting. A solution to this may be to add visual guides, for example, to aid

participants in reporting their procedure. This would not combat the issue of patients who have had multiple recent procedures but could help with those who are uncertain from the text descriptions about which procedure they had. A more accurate approach would be for staff issuing the questionnaire to mark the procedure undertaken. This could take the form of a sticker or letter printed on the inside cover but would be labour intensive and may not be possible in a non-research setting.

7.3.3. Questionnaire length

The pilot PREM was a fifteen-page booklet with 73 questions (including patient characteristics, 'explanatory' questions and section C). The number of missing responses did not systematically decrease as the questionnaire progressed, suggesting that length was not an issue for patients who responded to the questionnaire. Other studies comparing long and short versions of questionnaires have shown no significant effect of questionnaire length on response rate (Mond *et al.*, 2004; Robb *et al.*, 2017; Koitsalu *et al.*, 2018). As a result, item reduction- here and in the future- should concentrate on removing questions that did/do not perform well and allow retention of most questions to address the whole patient experience, as described in the qualitative interviews.

7.3.4. Questionnaire versions

In order to reduce the effect of patients reporting the incorrect procedure, different paper versions of the questionnaire could be used, for example, creating procedure-specific questionnaires with the procedure printed on the questionnaire. This could also include colour coding questionnaires according to procedure and removing section C (*Preparing for the test)* from questionnaires given to OGD patients.

An alternative to paper questionnaires could be converting the PREM to an online questionnaire. This would result in a lower price per respondent, as physical copies of the questionnaire, postage and return envelopes would not be required. Consideration would need to be given to the issue of online data security and how much potentially identifiable information is collected, in addition to the acceptability of an online questionnaire in specific patient groups, for example, older age or those without internet access. A study in Poland investigated the difference in asking patients to complete a paper based questionnaire (asking questions about comfort and complications) following screening colonoscopy, compared with an intervention

group who were given the choice of paper, telephone or an online version of the questionnaire (Bugajski *et al.*, 2019). This found no difference in the overall response rate, but significantly improved response rate of patients <60 years old in the intervention group. The response rate in the current study was lowest in patients aged <55 years. A digital version of the questionnaire may increase response in this group but would require further validation and testing of acceptability.

7.3.5. Timing of questionnaire

The timing of questionnaire distribution has been discussed elsewhere in this thesis (sections 3.2.3, 3.3.4, 6.11.3). In this study, the questionnaire was handed to patients in the endoscopy/ radiology department and they were asked to return it within two weeks. There was variation in the time taken to return the questionnaire, with evidence that some respondents completed it on the day of the procedure. Further study is suggested in which the questionnaire is administered at different time points, for example, in the department and two weeks following the procedure. This would provide further information about the reliability of the PREM but also about whether patients report their experience differently at varying stages of the procedure process.

7.4. Future Research

In addition to the psychometric properties and refinements discussed in this thesis (chapter six and seven), further analysis is suggested prior to use of the ENDOPREM™.

Further research could focus on administering the questionnaire at different time points and comparing the responses, for example, on the day of the procedure and two weeks later. Comparison of the results would identify whether the measurement is stable over time (test-retest reliability) and whether the instrument responds to changes over time, for example before and after the patient receives results (responsiveness) (Streiner *et al.*, 2008).

A measure of depression, anxiety and stress (DASS 21) and a quality of life measure (EQ5D) were included in the pilot questionnaire booklet. The ENDOPREM™ was designed to measure patient experience of GI procedures and not solely state anxiety or quality of life. Further analysis could focus on whether these measures

correlate with the ENDOPREM™, to ensure discriminant validity, i.e. whether ENDOPREM™ measures different aspects from the quality of life measure (Streiner *et al.*, 2008). As anxiety was an over-arching theme identified in the qualitative interviews, the DASS 21 may correlate to some extent with the ENDOPREM™. Further analysis could therefore assess the convergent validity of the PREM. In addition to this, comparison of different anxiety states and patient reported quality of life could be undertaken to identify their effect, if any, on patient experience of GI procedures.

Analysis could be undertaken to describe the patient experience in the pilot study. This could include comparison of different groups (for example, sex, age groups, procedure) and use of the 'explanatory' questions to identify whether endoscopist/ operator gender or cancellation of the initial appointment affects experience.

Although individuals who had undergone transnasal endoscopy were included in the pilot questionnaire phase, they only accounted for 0.8% of participants. Further research could be undertaken in this patient group to identify how the questionnaire performs in this group. Additional groups in whom the ENDOPREM™ could be tested include those undergoing video capsule endoscopy.

The ENDOPREM™ was only tested in English in this pilot work. Future research could include translation of the questionnaire with subsequent validation studies. The benefits of this could include improved uptake of non-White British participants, for example, or use of the ENDOPREM™ in different countries.

7.5. Summary

In summary, this thesis has described the stages of the ENDOPREM™ questionnaire development and its psychometric properties. Further analysis of responsiveness and test-retest reliability are recommended prior to use. Future potential uses include comparing patient experience in single units over time, across multiple sites or within research to explore patient experience in response to interventions.

Chapter Eight: Student Reflection

Undertaking this research project has been an informative experience. The mixed methods approach has enabled me to learn and develop skills in different research areas. I have developed skills in qualitative interviewing and analysis. Exploring in-depth experiences of GI procedures with participants challenged my own practice as an endoscopist, and really impressed upon me the importance of good communication with patients during these procedures. A key challenge within the qualitative phase (both the qualitative interviews and later the cognitive interviews) was my dual role as an endoscopist and researcher. I learned the importance of maintaining an impartial, academic approach to the interviews and analysis. This was mitigated somewhat by having a non-GI supervisory team and wider study team.

Item generation for the questionnaire involved several team members, detailed in the methods chapter. Working in a team can be challenging in terms of bridging different views and opinions. Despite being familiar with working in and leading a clinical team, I developed teamworking and leadership skills throughout this project within a completely different team dynamic.

I generated the initial items and coordinated circulation of the question bank, teleconferences and refinement of the final questionnaire. I realised the importance of cognitive pre-testing with a range of patients and its role in identifying 'problem' questions. Prior to this study I had some experience of statistical analysis, having undertaken a Postgraduate Diploma in Clinical Research at Newcastle University. Investigating the psychometric properties of the questionnaire allowed me to build on this knowledge, assess the appropriateness of various statistical techniques and evaluate the results. I am now much more confident with statistics and SPSS® as a result. Completing this thesis has further developed my skills in academic writing and reporting results.

Managing a multi-phase study across several sites allowed me to further develop skills in organisation, team-working, time management and problem-solving, all of which are transferable skills useful for future practice.

A personal challenge in completing this thesis was doing so while working in a busy clinical role, completing clinical training and commencing a consultant post. This has required good time management and organisational skills. The importance of enjoying life away from work has become clear to me in terms of relaxation and improving productivity when working to a long-term deadline.

I hope to continue to use and build on the skills learned during this project in future research work and in my clinical practice.

Appendices

Appendix A: Patient Information Sheet for interviews

Patient Experience Research Project: Patient Information Sheet

Study Comparing Outcomes and Patient Experience Measures for GI Endoscopy (SCOPE-ME) – Patient Reported Experience Measure (PREM) Development Phase

Focus groups and cognitive interviews

Chief investigator – Professor Colin Rees

We would like to invite you to take part in a research study. Before you decide if you want to take part, we would like you to understand why the research is being done and what it would involve for you. Please take some time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of this sheet will explain about the study and what will happen to you if you take part.

Part 2 of this sheet will give more detailed information about the way the study will be conducted.

Please ask us if there is anything that is not clear, or you would like more information. Take time to decide if you wish to take part.

Part 1

What is the purpose of this study?

Many people will need to have an endoscopy procedure or an examination of their bowel at some point in their lives. Doctors know a lot about the technical aspects of these procedures, and we know how accurate the tests are at detected abnormalities. We know less about the experience of having the test from the patient perspective. We feel that this should be better understood, and changes made to the tests if necessary to improve patient experience. There are some tools being used to assess experience of endoscopy and X ray tests, but these have all been developed by healthcare professionals rather than with direct input from patients. We aim to develop a new tool to properly understand how patients find these tests.

More of the scientific background to this is given in part 2 – "background to the study".

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

We will invite you to come to South Tyneside Hospital to take part in an interview called a "focus group" or "semi-structured interview." This will be a group of 6-8 people who all have had an endoscopy or X ray test of the bowel or alternatively you may be interviewed by the researcher alone. You may also choose to have an interview over the telephone. The interview will be led by a researcher, who will lead you in a discussion about these tests. You will have the opportunity to tell us your thoughts on the whole process, including the preparation for the test at home, the hospital department, the test itself, and your experiences following the test. We have sent this information to you to read before you come for your test. If you are interested in taking part, a research team member will be available in the department when you attend for your test to arrange the next step, which will be coming to a discussion group at the hospital at a later date.

The sessions will take about an hour – you will first have the chance to go through the study details on your own with a researcher who will answer any questions you have and fill in the consent form for the study. Then you will enter the focus group, and this part of the session will take around 45-60 minutes. The discussions will be audio recorded so we can review what was talked about later. We will keep the recordings in a secure office and transfer them securely to Durham University where a team will write down what was said and send it securely back to us. After the discussions have been written down we will delete the audio recording. We will keep the written copies securely in the hospital.

If you choose to have a telephone interview, a member of the research team will contact you via telephone to confirm your interest and go through the consent form and confirm a date for the interview. You will then be asked to post the consent form back to the team. On the date of the interview, a member of the research team will telephone you and confirm that you wish to take part. The interview will then start and the conversation will be audio recorded so we can review what was talked about later, and stored and transferred as above. The discussion will take around 45-60 minutes.

Any comments you make in the discussion group will be confidential and will not affect the way your doctor cares for you. This session is in addition to your usual clinic appointments; it does not replace any of your other appointments.

After the discussion group or interview, we will need some people to agree to come back to the hospital for a further interview to review the questionnaire tool that we develop. We will ask you at your discussion group if you are interested in taking part in this next part of the study. You would need to come to an interview with one of the research team at the hospital. This would last approximately one hour, and would be a few months after the focus group. You would complete a new consent form, and again, the session would be recorded and written up in the same way as the discussion group.

Expenses and payments

We will help you with the cost of coming to the focus group session and interviews by reimbursing your public transport expenses or car parking costs.

What are the possible disadvantages and risks of taking part?

In the unlikely event that the process of discussion in focus groups causes you any distress, then appropriate procedures for support will be available through your GP or the hospital doctor who you see in clinic. At least one of the two researchers who lead the discussion group or interview will have experience of endoscopy, and should be able to answer any questions about the tests that you may have, although they would not be able to discuss your test results specifically. There are also contact details for the research team at the end of this form.

There are not expected to be any risks or side effects of taking part.

What are the possible benefits of taking part?

This study gives you an opportunity to tell us your experiences of coming for an endoscopy test. The results of the study will not make any difference to your current care, but may help us to improve the way in which we deliver the tests in the future. We will be able to more accurately assess your experience of the test.

What happens when the research study stops?

The care you receive from the hospital will not change. After you have taken part in the study, you will continue to have follow up with your consultant as previously arranged.

What if there is a problem?

Any complaint about the way you have been dealt with during the study, or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. More details are included in Part 2.

This completes Part 1. If the information on Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.

Part 2

Background to the study

Examinations of the stomach and bowel are widely performed with around 1.5 million procedures per year in the UK. The lifetime chance of requiring one of these tests is now greater than 1 in 3. We know that consistent high quality is essential to ensure that procedures are safe and that abnormalities are

not missed. A positive experience of the test is important to ensure patients attend for their tests and any further tests that may be required in the future. At present all the tools (such as questionnaires) used to assess patient experience of these tests are written by healthcare professionals. Recent research has shown that there is a large variation between what doctors and nurses think is important to patients during these tests and what patients themselves think is important. It is increasingly recognized that designing questionnaires based on patient's experiences rather than healthcare professionals perceptions leads to better quality tools to assess the experience.

We currently look at the upper part of the gastrointestinal tract (food pipe and stomach) using either a camera test through the mouth or a thinner camera passed through the nose. The lower bowel is examined either using a flexible camera passed through the anus or using a CT scan after clearing the bowel with laxative medication. The aim of this study is to develop two separate tools based on patient reports of these tests that will enable us to accurately assess patient experience.

What if relevant new information becomes available?

If new information answering the questions we are asking becomes available during the study, then we will decide if we need to proceed with our study. If we decide to stop the study, we will let you know. Any information we have gathered up to that point may still be used.

What will happen if I don't want to carry on with the study?

You can withdraw from the focus group or interview at any time. Information collected before you leave may still be used.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details are at the end of this leaflet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against South Tyneside NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms (through the Patient Advice and Liaison Service (PALS), details of which are at the end of this leaflet) will still be available to you.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential, and any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised. Records will not be publicly available.

Involvement of your General Practitioner (GP)

Your GP will be informed that you are participating in a study, and information about the study will be sent to them.

What will happen to the results of the research study?

The intention is for the results to be published in a medical journal. You will not be able to be identified from these results. We hope to use the questionnaire tool that we develop in this study to help assess patient experience in future endoscopy studies.

Who is organizing and funding the research?

The sponsor is South Tyneside NHS Foundation Trust. The organising doctor is Professor Colin Rees.

Who has reviewed the study?

This research has been looked at by independent group of people, the London Stanmore Research Ethics Committee. This is to protect your safety, rights, wellbeing and dignity.

For further information please contact one of the study team:

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Other contacts:

Patient Advice and Liaison Service (PALS) – 0191 404 1073

Consultant secretaries:

Professor Colin Rees and Dr Jo Topping 0191 404 1000 ext 4028

Dr Simon Panter and Dr Faheem Butt 0191 404 1000 ext 4035

Dr Oliver Schulte 0191 404 1000 ext 3187

Appendix B: Ethical Approval

NHS
Health Research Authority

NRES Committee London - Stanmore
Skipton House
Ground Floor
NRES/HRA
80 London Road
London
SE1 6LH

Telephone: 020 797 22560

20 March 2014

Prof Colin Rees
Consultant Gastroenterologist
South Tyneside NHS Foundation Trust
Harton Lane
Sout Shields
NE34 0PL

Dear Prof Rees,

Study title:	**Study Comparing Outcomes and Patient Experience Measures for GIEndoscopy (SCOPE-ME) - Patient Reported Experience Measure (PREM) development phase**
REC reference:	**14/LO/0557**
IRAS project ID:	**148469**

The Proportionate Review Sub-committee of the NRES Committee London - Stanmore reviewed the above application on 20 March 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Mrs Julie Kidd, NRESCommittee.London-Stanmore@nhs.net.

Ethical opinion

The PRS Sub-Committee agreed that this was a well thought out study and the invitation and consent forms are good.

It was noted that there was no record of the REC name in the information sheets. The staff interview information sheet, second heading should be headed participant information sheet as

they are not patients, and this may distress some participants.

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

1. Add the name of the REC to the information sheets
2. Change the Staff Information Sheet heading from "patient" to "participant."

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering Letter - Email from Simon Dunn		14 March 2014
GP/Consultant Information Sheets		
Investigator CV - Professor Colin John Rees		12 August 2013
Letter of invitation to participant		
Other: South Tyneside - Funding Letter		11 March 2014
Participant Consent Form: Focus Group	2.0	27 February 2014
Participant Consent Form: NHS Staff Interviews	2.0	27 February 2014
Participant Consent Form: Cognitive Interviews	2.0	27 February 2014
Participant Consent Form: Pilot PREM Questionnaire	2.0	27 February 2014
Participant Information Sheet: Focus Groups and Cognitive Interviews	2.0	27 February 2014
Participant Information Sheet: Interviews for NHS Staff	2.0	27 February 2014
Participant Information Sheet: Pilot PREM Questionnaire	2.0	27 February 2014
Protocol	2.3	20 February 2014
REC application	148469/579753/1/716	13 March 2014

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
information is available at National Research Ethics Service website > After Review

14/LO/0557	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely
pp

Mrs Rosemary Hill
Chair

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Appendix C: HRA Approval

NHS
Health Research Authority

Prof Colin Rees
Consultant Gastroenterologist
South Tyneside NHS Foundation Trust
Harton Lane
Sout Shields
NE34 0PL

Email: hra.approval@nhs.

07 July 2017

Dear Professor Rees

Letter of HRA Approval for a study processed through pre-HRA Approval systems

Study title:	**Study Comparing Outcomes and Patient Experience Measures for GIEndoscopy (SCOPE-ME) - Patient Reported Experience Measure (PREM) development phase**
IRAS project ID:	**148469**
Sponsor	**South Tyneside NHS Foundation Trust**
Amendment number:	**Non Substantial Amendment 5**
Amendment date:	**6 June 2017**

Thank you for your request to bring the above referenced study, processed under pre-HRA Approval systems, under HRA Approval.

I am pleased to confirm that the study has been given **HRA Approval**. This has been issued on the basis of an existing assessment of regulatory compliance, which has confirmed that the study is compliant with the UK wide standards for research in the NHS.

The extension of HRA Approval to this study on this basis allows the sponsor and participating NHS organisations in England to set-up the study in accordance with HRA Approval processes, with decisions on study set-up being taken on the basis of capacity and capability alone.

Please note that the amendment submitted to bring this study under HRA Approval (referenced above) is also approved by issue of this letter. You should not expect anything further from the HRA regarding the amendment. If the submitted amendment included the addition of a new NHS organisation in England, the addition of the new NHS organisation is also approved and should be set up in accordance with HRA Approval processes (e.g. the organisation should be invited to assess and arrange its capacity and capability to deliver the study and confirm once it is ready to do so).

Participation of NHS Organisations in England

Please note that full information to enable set up of participating NHS organisations in England is not provided in this letter, on the basis that activities to set up these NHS organisations is likely to be underway already.

The sponsor should provide a copy of this letter, together with the local document package and a list of the documents provided, to participating NHS organisations in England that are being set up in accordance with HRA Approval Processes. It is for the sponsor to ensure that any documents provided to participating organisations are the current, approved documents.

For non-commercial studies the local document package provided to NHS organisations should include an appropriate Statement of Activities and HRA Schedule of Events. The sponsor should also provide the template agreement to be used in the study, where the sponsor is using an agreement in addition to the Statement of Activities. Participating NHS organisations in England should be aware that the Statement of Activities and Schedule of Events for this study have not been validated by the HRA, but the HRA expects that the sponsor provides these to participating NHS organisations. Any changes that are appropriate to the content of the Statement of Activities and Schedule of Events should be agreed in a pragmatic fashion as part of the process of assessing, arranging and confirming capacity and capability to deliver the study.

It is critical that you involve both the research management function (e.g. R&D office and, if the study is on the NIHR portfolio, the LCRN) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

If subsequent NHS organisations in England are added, an amendment should be submitted to the HRA.

After HRA Approval

In addition to the document, *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC Favourable Opinion, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval.

Scope

IRAS project ID	148469

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/.

Your IRAS project ID is 148469. Please quote this on all correspondence.

Yours sincerely

Isobel Lyle | Senior Assessor
Health Research Authority
Room 002, TEDCO Business Centre, Rolling Mill Rd, Jarrow NE32 3DT
T: 0207 972 2496
Hra.approval@nhs.net or Isobel.lyle@nhs.net
www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest

Copy to: *Dr Simon Dunn, Sponsor contact, South Tyneside NHS Foundation Trust*
Claire Livingstone, R&D contact, South Tyneside NHS Foundation Trust

Appendix D: Interview Topic Guide

SCOPE ME Interview Schedule

This interview schedule is intended to be a guide for the researcher conducting the interviews. Not all of the questions listed will be asked, and the order of the questions may vary; this will depend on the participants' responses.

Introduction

The purpose of this interview study is to explore your experience of gastrointestinal procedures, in order to develop a questionnaire which can be used to assess patient experience. To do this, I will ask you questions regarding your recent test. Please go into as much detail as you can, what you have to say is very valuable information.

The interview will last approximately 30 minutes. Everything you say is strictly confidential and anonymous, and you don't have to talk about anything that you find uncomfortable. This is not a test so there are no wrong answers, so please be as honest as you can. Remember, you are free to withdraw at any time and do not need to give a reason for withdrawal. A decision not to take part or to withdraw your consent will not affect any of your future treatments within the NHS.

Do you mind if I tape record our interview?

Are you happy to continue?

General Background

- Could you start off by telling me a little bit about yourself please?
- So to begin with, is this the first time you've had the test?
    - *Any previous endoscopies?*

The Procedural Experience

- Please can you tell me about your experience of the test? We're thinking about the process as a whole- from the time you were referred to the results. Tell me about the events and experiences which were important for you.

- Pre-test
    - *How did you come to be referred for the test?*
        - *Did you understand why you were having the test? Did you have a choice?*
    - *How did you feel about having the test?*
        - *Did you know what to expect? How long did you have to wait?*
        - *Did you have enough information about the test, pros and cons?*
    - *How did you get on with the preparation?*

        - *How did you get on when you arrived at the hospital to have your test?*
            - *Any problems with arriving at the hospital?*
            - *Was there anything that made waiting for your appointment easier or more difficult?*
                - *Eg appointment times, choice, availability*
            - *How did you feel about getting ready to have the test? Was there anything that made getting ready for the test easier or more difficult?*
                - *Did you need to do anything specific before the test? (eg change clothes, decide about sedation)*
                - *What are your views on the hospital facilities?*
    - During the test
        - *How did you feel while you were having the test?*
            - *How did the procedure go? Some people say they don't feel a thing, some say it's uncomfortable and some say it's painful to various degrees. What would you say?*
            - *Was there anything that made having the test easier or more difficult?*
            - *Did you have sedation? How did you decide on this? Choice?*
            - *Was there anything that stuck out about the various members of staff that you met during the process? How did the staff treat you?*
                - *If satisfied with staff, ask if there was anyone they were not impressed with or less impressed with*
    - After the test
        - *How did you feel immediately after having the test?*
            - *Was there anything that made the recovery process easier or more difficult?*
        - *How did you feel in the days following the test?*
            - *Was there anything that made the recovery process easier or more difficult?*
            - *Did you know what was going to happen next?*
        - *How do you feel now about having had the test?*
            - *How would you feel if you had to have the test again?*
        - *Were the test results explained to you? Have you received the results of your test?*

    - What advice would you give to someone having the test?

Summary

- What things do you think are important in making sure patients have a good experience of the process?
- What things do you think can make patients have a more difficult experience of the process?

- What part of the procedure were you most satisfied with?
- What part of the process did you find most difficult?

Closing the Interview

- Is there anything about your experience I haven't asked that you would like to talk about?

We will transcribe this interview and once all of the interviews we are conducting are transcribed, we will begin to analyse them. Any identifiable information about you (eg your name) will be kept separate from the data file so that you cannot be recognised from it. Any names that you have mentioned during the interview will also be changed in order to ensure anonymity and confidentiality. The results will be presented at medical conferences and published in academic journals. You will not be identified in any publication. Unless there is anything else you would like to add, I will turn the tape recorder off now.

Appendix E: Study Team

This appendix describes the members of the wider study team and their roles within this study (supervisory roles are not described in detail here):

- **Laura Neilson**, LN (student): Gastroenterology research fellow
  - *Contributed to methodological approach. Undertook qualitative interviews, qualitative analysis and focused literature review to identify initial topics. Generated initial question bank and led review and revision process within wider team. Worked with graphic designer to design questionnaire layout and appearance. Undertook cognitive interviews and analysis, with revision of questions and review with team where needed. Developed additional information sheets and led questionnaire phase. Cleaned questionnaire data and performed statistical analysis.*
- **Colin Rees**, CR (clinical supervisor): Professor of Gastroenterology/ Consultant Gastroenterologist
  - *Chief investigator. Devised idea and methodology. Oversaw all phases of project. Participated in review and revision of questions.*
- **Linda Sharp**, LS (academic supervisor): Professor of Cancer Epidemiology with an interest in patient experience measures and patient reported outcomes (LS)
  - *Contributed to methodological approach. Reviewed qualitative interview transcripts and supervised qualitative analysis. Advised on cognitive interviewing techniques, supervised analysis of cognitive interviews. Supervised statistical analysis.*
- **Joanne Patterson**, JP (academic supervisor): Clinical Academic Speech & Language Therapist and Clinical Lecturer with an interest in patient reported outcome and experience measures
  - *Contributed to methodological approach. Reviewed qualitative interview transcripts and supervised qualitative analysis. Advised on cognitive interviewing techniques, supervised analysis of cognitive interviews.*
- **Christian von Wagner**, CW: Reader in Behavioural Science in Health with an interest in the acceptability and patient experience of participation in colorectal cancer screening
  - *Participated in review and revision of questionnaire items*

- **Paul Hewitson**, PH: Senior Research Officer with an interest in the design and construction of questionnaires, development and evaluation of PROMs and PREMs
    - *Participated in review and revision of questionnaire items*
- **Lesley McGregor**, LM: Academic Psychologist with an interest in qualitative methodology and PREMs
    - *Advised on qualitative interview technique. Double coded three qualitative interview transcripts*

Appendix F: Pilot PREM

STUDY ID

Patient Questionnaire

EndoPREM:
Patient Reported Experience Measure for Gastrointestinal Endoscopy

Newcastle University
UK | Malaysia | Singapore

NREG
Northern Region Endoscopy Group

NHS
South Tyneside
NHS Foundation Trust

Thank you for agreeing to take part - we really appreciate you taking the time to complete this questionnaire about your experience of having an endoscopy (camera) test or CT scan.

Completing the survey

Please fill in this questionnaire for your most recent test. If you had two tests on the same day please fill in the questionnaire for the test you had first.

The survey will take about 10 - 15 minutes to complete. All of the questions are important so please try to answer them all. There are no right or wrong answers - we are just interested in hearing about your experience so we can make improvements to the way we deliver the service.

If you need help filling in the survey you can ask someone to help you.

Confidentiality

Everything you tell us will be kept strictly confidential. Your name is not on the questionnaire - instead there is a reference number and only the research team can identify you from this.

Questions

If you have any questions or would like more information about the study, please ring 0191 404 1000 and ask for:

Dr Sara Koo (research doctor) on 0191 404 1000, extension 2899

or

Mrs Madeleine McKee (research nurse) on 0191 404 1000, extension 2754

Before you start, please tick here to indicate that you are happy to take part in the study ○

The return of a completed questionnaire is confirmation of your consent to take part in the study and allows researchers to use personal information you provide in their research. This information will not be given to anyone outside of the study team. All data you provide to the researchers will be treated in the strictest confidence and will be stored in accordance with the Data Protection Act 1998.

Section A: Completing this survey

Please answer all of the questions in this section by writing in the boxes or putting a '✔' next to the answer that applies to you.

A1. Please fill in today's date d: ☐☐ m: ☐☐ y: ☐☐☐☐

A2. How long ago was your most recent test? Weeks:_____ Days:_____

A3. Please fill in your age (in years) ☐

A4. Are you? ❍ Male ❍ Female

A5. How many years of full time education have you completed? ☐

A6. To which of these ethnic groups would you say you belong?

White
(Including English/Welsh/Scottish, Northern Irish, British, Irish, Gypsy or Irish Traveller or any other White background) ❍

Mixed/Multiple ethnic groups
(Including White and Black Caribbean, White and Black African, White and Asian or any other mixed/multiple ethnic background) ❍

Asian/British Asian
(Including Indian, Pakistani, Bangladeshi, Chinese or any other Asian background) ❍

Black/African/Caribbean/Black British
(Including Black African, Black Caribbean or any other Black/African/Caribbean background) ❍

Other ethnic group ❍

A7. Please tell us if someone is helping you complete this survey

I am completing this survey by myself ❍

Someone is helping me complete the survey ❍

A8. Which test did you have on this occasion?

Colonoscopy
(Camera or tube inserted through the back passage) ◯

Gastroscopy
(Camera or tube inserted through the mouth into the stomach) ◯

Transnasal Gastroscopy
(Camera or tube inserted through the nose into the stomach) ◯

CT Colonoscopy/pneumocolon
(CT scan where a short tube is inserted into the back passage - done in the x-ray department) ◯

I'm not sure ◯

A9. Have you had another camera test or CT scan in the past?

Yes ◯ No ◯

Including your most recent test, please indicate which tests and how many you have had

Colonoscopy
(Camera or tube inserted through the back passage) ◯ Number ____

Gastroscopy
(Camera or tube inserted through the mouth into the stomach) ◯ Number ____

Transnasal Gastroscopy
(Camera/tube inserted through the nose into the stomach) ◯ Number ____

CT Colonoscopy/pneumocolon
(CT scan where a short tube is inserted into the back passage - done in the x-ray department) ◯ Number ____

Flexible Sigmoidoscopy
(Camera inserted through the back passage into the last part of the bowel only - usually only requires an enema) ◯ Number ____

A10. How were you referred for your most recent test?

I was referred directly by my GP (without seeing a hospital doctor) ◯

The test was organised by a hospital doctor ◯

I have regular tests to monitor a medical condition ◯

I have regular tests because of my family history ◯

I was referred in another way (please tell us more in the box below) ◯

Section B: Before coming to hospital for your test

In this section we want to find out about the time leading up to your test, before you came to hospital. Please answer all of the questions in this section by putting a '✔' next to the answer that applies to you.

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
B1.	I was happy with the way I was referred for the test	❍	❍	❍	❍	❍
B2.	The time from first being referred to having the test done was satisfactory	❍	❍	❍	❍	❍
B3.	I felt able to change the appointment if it didn't suit me	❍	❍	❍	❍	❍

B4. My appointment was cancelled or changed by the hospital

Yes ❍ No ❍ Not sure / can't remember ❍

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
B5.	Before coming for the test, I was given enough information about what the test would involve	❍	❍	❍	❍	❍
B6.	The information I received before the test was easy to understand	❍	❍	❍	❍	❍
B7.	After reading the information, I did not have any questions about the test	❍	❍	❍	❍	❍

Before coming for the test:	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
B8. The instructions on what I needed to do before the test were easy to follow	❍	❍	❍	❍	❍
B9. I had enough time to discuss the test with the person who referred me	❍	❍	❍	❍	❍
B10. I felt anxious about what the test would involve	❍	❍	❍	❍	❍
B11. I was made anxious by talking to other people who had previously had the test	❍	❍	❍	❍	❍

Before coming for the test:	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
B12. I felt anxious about the results of the test	❍	❍	❍	❍	❍
B13. I expected the test to be uncomfortable	❍	❍	❍	❍	❍
B14. I expected the test to be painful	❍	❍	❍	❍	❍
B15. I was worried that inserting the tube/camera would be uncomfortable	❍	❍	❍	❍	❍
B16. I hoped the person doing the test would be the same sex as me	❍	❍	❍	❍	❍

Section C: Preparing for your test

Please **ONLY** answer the questions in this section if you had a colonoscopy or CT colonoscopy/ pneumocolon by putting a '✔' next to the answer that applies to you.

If you had a different test, please go to Section D on the next page

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
C1.	The bowel preparation had an unpleasant taste	❍	❍	❍	❍	❍
C2.	The bowel preparation tasted better than I expected	❍	❍	❍	❍	❍
C3.	The volume *(amount)* of the bowel preparation was more than I expected	❍	❍	❍	❍	❍
C4.	The amount of bowel preparation I had to drink was manageable	❍	❍	❍	❍	❍
C5.	I was worried that the bowel preparation would not clear my bowel properly	❍	❍	❍	❍	❍
C6.	I had enough privacy when getting ready for the test *(eg when changing clothes)*	❍	❍	❍	❍	❍

Please go to section D

Section D: At the hospital, before the test

In this section we would like to know about your experience of arriving at the hospital, getting ready and waiting for the test. Please complete ALL of the remaining sections of this survey, regardless of what test you had by putting a '✔' next to the answer that applies to you.

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
D1.	I waited longer in the department than I expected	❍	❍	❍	❍	❍
D2.	I was comfortable while sitting in the waiting area	❍	❍	❍	❍	❍
D3.	I felt able to ask the staff any questions before the test	❍	❍	❍	❍	❍
D4.	I had no unanswered questions before the test	❍	❍	❍	❍	❍
D5.	I had enough privacy when waiting for the test	❍	❍	❍	❍	❍

Section E: During the test

In this section we would like to know about your experience of the test, from arriving in the procedure room until it was time to leave the procedure room. Please answer by putting a '✔' next to the answer that applies to you.

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
E1.	During the test my dignity was maintained at all times	❍	❍	❍	❍	❍
E2.	I felt free to choose what medication to take *(eg throat spray, sedative, no medication)*	❍	❍	❍	❍	❍
E3.	The medication *(eg throat spray, sedative)* worked as well as I expected	❍	❍	❍	❍	❍
		I did not have any medication ❍				

E4. The person doing the test *(inserting the tube or camera)* was:

Male ❍ Female ❍

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
E5.	I felt confident that the person doing the test knew what they were doing	❍	❍	❍	❍	❍
E6.	The person doing the test did their best to put me at ease	❍	❍	❍	❍	❍

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
E7.	The other staff in the test room did their best to put me at ease	❍	❍	❍	❍	❍
E8.	I was satisfied with the explanation given to me about the test	❍	❍	❍	❍	❍
E9.	The person doing the test addressed any concerns I had	❍	❍	❍	❍	❍
E10.	I felt I could stop the test if it became too uncomfortable	❍	❍	❍	❍	❍
E11.	I felt embarrassed during the test	❍	❍	❍	❍	❍
E12.	The test took longer than I expected	❍	❍	❍	❍	❍

E13. How would you rate the level of discomfort you experienced during the test?

Please mark a cross (x) on the line below:

No discomfort _____ Worst discomfort imaginable

0 1 2 3 4 5 6 7 8 9 10

E14. How long did the discomfort last during the test?

I didn't have discomfort ❍ A short time ❍ A moderate time ❍ A long time ❍

E15. How many times did you experience discomfort during the test?

None ❍ 1 or 2 times ❍ 3 or 4 times ❍ More than 4 ❍ Constantly ❍

Section E: During the test *continued...*

E16. How would you rate the level of pain you experienced during the test?

Please mark a cross (x) on the line below:

No pain ——————————————— Worst pain imaginable

0 1 2 3 4 5 6 7 8 9 10

E17. How long did the pain last during the test?

I didn't have pain	A short time	A moderate time	A long time
❍	❍	❍	❍

E18. How many times did you experience pain during the test?

None	1 or 2 times	3 or 4 times	More than 4 times	Constantly
❍	❍	❍	❍	❍

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
E19. Overall, the test was more uncomfortable than I expected	❍	❍	❍	❍	❍
E20. Overall, the test was more painful than I expected	❍	❍	❍	❍	❍
E21. I felt embarrassed by the discomfort I experienced	❍	❍	❍	❍	❍
E22. I felt embarrassed by the pain I experienced	❍	❍	❍	❍	❍

Section F: After the test

In this section we would like to know about your experience after the test including the results, if you've had them. Please answer by putting a '✔' next to the answer that applies to you.

After the test:		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
F1.	I was satisfied by the explanation given to me by the person doing the test	❍	❍	❍	❍	❍
F2.	I was pleased with the refreshments offered	❍	❍	❍	❍	❍
		I was not offered refreshments ❍				
F3.	I had discomfort **before** I left the hospital/clinic	❍	❍	❍	❍	❍
F4.	I had discomfort **after** I left the hospital/clinic *(eg when I got home)*	❍	❍	❍	❍	❍
F5.	It took longer than I expected to recover from the test	❍	❍	❍	❍	❍
F6.	I was worried about the test results	❍	❍	❍	❍	❍

Section F: After the test *continued...*

F7. How did you receive the results of your test? *(Please tick all that apply)*

- I do not have my results ❍
- I was told some results but have to wait for a biopsy/tissue sample ❍
- I was told all of the results before I left the hospital ❍
- The results were posted to me ❍
- I received a written copy of all of the results before I left the hospital ❍
- I received a written copy of some of the results before I left the hospital but have to wait for a biopsy/tissue sample ❍
- I received my results in a different way ❍
  (If so, please tell us how in the box below)

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	
F8. When I left the hospital, I was unsure of how I would get the results of my test	❍	❍	❍	❍	❍	*I already had my results* ❍
F9. I was happy with the way I received the results of my test	❍	❍	❍	❍	❍	*I do not have my results* ❍
F10. I received the results of my test sooner than I expected	❍	❍	❍	❍	❍	*I do not have my results* ❍
F11. I know what the next steps are going to be *(eg clinic appointment, medication change, discharge)*	❍	❍	❍	❍	❍	

Section G: Overall experience

In this section we would like to know how you feel now about your overall experience. Please answer by putting a '✔' next to the answer that applies to you.

After the test:	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
G1. Overall I was satisfied with my experience of the test	❍	❍	❍	❍	❍
G2. Overall the experience was better than I expected	❍	❍	❍	❍	❍

G3. If there is something else you would like to tell us about your test, please use the space below.

Section H: How you are feeling this week

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you OVER THE PAST WEEK. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:
0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1.	I found it hard to wind down	0	1	2	3
2.	I was aware of dryness of my mouth	0	1	2	3
3.	I couldn't seem to experience any positive feeling at all	0	1	2	3
4.	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5.	I found it difficult to work up the initiative to do things	0	1	2	3
6.	I tended to over-react to situations	0	1	2	3
7.	I experienced trembling (e.g. in the hands)	0	1	2	3
8.	I felt that I was using a lot of nervous energy	0	1	2	3
9.	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10.	I felt that I had nothing to look forward to	0	1	2	3
11.	I found myself getting agitated	0	1	2	3
12.	I found it difficult to relax	0	1	2	3
13.	I felt down-hearted and blue	0	1	2	3
14.	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15.	I felt I was close to panic	0	1	2	3
16.	I was unable to become enthusiastic about anything	0	1	2	3
17.	I felt I wasn't worth much as a person	0	1	2	3
18.	I felt that I was rather touchy	0	1	2	3
19.	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20.	I felt scared without any good reason	0	1	2	3
21.	I felt that life was meaningless	0	1	2	3

Section I: Your health today

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ○
- I have slight problems in walking about ○
- I have moderate problems in walking about ○
- I have severe problems in walking about ○
- I am unable to walk about ○

SELF-CARE

- I have no problems washing or dressing myself ○
- I have slight problems washing or dressing myself ○
- I have moderate problems washing or dressing myself ○
- I have severe problems washing or dressing myself ○
- I am unable to wash or dress myself ○

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ○
- I have slight problems doing my usual activities ○
- I have moderate problems doing my usual activities ○
- I have severe problems doing my usual activities ○
- I am unable to do my usual activities ○

PAIN / DISCOMFORT

- I have no pain or discomfort ○
- I have slight pain or discomfort ○
- I have moderate pain or discomfort ○
- I have severe pain or discomfort ○
- I have extreme pain or discomfort ○

ANXIETY / DEPRESSION

- I am not anxious or depressed ○
- I am slightly anxious or depressed ○
- I am moderately anxious or depressed ○
- I am severely anxious or depressed ○
- I am extremely anxious or depressed ○

Section I: *continued...*

We would like to know how good or bad your health is TODAY.

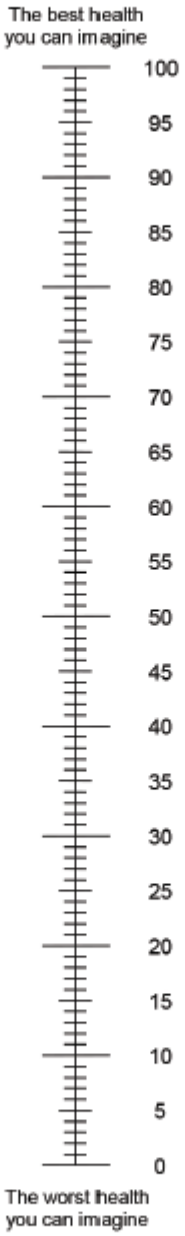
This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Please return the survey by post using the envelope provided within two weeks

Thank you for taking the time to complete this survey

This questionnaire was developed by Laura Neilson, Colin Rees, Linda Sharp, Joanne Patterson, Christian Von Wagner and Paul Hewitson in collaboration with South Tyneside NHS Foundation Trust and Newcastle University.

Appendix G : Pilot questionnaire participant information sheet

choose

South Tyneside NHS
NHS Foundation Trust

Patient Experience Research Project: Patient Information Sheet

Study Comparing Outcomes and Patient Experience Measures for GI Endoscopy (SCOPE-ME) – Patient Reported Experience Measure (PREM) Development Phase

Pilot PREM Questionnaire

Chief investigator – Professor Colin Rees

We would like to invite you to take part in a research study. Before you decide if you want to take part, we would like you to understand why the research is being done and what it would involve for you. Please take some time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of this sheet will explain about the study and what will happen to you if you take part.

Part 2 of this sheet will give more detailed information about the way the study will be conducted.

Please ask us if there is anything that is not clear, or you would like more information. Take time to decide if you wish to take part.

Part 1

What is the purpose of this study?

Many people will need to have an endoscopy procedure or an examination of their bowel at some point in their lives. Doctors know a lot about the technical aspects of these procedures, and we know how accurate the tests are at detecting abnormalities. We know less about the experience of having the test from the patient perspective. We feel that this should be better understood, and changes made to the tests if necessary to improve patient experience. There are some tools being used to assess experience of endoscopy and X ray tests, but these have all been developed by healthcare

professionals rather than with direct input from patients. We aim to develop a new tool to properly understand how patients find these tests.

More of the scientific background to this is given in part 2 – "background to the study".

Do I have to take part?

It is up to you to decide to take part. This information sheet describes the study. If you are willing to take part, we ask you to return the pilot questionnaire within two weeks. You can decide not to take part, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

This pack includes: this information leaflet, a pilot questionnaire form, and a pre-paid return envelope. The pilot questionnaire has been developed by the research team at South Tyneside hospital as a way of assessing your experience of endoscopy and X ray tests of the bowel. We developed this questionnaire after holding discussion groups and interviews with patients who have experienced the tests before, and asked them to tell us which aspects of the test were important to how they felt about the test. We now need to test the questionnaire by sending it to a large number of people undergoing the tests and getting them to fill in the questionnaire. The questionnaire includes questions about the test you have had done, as well as some questions about you, and questions about how easy it was to complete. The whole pack should take less than 10-15 minutes to complete. We ask you to complete it within two weeks of your test – we will post a reminder to you after two weeks. Once you have completed the questionnaire, please return it to us in the pre-paid envelope.

Once we have received your questionnaire we will collect anonymous information about your procedure and demographics. We will not collect information which could be used to identify you. The results of the questionnaires will be collected together, anonymised, and sent to a research team at Oxford University who will analyse the results to make sure the questionnaire is effective.

Any comments you make in the questionnaire will be confidential and will not affect the way your doctor cares for you. This questionnaire is in addition to your usual clinic appointments; it does not replace any of your other appointments.

Expenses and payments

We have provided a pre-paid return envelope for you to send the questionnaire back to us. We are not offering any other payment for taking part.

What are the possible disadvantages and risks of taking part?

In the unlikely event that the process of completing the questionnaire causes you any distress, then appropriate procedures for support will be available through your GP or the hospital doctor who you see in clinic. There are also contact details for the research team at the end of this form.

There are not expected to be any risks or side effects of taking part.

What are the possible benefits of taking part?

This study gives you an opportunity to tell us your experiences of coming for an endoscopy or X ray test. The results of the study will not make any difference to your current care, but may help us to improve the way in which we deliver the tests in the future. We will be able to more accurately assess the experience of the test.

What happens when the research study stops?

The care you receive from the hospital will not change. After you have taken part in the study, you will continue to have follow up with your consultant as previously arranged.

What if there is a problem?

Any complaint about the way you have been dealt with during the study, or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. More details are included in Part 2.

This completes Part 1. If the information on Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.

Part 2

Background to the study

Examinations of the stomach and bowel are widely performed with around 1.5 million procedures per year in the UK. The lifetime chance of requiring one of these tests is now greater than 1 in 3. We know that consistent high quality is essential to ensure that procedures are safe and that abnormalities are not missed. A positive experience of the test is important to ensure patients attend for their tests and any further tests that may be required in the future. At present all the tools (such as questionnaires) used to assess patient experience of these tests are written by healthcare professionals. Recent research has shown that there is a large variation between what doctors and nurses think is important to patients during these tests and what patients themselves think is important. It is increasingly recognized that designing questionnaires based on patients' experiences rather than healthcare professionals' perceptions leads to better quality tools to assess the experience.

We currently look at the upper part of the gastrointestinal tract (food pipe and stomach) using either a camera test through the mouth or a thinner camera passed through the nose. The lower bowel is examined either using a flexible camera passed through the anus or using a CT scan after clearing the bowel with laxative medication. The aim of this study is to evaluate a tool that assesses patient experience of these tests.

What if relevant new information becomes available?

If new information answering the questions we are asking becomes available during the study, then we will decide if we need to proceed with our study. If we decide to stop the study, we will let you know. Any information we have gathered up to that point may still be used.

What will happen if I don't want to carry on with the study?

You do not have to complete the questionnaire or return it to us.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details are at the end of this leaflet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against South Tyneside NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms (through the Patient Advice and Liaison Service (PALS), details of which are at the end of this leaflet) will still be available to you.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential, and no information about you that has your name or address will leave the hospital so that you cannot be recognised. Records will not be publicly available.

What will happen to the results of the research study?

The intention is for the results to be published in a medical journal. You will not be able to be identified from these results. We hope the questionnaire tool that we have developed, and evaluated in this study will help assess patient experience in future endoscopy studies.

Who is organizing and funding the research?

The sponsor is South Tyneside NHS Foundation Trust. The organising doctor is Professor Colin Rees.

Who has reviewed the study?

This research has been looked at by independent group of people, the London Stanmore Research Ethics Committee. This is to protect your safety, rights, wellbeing and dignity.

For further information please contact one of the study team:

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Harton Lane

South Shields

NE34 0PL

Other contacts:

Patient Advice and Liaison Service (PALS) – 0191 404 1073

Consultant secretaries:

Professor Colin Rees and Dr Jo Topping 0191 404 1000 ext 4028

Dr Simon Panter and Dr Faheem Butt 0191 404 1000 ext 4035

Dr Oliver Schulte 0191 404 1000 ext 3187

Appendix H: Additional information data collection

South Tyneside NHS
NHS Foundation Trust

SCOPE-ME Pilot Questionnaire Phase Outcome Information

The following questionnaires have now been returned. Please fill in the missing data from the patient record/ recruitment log and send back to the research team at South Tyneside (key below). Boxes with a * will be completed by the South Tyneside Research Team. Please do not enter any patient identifiable data on this form.

1. QUESTIONNAIRE ID NUMBER*	2. DATE QUESTIONNAIRE GIVEN	3. DATE RETURNED*	4. DATE REMINDER SENT	5. PROCEDURE UNDERTAKEN	6. PRIMARY INDICATION	7. MEDICATION GIVEN (Excluding Buscopan)	8. PRIMARY DIAGNOSIS	9. ENDOSCOPIST GRADE	10. COMPLICATIONS

Outcome Information Key

Procedure Undertaken

1	OGD
2	Transnasal endoscopy
3	Colonoscopy
4	CT Pneumocolon/ CT Colonoscopy

Indication

OGD and TNE		Colonoscopy and CTC	
1	Dysphagia	20	Diarrhoea (looser stools/ more frequent)
2	Weight loss	21	Constipation
3	Dyspepsia (inc heartburn, reflux, epigastric pain)	22	Rectal bleeding
4	Persistent nausea/vomiting	23	Iron deficiency anaemia
5	Upper abdominal mass	24	Family history of colorectal cancer
6	Iron deficiency anaemia	25	Polyp surveillance
7	Abnormal imaging	26	Abdominal pain
8	Confirm ulcer healing	27	Abnormal imaging
9	Coeliac disease diagnosis/ Positive TTG or anti EMA	28	IBD assessment/ surveillance
10	Barrett's surveillance	29	Surveillance after colorectal cancer resection
11	Varices surveillance	30	Planned polypectomy
12	Suspected GI bleeding	31	Planned stricture dilatation
13	Oesophageal dilatation	32	Other
14	Other		

Medication given (excluding buscopan)

1	Midazolam only
2	Midazolam and Pethidine/Fentanyl
3	Midazolam, Pethidine/Fentanyl and Entonox
4	Pethidine/Fentanyl only
5	Pethidine/Fentanyl and Entonox
6	Midazolam and Entonox
7	Entonox only
8	No medication
9	Other analgesia/sedative

Primary Diagnosis (main diagnosis)

OGD and TNE		Colonoscopy and CTC	
1	Normal	20	Normal
2	Upper GI Cancer	21	Lower GI Cancer
3	Polyp(s)	22	Polyp(s)
4	Oesophagitis/ Gastritis/ Duodenitis	23	Diverticular disease
5	Peptic Ulcer (any site)	24	Inflammatory Bowel Disease
6	Varices	25	Angiodysplasia
7	Other	26	Other

Endoscopist Grade

1	Consultant Surgeon
2	Consultant Gastroenterologist
3	Trainee (supervised)
4	Trainee (unsupervised)
5	Staff Grade/ Associate Specialist (supervised)
6	Staff Grade/ Associate Specialist (unsupervised)
7	Nurse endoscopist (supervised)
8	Nurse endoscopist (unsupervised)
9	Other
10	CTC so no endoscopist

Complications

1	Bleeding requiring admission/transfusion
2	Perforation
3	Hospital admission
4	Reversal of sedation
5	No complication

Appendix I: Pain and discomfort review

For patients undergoing colonoscopy, some described pain or discomfort at very distinct stages of the procedure, for example, when the camera was '*going round a bend'* or inserting the camera. Others felt the whole procedure was painful or uncomfortable and others felt no pain or discomfort. For CTC patients who experienced pain or discomfort, the majority did not associate this with a specific stage of the procedure. Two patients attributed their discomfort to air being inserted. There was variation in OGD patient's description of discomfort. Some felt that insertion of the camera was the most uncomfortable part, whereas others described general discomfort. Compared to the CTC and colonoscopy groups, these patients tended to use the words 'uncomfortable' or 'discomfort' rather than pain. Some participants described nausea and retching as contributing to their discomfort. One participant described a difference between pain and discomfort:

> "*When I say it wasn't painful, it wasn't as though somebody was sticking a knife in you, it was just uncomfortable*." G4

Following review of the qualitative data, a focused literature review was conducted to identify descriptions of pain and discomfort and the potential differences between the two. Jensen et al (1986) compared six different methods of measuring the intensity of clinical pain in patients with chronic pain. The study found similar performance of visual analogue scales (VAS), numerical rating scales (NRS), verbal rating scales (VRS), behaviour rating scales (BRS) and box scales. A more recent systematic review concluded that NRS tended to have high compliance rates and were easy to use compared to VRS and VAS, but corresponded well with VAS scores (Hjermstad *et al.*, 2011). Various tools to measure pain and discomfort already exist, for example, the McGill Pain Questionnaire. This is a multidimensional tool which assesses pain using different scales and descriptors, however, the language and detail within this tool did not reflect the experience detailed in our qualitative analysis (Melzack, 1975).

Specific to GI procedures, a four point Likert scale was developed in the UK to enable nursing assessment of patient discomfort during colonoscopy using four descriptors: no discomfort, mild discomfort, moderate discomfort and severe

discomfort (Rostom et al, 2013). This score correlated moderately well with the patient's recalled comfort score on discharge. A Norwegian group designed a post-procedure questionnaire for colonoscopy, asking patients if the examination was painful, in addition to whether 'colicky' pain or other discomfort was experienced during the procedure (Hoff *et al.*, 2006). A four-point VRS was used, in addition to a similar question format asking how long the pain or discomfort lasted. This was validated in the screening colonoscopy population and later used in observational studies (Bugajski *et al.*, 2018). A different approach using a 100mm VAS assessed real-time insertion pain during colonoscopy when comparing water exchange colonoscopy with water immersion (Cadoni *et al.*, 2015). This score significantly correlated with patient-reported recalled pain using the same tool on discharge from the endoscopy unit. Similar VAS tools have been used to assess discomfort in patients undergoing OGD, colonoscopy and CTC (Bretthauer et al., 2002; Cheung et al., 2008; De Silva et al., 2009). In the United Kingdom and Ireland, it is recommended that the modified Gloucester comfort score is used to assess patient discomfort (NHS Bowel Cancer Screening Programme, 2011; Conjoined Board in Ireland of the Royal College of Physicians and Royal College of Surgeons, 2016). This non-validated tool consists of a 5-point scale with descriptors including: 1= no discomfort, 2=minimal discomfort, 3= mild discomfort, 4= moderate discomfort, 5= severe discomfort (Ekkelenkamp et al, 2011). Other studies report using similar Likert-style response options to the Gloucester comfort score (Bretthauer et al, 2016; Ngu et al, 2019). Ngu et al, 2019, broke down discomfort according to intensity, number of episodes, length of each episode and at specific time points in the procedure, using Likert style responses. This study assessed the use of a device placed on the end of the colonoscope and specifically asked patients about camera insertion to determine whether use of the device increased the discomfort of colonoscope insertion. Those with the device found insertion more uncomfortable, whereas all other comfort domains were comparable (Ngu et al, 2019). The majority of these studies used the terminology 'discomfort' rather than 'pain.'

Appendix J: Initial questions addressing comfort

E15. Overall, the test was more uncomfortable than I had expected

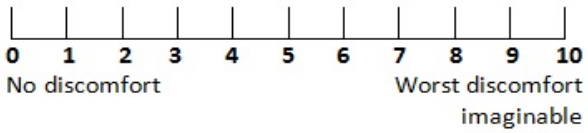
Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree ☐

E16. Overall, the test was more painful than I had expected

Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree ☐

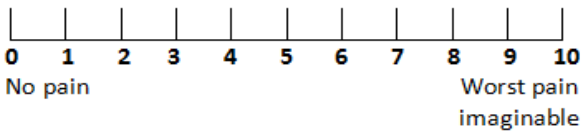
E17. How would you rate the <u>overall</u> level of discomfort you experienced during the test?

Please mark a cross (×) on the line below:



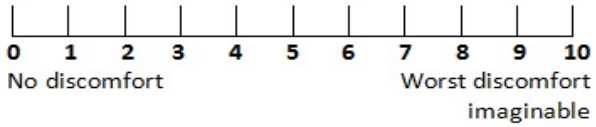
E18. How would you rate the <u>overall</u> level of pain you experienced during the test?

Please mark a cross (×) on the line below:



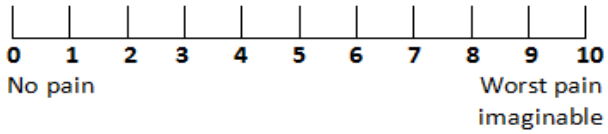
E19. <u>At its worst,</u> how would you rate the intensity of discomfort you experienced during the test?

Please mark a cross (×) on the line below:



E20. <u>At its worst,</u> how would you rate the intensity of pain you experienced during the test?

Please mark a cross (×) on the line below:



E21. How many times did you experience discomfort during the test?

None ☐ 1 or 2 times ☐ 3 or 4 times ☐ More than 4 times ☐ Constantly ☐

E22. How many times did you experience pain during the test?

None ☐ 1 or 2 times ☐ 3 or 4 times ☐ More than 4 times ☐ Constantly ☐

E23. <u>At its worst</u>, how long did the discomfort last during the test?

I didn't have discomfort ☐ A short time ☐ A moderate time ☐ A long time ☐

E24. <u>At its worst</u>, how long did the pain last during the test?

I didn't have pain ☐ A short time ☐ A moderate time ☐ A long time ☐

E25. <u>Overall</u>, how long did the discomfort last during the test?

I didn't have discomfort ☐ A short time ☐ A moderate time ☐ A long time ☐

E26. <u>Overall</u>, how long did the pain last during the test?

I didn't have pain ☐ A short time ☐ A moderate time ☐ A long time ☐

Appendix K: Inter-item correlations

	B1	B2	B3	B5	B6	B7	B8	B9	B10	B11	B12	B13	B15	B16
B1	**1.000**	0.634	0.409	0.510	0.491	0.428	0.479	0.495	0.057	0.072	-0.016	-0.046	0.016	0.074
B2	0.634	**1.000**	0.359	0.475	0.464	0.338	0.428	0.409	0.049	0.075	0.002	-0.042	0.007	0.054
B3	0.409	0.359	**1.000**	0.281	0.299	0.277	0.335	0.353	0.065	0.071	0.065	0.038	0.052	0.070
B5	0.510	0.475	0.281	**1.000**	**0.825**	0.645	0.660	0.531	0.205	0.133	0.072	-0.069	0.029	0.073
B6	0.491	0.464	0.299	0.825	**1.000**	0.669	0.772	0.513	0.177	0.115	0.071	-0.061	0.047	0.060
B7	0.428	0.338	0.277	0.645	0.669	**1.000**	0.584	0.543	0.180	0.153	0.065	-0.021	0.048	0.045
B8	0.479	0.428	0.335	0.660	0.772	0.584	**1.000**	0.555	0.186	0.125	0.101	-0.036	0.020	0.064
B9	0.495	0.409	0.353	0.531	0.513	0.543	0.555	**1.000**	0.168	0.070	0.069	0.035	0.046	0.059
B10	0.057	0.049	0.065	0.205	0.177	0.180	0.186	0.168	**1.000**	0.522	0.519	0.345	0.532	0.258
B11	0.072	0.075	0.071	0.133	0.115	0.153	0.125	0.070	0.522	**1.000**	0.353	0.154	0.345	0.223
B12	-0.016	0.002	0.065	0.072	0.071	0.065	0.101	0.069	0.519	0.353	**1.000**	0.338	0.443	0.232
B13	-0.046	-0.042	0.038	-0.069	-0.061	-0.021	-0.036	0.035	0.345	0.154	0.338	**1.000**	0.547	0.133
B15	0.016	0.007	0.052	0.029	0.047	0.048	0.020	0.046	0.532	0.345	0.443	0.547	**1.000**	0.268
B16	0.074	0.054	0.070	0.073	0.060	0.045	0.064	0.059	0.258	0.223	0.232	0.133	0.268	**1.000**
D1	0.116	0.129	0.119	0.090	0.097	0.089	0.108	0.017	0.070	0.100	0.078	0.087	0.138	0.092
D2	0.188	0.192	0.210	0.241	0.256	0.164	0.268	0.167	0.136	0.133	0.127	0.077	0.082	0.107
D3	0.341	0.308	0.297	0.386	0.386	0.273	0.381	0.295	0.117	0.099	0.040	-0.056	-0.013	0.078
D4	0.317	0.262	0.259	0.369	0.351	0.314	0.368	0.246	0.103	0.098	0.056	-0.040	0.029	0.082
D5	0.288	0.247	0.265	0.331	0.331	0.245	0.380	0.248	0.152	0.074	0.087	0.002	0.075	0.066
E1	0.404	0.338	0.254	0.490	0.480	0.350	0.457	0.309	0.057	0.036	0.005	-0.098	-0.029	0.086
E2	0.334	0.309	0.304	0.446	0.432	0.291	0.385	0.257	0.077	0.042	0.017	-0.100	-0.040	0.128

Continued from page 223 (Inter-item correlations)

	D1	D2	D3	D4	D5	E1	E2	E3	E5	E6	E7	E8	E9	E10
B1	0.116	0.188	0.341	0.317	0.288	0.404	0.334	0.165	0.377	0.372	0.424	0.410	0.425	0.331
B2	0.129	0.192	0.308	0.262	0.247	0.338	0.309	0.158	0.316	0.318	0.386	0.359	0.386	0.282
B3	0.119	0.210	0.297	0.259	0.265	0.254	0.304	0.140	0.227	0.233	0.302	0.284	0.311	0.274
B5	0.090	0.241	0.386	0.369	0.331	0.490	0.446	0.226	0.447	0.449	0.497	0.526	0.452	0.348
B6	0.097	0.256	0.386	0.351	0.331	0.480	0.432	0.217	0.441	0.396	0.462	0.522	0.423	0.318
B7	0.089	0.164	0.273	0.314	0.245	0.350	0.291	0.188	0.303	0.333	0.325	0.395	0.334	0.259
B8	0.108	0.268	0.381	0.368	0.380	0.457	0.385	0.201	0.427	0.408	0.433	0.532	0.435	0.269
B9	0.017	0.167	0.295	0.246	0.248	0.309	0.257	0.160	0.272	0.292	0.333	0.363	0.336	0.293
B10	0.070	0.136	0.117	0.103	0.152	0.057	0.077	0.176	0.032	0.080	0.088	0.128	0.071	0.121
B11	0.100	0.133	0.099	0.098	0.074	0.036	0.042	0.094	0.020	0.021	0.026	0.063	0.012	0.043
B12	0.078	0.127	0.040	0.056	0.087	0.005	0.017	0.078	-0.028	0.009	-0.014	0.029	0.044	0.037
B13	0.087	0.077	-0.056	-0.040	0.002	-0.098	-0.100	0.051	-0.069	-0.033	-0.097	-0.066	-0.037	0.003
B15	0.138	0.082	-0.013	0.029	0.075	-0.029	-0.040	0.144	-0.001	0.015	0.004	0.039	0.023	0.095
B16	0.092	0.107	0.078	0.082	0.066	0.086	0.128	0.067	0.116	0.059	0.094	0.105	0.090	0.023
D1	**1.000**	0.259	0.171	0.138	0.266	0.109	0.050	0.094	0.096	0.134	0.076	0.106	0.141	0.092
D2	0.259	**1.000**	0.472	0.469	0.530	0.267	0.262	0.122	0.230	0.205	0.258	0.281	0.265	0.253
D3	0.171	0.472	**1.000**	0.677	0.619	0.502	0.458	0.172	0.412	0.362	0.488	0.490	0.448	0.379
D4	0.138	0.469	0.677	**1.000**	0.567	0.478	0.409	0.125	0.370	0.357	0.434	0.461	0.436	0.305
D5	0.266	0.530	0.619	0.567	**1.000**	0.410	0.403	0.169	0.341	0.321	0.379	0.384	0.429	0.350
E1	0.109	0.267	0.502	0.478	0.410	**1.000**	0.591	0.256	0.613	0.566	0.662	0.589	0.560	0.422
E2	0.050	0.262	0.458	0.409	0.403	0.591	**1.000**	0.163	0.451	0.414	0.567	0.496	0.445	0.352

Continued from page 224 (Inter-item correlations)

	E12	E14	E15	E19	E21	F1	F2	F3	F4	F5	F6	F8	F9	F10	F11
B1	0.119	0.042	0.039	0.105	0.107	0.390	0.126	0.118	0.115	0.154	0.048	0.021	0.059	0.002	0.247
B2	0.076	0.047	0.072	0.154	0.116	0.305	0.114	0.092	0.090	0.103	0.038	0.002	0.024	-0.002	0.209
B3	0.119	0.014	0.027	0.059	0.081	0.279	0.104	0.101	0.155	0.144	0.053	0.007	0.038	0.025	0.163
B5	0.146	0.054	0.025	0.146	0.167	0.462	0.157	0.080	0.099	0.092	0.088	0.035	0.031	0.007	0.205
B6	0.168	0.047	0.016	0.129	0.123	0.428	0.146	0.094	0.098	0.126	0.131	0.069	0.050	0.009	0.231
B7	0.135	0.034	0.039	0.130	0.091	0.379	0.165	0.079	0.080	0.107	0.070	0.043	0.080	0.040	0.208
B8	0.156	0.039	0.053	0.120	0.161	0.438	0.205	0.142	0.154	0.135	0.115	0.054	0.036	0.021	0.248
B9	0.170	0.115	0.111	0.135	0.051	0.338	0.194	0.196	0.168	0.129	0.076	0.048	0.055	0.036	0.191
B10	0.153	0.127	0.118	0.167	0.172	0.095	0.097	0.045	0.100	0.084	0.382	0.015	0.074	-0.003	0.069
B11	0.098	0.013	0.007	0.111	0.101	0.070	0.109	-0.010	0.015	0.034	0.262	0.011	0.156	0.104	0.056
B12	0.160	0.128	0.139	0.151	0.136	0.003	0.071	0.019	0.078	0.030	0.567	0.009	0.056	-0.001	0.064
B13	0.107	0.258	0.279	0.173	0.096	-0.033	-0.036	0.063	0.130	0.061	0.202	-0.016	-0.007	-0.048	0.037
B15	0.136	0.241	0.281	0.240	0.162	-0.023	0.005	0.067	0.096	0.071	0.284	0.005	0.051	-0.001	0.004
B16	0.170	0.087	0.066	0.125	0.220	0.049	0.199	0.148	0.167	0.116	0.206	0.070	-0.030	-0.048	0.106
D1	0.099	0.147	0.116	0.155	0.106	0.134	-0.091	0.071	0.124	0.139	0.072	0.035	0.053	0.008	0.070
D2	0.203	0.121	0.112	0.146	0.254	0.251	-0.013	0.152	0.168	0.175	0.188	0.079	0.043	0.031	0.209
D3	0.171	0.101	0.075	0.143	0.191	0.394	0.052	0.200	0.179	0.179	0.129	0.155	0.084	0.039	0.343
D4	0.178	0.068	0.060	0.152	0.237	0.363	0.022	0.129	0.123	0.126	0.123	0.144	0.040	0.012	0.324
D5	0.124	0.170	0.149	0.118	0.165	0.322	0.012	0.172	0.191	0.189	0.187	0.082	0.021	-0.006	0.263
E1	0.185	0.136	0.131	0.210	0.314	0.491	0.182	0.207	0.179	0.222	0.080	0.150	-0.037	-0.033	0.285
E2	0.130	0.107	0.074	0.167	0.245	0.355	0.170	0.148	0.114	0.144	0.067	0.124	-0.132	-0.142	0.254

Continued from page 225 (Inter-item correlations)

	B1	B2	B3	B5	B6	B7	B8	B9	B10	B11	B12	B13	B15	B16
E3	0.165	0.158	0.140	0.226	0.217	0.188	0.201	0.160	0.176	0.094	0.078	0.051	0.144	0.067
E5	0.377	0.316	0.227	0.447	0.441	0.303	0.427	0.272	0.032	0.020	-0.028	-0.069	-0.001	0.116
E6	0.372	0.318	0.233	0.449	0.396	0.333	0.408	0.292	0.080	0.021	0.009	-0.033	0.015	0.059
E7	0.424	0.386	0.302	0.497	0.462	0.325	0.433	0.333	0.088	0.026	-0.014	-0.097	0.004	0.094
E8	0.410	0.359	0.284	0.526	0.522	0.395	0.532	0.363	0.128	0.063	0.029	-0.066	0.039	0.105
E9	0.425	0.386	0.311	0.452	0.423	0.334	0.435	0.336	0.071	0.012	0.044	-0.037	0.023	0.090
E10	0.331	0.282	0.274	0.348	0.318	0.259	0.269	0.293	0.121	0.043	0.037	0.003	0.095	0.023
E11	0.131	0.072	0.070	0.255	0.202	0.199	0.188	0.086	0.321	0.188	0.156	0.099	0.169	0.291
E12	0.119	0.076	0.119	0.146	0.168	0.135	0.156	0.170	0.153	0.098	0.160	0.107	0.136	0.170
E14	0.042	0.047	0.014	0.054	0.047	0.034	0.039	0.115	0.127	0.013	0.128	0.258	0.241	0.087
E15	0.039	0.072	0.027	0.025	0.016	0.039	0.053	0.111	0.118	0.007	0.139	0.279	0.281	0.066
E19	0.105	0.154	0.059	0.146	0.129	0.130	0.120	0.135	0.167	0.111	0.151	0.173	0.240	0.125
E21	0.107	0.116	0.081	0.167	0.123	0.091	0.161	0.051	0.172	0.101	0.136	0.096	0.162	0.220
F1	0.390	0.305	0.279	0.462	0.428	0.379	0.438	0.338	0.095	0.070	0.003	-0.033	-0.023	0.049
F2	0.126	0.114	0.104	0.157	0.146	0.165	0.205	0.194	0.097	0.109	0.071	-0.036	0.005	0.199
F3	0.118	0.092	0.101	0.080	0.094	0.079	0.142	0.196	0.045	-0.010	0.019	0.063	0.067	0.148
F4	0.115	0.090	0.155	0.099	0.098	0.080	0.154	0.168	0.100	0.015	0.078	0.130	0.096	0.167
F5	0.154	0.103	0.144	0.092	0.126	0.107	0.135	0.129	0.084	0.034	0.030	0.061	0.071	0.116
F6	0.048	0.038	0.053	0.088	0.131	0.070	0.115	0.076	0.382	0.262	0.567	0.202	0.284	0.206
F8	0.021	0.002	0.007	0.035	0.069	0.043	0.054	0.048	0.015	0.011	0.009	-0.016	0.005	0.070
F9	0.059	0.024	0.038	0.031	0.050	0.080	0.036	0.055	0.074	0.156	0.056	-0.007	0.051	-0.030
F10	0.002	-0.002	0.025	0.007	0.009	0.040	0.021	0.036	-0.003	0.104	-0.001	-0.048	-0.001	-0.048
F11	0.247	0.209	0.163	0.205	0.231	0.208	0.248	0.191	0.069	0.056	0.064	0.037	0.004	0.106

Continued from page 226 (Inter-item correlations)

	D1	D2	D3	D4	D5	E1	E2	E3	E5	E6	E7	E8	E9	E10
E3	0.094	0.122	0.172	0.125	0.169	0.256	0.163	**1.000**	0.233	0.281	0.296	0.274	0.270	0.320
E5	0.096	0.230	0.412	0.370	0.341	0.613	0.451	0.233	**1.000**	**0.815**	0.669	0.692	0.628	0.444
E6	0.134	0.205	0.362	0.357	0.321	0.566	0.414	0.281	**0.815**	**1.000**	0.643	0.650	0.712	0.501
E7	0.076	0.258	0.488	0.434	0.379	0.662	0.567	0.296	0.669	0.643	**1.000**	**0.803**	0.637	0.463
E8	0.106	0.281	0.490	0.461	0.384	0.589	0.496	0.274	0.692	0.650	**0.803**	**1.000**	0.718	0.467
E9	0.141	0.265	0.448	0.436	0.429	0.560	0.445	0.270	0.628	0.712	0.637	0.718	**1.000**	0.521
E10	0.092	0.253	0.379	0.305	0.350	0.422	0.352	0.320	0.444	0.501	0.463	0.467	0.521	**1.000**
E11	0.121	0.235	0.231	0.230	0.206	0.247	0.202	0.078	0.152	0.180	0.172	0.193	0.169	0.183
E12	0.099	0.203	0.171	0.178	0.124	0.185	0.130	0.139	0.157	0.135	0.160	0.166	0.161	0.214
E14	0.147	0.121	0.101	0.068	0.170	0.136	0.107	0.164	0.112	0.154	0.101	0.097	0.119	0.167
E15	0.116	0.112	0.075	0.060	0.149	0.131	0.074	0.178	0.112	0.164	0.111	0.100	0.134	0.209
E19	0.155	0.146	0.143	0.152	0.118	0.210	0.167	0.276	0.220	0.249	0.223	0.204	0.196	0.304
E21	0.106	0.254	0.191	0.237	0.165	0.314	0.245	0.218	0.201	0.218	0.243	0.236	0.231	0.267
F1	0.134	0.251	0.394	0.363	0.322	0.491	0.355	0.182	0.581	0.602	0.548	0.608	0.639	0.416
F2	-0.091	-0.013	0.052	0.022	0.012	0.182	0.170	-0.033	0.116	0.121	0.108	0.079	0.114	0.072
F3	0.071	0.152	0.200	0.129	0.172	0.207	0.148	0.162	0.186	0.214	0.187	0.104	0.137	0.208
F4	0.124	0.168	0.179	0.123	0.191	0.179	0.114	0.181	0.166	0.200	0.146	0.084	0.152	0.206
F5	0.139	0.175	0.179	0.126	0.189	0.222	0.144	0.238	0.181	0.205	0.174	0.118	0.158	0.265
F6	0.072	0.188	0.129	0.123	0.187	0.080	0.067	0.097	0.005	0.026	0.056	0.062	0.108	0.054
F8	0.035	0.079	0.155	0.144	0.082	0.150	0.124	0.056	0.127	0.101	0.144	0.115	0.128	0.115
F9	0.053	0.043	0.084	0.040	0.021	-0.037	-0.132	0.022	0.019	0.057	-0.008	0.089	0.030	-0.010
F10	0.008	0.031	0.039	0.012	-0.006	-0.033	-0.142	-0.013	-0.017	0.032	-0.042	0.037	-0.005	-0.008
F11	0.070	0.209	0.343	0.324	0.263	0.285	0.254	0.182	0.233	0.222	0.305	0.315	0.260	0.269

Continued from page 227 (Inter-item correlations)

	E12	E14	E15	E19	E21	F1	F2	F3	F4	F5	F6	F8	F9	F10	F11
E3	0.139	0.164	0.178	0.276	0.218	0.182	-0.033	0.162	0.181	0.238	0.097	0.056	0.022	-0.013	0.182
E5	0.157	0.112	0.112	0.220	0.201	0.581	0.116	0.186	0.166	0.181	0.005	0.127	0.019	-0.017	0.233
E6	0.135	0.154	0.164	0.249	0.218	0.602	0.121	0.214	0.200	0.205	0.026	0.101	0.057	0.032	0.222
E7	0.160	0.101	0.111	0.223	0.243	0.548	0.108	0.187	0.146	0.174	0.056	0.144	-0.008	-0.042	0.305
E8	0.166	0.097	0.100	0.204	0.236	0.608	0.079	0.104	0.084	0.118	0.062	0.115	0.089	0.037	0.315
E9	0.161	0.119	0.134	0.196	0.231	0.639	0.114	0.137	0.152	0.158	0.108	0.128	0.030	-0.005	0.260
E10	0.214	0.167	0.209	0.304	0.267	0.416	0.072	0.208	0.206	0.265	0.054	0.115	-0.010	-0.008	0.269
E11	0.258	0.168	0.114	0.242	0.477	0.178	0.159	0.237	0.219	0.266	0.181	0.141	0.031	-0.018	0.205
E12	**1.000**	0.308	0.320	0.373	0.330	0.123	0.112	0.284	0.269	0.295	0.193	0.102	0.055	0.010	0.088
E14	0.308	**1.000**	0.752	0.566	0.364	0.084	-0.020	0.350	0.315	0.321	0.139	0.153	-0.078	-0.096	0.099
E15	0.320	0.752	**1.000**	0.606	0.356	0.110	-0.024	0.310	0.277	0.285	0.124	0.157	-0.015	-0.065	0.104
E19	0.373	0.566	0.606	**1.000**	0.525	0.182	0.008	0.342	0.290	0.344	0.165	0.171	-0.008	-0.064	0.139
E21	0.330	0.364	0.356	0.525	**1.000**	0.210	0.063	0.291	0.244	0.306	0.178	0.199	-0.026	-0.074	0.192
F1	0.123	0.084	0.110	0.182	0.210	**1.000**	0.155	0.119	0.123	0.181	0.081	0.196	0.013	-0.033	0.360
F2	0.112	-0.020	-0.024	0.008	0.063	0.155	**1.000**	0.056	0.077	0.080	0.078	0.048	-0.033	0.021	0.117
F3	0.284	0.350	0.310	0.342	0.291	0.119	0.056	**1.000**	**0.812**	0.570	0.158	0.211	-0.056	-0.072	0.190
F4	0.269	0.315	0.277	0.290	0.244	0.123	0.077	**0.812**	**1.000**	0.657	0.222	0.201	-0.079	-0.083	0.192
F5	0.295	0.321	0.285	0.344	0.306	0.181	0.080	0.570	0.657	**1.000**	0.141	0.181	-0.056	-0.082	0.173
F6	0.193	0.139	0.124	0.165	0.178	0.081	0.078	0.158	0.222	0.141	**1.000**	0.205	-0.073	-0.133	0.159
F8	0.102	0.153	0.157	0.171	0.199	0.196	0.048	0.211	0.201	0.181	0.205	**1.000**	-0.236	-0.283	0.322
F9	0.055	-0.078	-0.015	-0.008	-0.026	0.013	-0.033	-0.056	-0.079	-0.056	-0.073	-0.236	**1.000**	0.777	-0.171
F10	0.010	-0.096	-0.065	-0.064	-0.074	-0.033	0.021	-0.072	-0.083	-0.082	-0.133	-0.283	0.777	**1.000**	-0.182
F11	0.088	0.099	0.104	0.139	0.192	0.360	0.117	0.190	0.192	0.173	0.159	0.322	-0.171	-0.182	**1.000**

Appendix L: Publications

The results from the qualitative interviews were presented in poster form at the British Society of Gastroenterology annual conference June 2017 (Manchester) and United European Gastroenterology week October 2017 (Barcelona):

- Neilson LJ, Sharp L, Patterson J, Hewitson P, von Wagner C, Rees CJ (2017). 'PTH-023 Developing patient reported experience measures for GI endoscopy: results of patient interviews', *Gut* 66, pp A216-217
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